

ZEVEX®

Enteral Nutrition Delivery Systems



Infinity[∞] orange™ Small Volume
Enteral Feeding Pump

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PRODUCT OVERVIEW

The Infinity® Orange™ is a rotary peristaltic enteral feeding pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates. It is easy to use with a simple user interface and keypad. ZEVEX technology allows an accuracy rate of +/- 5% and the ability to safely operate in any orientation. The Infinity Orange system includes a complete line of Di(2-ethylhexyl)phthalate (DEHP) - free pump delivery sets with automatic free-flow protection.

The Infinity Orange is designed for both hospital and alternate care use. It is durable, water resistant, and easily carried in a ZEVEX carry pack. The Infinity Orange's size, weight, accuracy, and portability promote and support health improving physical activity.

INDICATIONS FOR USE

The Infinity Orange enteral feeding pump is a rotary peristaltic pump designed to deliver programmed doses of enteral nutrition solutions at selectable rates.

LIST OF WARNINGS AND CAUTIONS

Warnings

- ▶ Use ONLY feeding solutions prescribed by the responsible physician, registered dietitian, registered nurse, or other licensed practitioner.
- ▶ Use ONLY Infinity brand disposable sets to ensure proper fluid delivery. Others will not deliver the correct dose, may allow dangerous free-flow conditions, and may generate hazardous fluid pressures which may activate occlusion alarms at unpredictable pressures.
- ▶ 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, allow proper air and occlusion sensing, and prevent growth of bacteria. DO NOT PROGRAM RATE AND DOSE COMBINATIONS WHICH EXCEED A 24 HOUR FEED REGIMEN.
- ▶ The battery capacity is an approximation. If you are unsure that enough capacity remains for your intended use, recharge it.
- ▶ To avoid electrical shock, never clean pump with charger plugged into an outlet or when pump is on.
- ▶ Make sure the Infinity AC Adapter/Charger is completely dry before plugging into an electrical outlet.
- ▶ Do not use Infinity Orange enteral feeding pump for delivery of non-enteral solutions. Serious injury may result.
- ▶ If an error occurs (ER01 - ER99 will appear in display), all settings and volume counters should be checked and verified before starting a feeding.
- ▶ Prior to starting the pump, confirm rate, dose, and food type are programmed as prescribed to avoid an unsafe feeding condition.

Cautions

- ▶ Federal law (U.S.A.) restricts this device to sale by or on the order of a physician, registered dietitian, registered nurse, or other licensed practitioner.
- ▶ Dispose of Infinity Orange Disposable Sets properly, as required by local law.
- ▶ If any leaks are detected in the disposable set, stop pump operation and disconnect set from patient and replace with a new disposable set.
- ▶ Care should be used when manually priming delivery set to ensure cassette is not damaged by excess force.
- ▶ Do not overload carry packs with personal items. Pump function may be affected by kinked or pinched tubing and/or unintentional button presses.

1. PUMP COMPONENTS

Infinity Orange Small Volume Enteral Feeding Pump

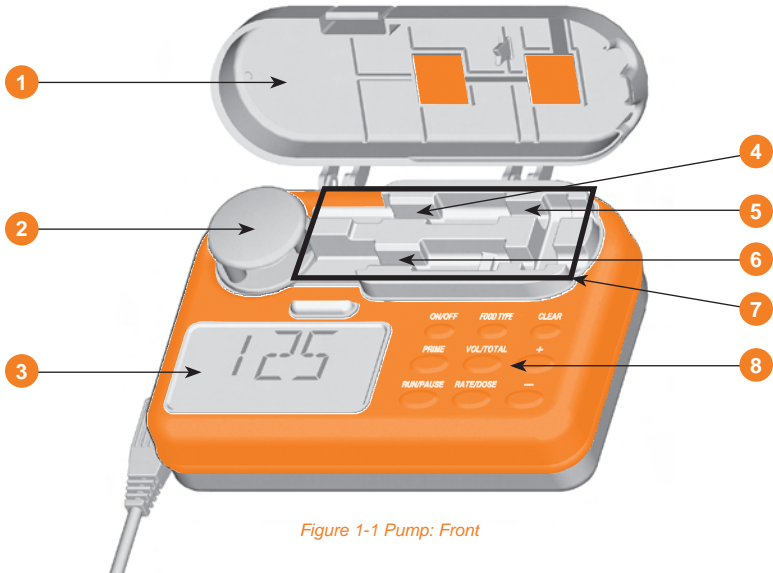


Figure 1-1 Pump: Front

1. Door
2. Pump Wheel
3. Display
4. Upstream Pressure Sensor
5. Air Sensor
6. Downstream Pressure Sensor
7. Receptacle for Cassette
8. Keypad

Infinity Orange Small Volume Enteral Feeding Pump

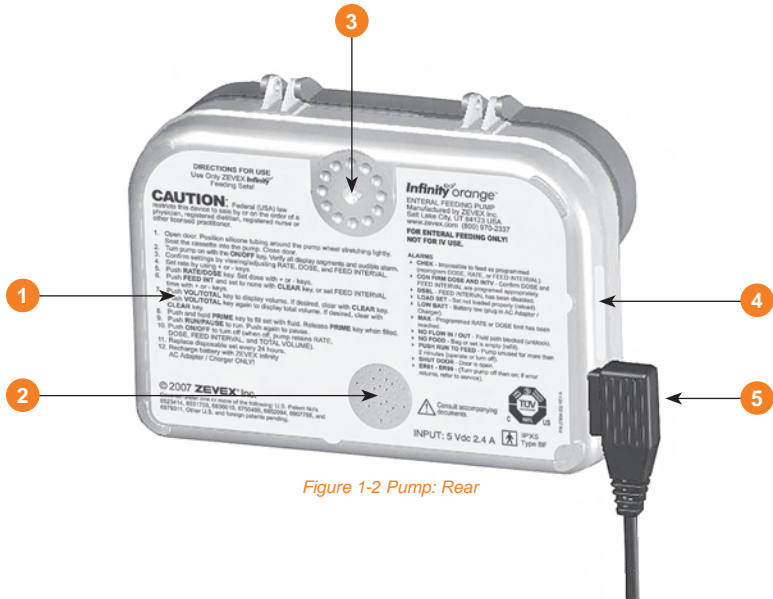


Figure 1-2 Pump: Rear

1. Pump Instruction Label
2. Speaker
3. Receptacle for Pole Clamp
4. Serial Number Label
5. Charger/Power Connector

Keypad



Press **ON/OFF** key for 1.5 seconds to either turn Infinity Orange on or off.



Press and hold **PRIME** key to rapidly fill disposable set with fluid. Release key to stop.



Press **RUN/PAUSE** key to start or pause pump, or to clear an alarm.



Press **FOOD TYPE** key to display and select type of food to be delivered (formula or human milk).



Press **VOL/TOTAL** key once to display volume delivered for current feeding. Press key again to display total cumulative volume delivered in all feed cycles since total volume was last cleared.



Press **RATE/DOSE** key to transition between rate and dose settings.



Press **CLEAR** key to reset displayed function to its minimum value. Press and hold for three seconds to clear rate, dose, and volume delivered to minimum values at the same time.



Press **+** key to increase displayed feed function. Press and hold key to increase value rapidly.



Press **-** key to decrease displayed feed function. Press and hold key to decrease value rapidly.

NOTE: The following keys only function when pump is in pause mode: **PRIME**, **CLEAR**, **+**, and **-**.

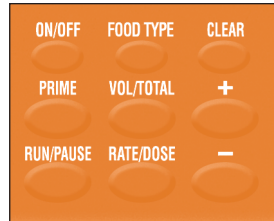


Figure 1-3 Keypad Layout

Display

The display includes large alphanumeric characters, as well as smaller symbols and words. All segments and symbols on the display are shown in *Figure 1-4*.

Settings and messages are displayed in large alphanumeric characters (*Figure 1-5*).

When the large alphanumeric characters display numbers, one of the smaller words below the characters indicates which function is being displayed (*Figure 1-6*).

The run symbol indicates pump is in run mode (*Figure 1-7*).

The wall plug symbol indicates the charger is plugged in, and connected to a live power outlet. The battery symbol indicates pump is running on battery power only. The fuel gauge symbol indicates how much battery charge remains (*Figure 1-8*).

NOTE: When operating on A/C power the display light will remain on. When operating on battery power the display light will automatically turn off 10 seconds after the last key is pressed. If you would prefer the light to turn off when connected to an outlet, you can change the pump light setting to OFF. See the User Preference Settings section (*Page 16*) for instructions to change this setting.

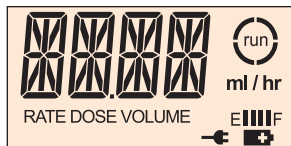


Figure 1-4 Display Segments

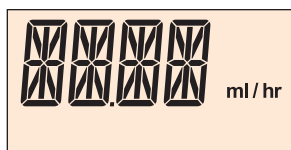


Figure 1-5 Alphanumeric Characters and Units

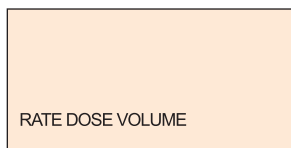


Figure 1-6 Setting Indicators



Figure 1-7 Run Indicators



Figure 1-8 Power Indicators

Disposable Set

The only disposable sets approved for use with Infinity Orange pump are:

- ▶ Infinity Orange 100 ml Bag Set - Order Number INF0100
- ▶ EnteraLite Infinity 500 ml Bag Set - Order Number INF0500
- ▶ EnteraLite Infinity 1200 ml Bag Set - Order Number INF1200
- ▶ EnteraLite Infinity Spike Set - Order Number INF0010

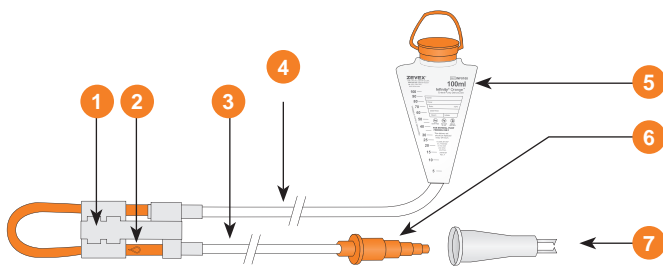


Figure 1-9 Infinity Brand 100 ml, 500 ml, or 1200 ml Bag Set

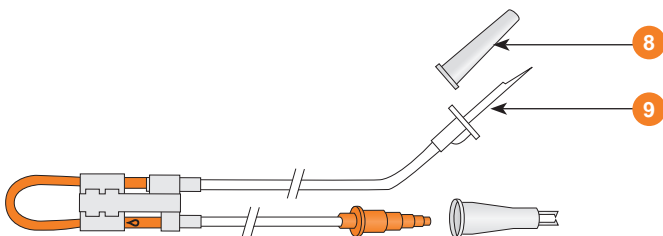


Figure 1-10 Infinity Brand Spike Set

1. Cassette
2. "drip" Symbol
3. Downstream Tubing
4. Upstream Tubing
5. 100 ml, 500 ml, or 1200 ml Feeding Bag
6. Barbed Enteral Adapter
7. Adapter Protective Cover
8. Spike Protective Cover
9. Spike

Symbols

Brief instructions for operation of pump as well as a brief explanation of each alarm message which pump may communicate are printed on the label attached to 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 Infinity Orange.



Consult
Accompanying
Documents

*Figure 1-11 Consult
Accompanying Documents*

The bag symbol is printed on pump door over port where upstream tubing enters pump.



*Figure 1-12
Feeding Bag Connection*

The patient symbol is printed on pump door over port where downstream tubing exits pump.



Figure 1-13 Patient Connection

EN 60601-1 Type BF degree of protection against electrical shock. No electrical connection to patient. Drop from any angle from height of 3 feet shall not damage pump operation.



*Figure 1-14
TYPE BF Shock Protection*

IEC 529 degree of protection against water entering the enclosure. Water jets from any direction shall have no effect.

IPX5

Figure 1-15 IEC 529

This symbol is printed on pump delivery sets. It indicates only one patient should use each disposable set.



Figure 1-16 Single Patient Use

This symbol is printed on pump delivery sets. It indicates pump delivery sets are made with materials that do not contain the plasticizer DEHP.



Figure 1-17 DEHP-free

This symbol is printed on pump delivery sets. It indicates pump delivery sets should be replaced every 24 hours.



*Figure 1-18
Replace Every 24 Hours*

2. DIRECTIONS FOR USE

Recommendation for First Use:

Since battery may not be fully charged when pump is first received, it is recommended that battery be charged for 6 hours prior to operating on battery power (see Page 15 for additional information).

Priming and Loading the Disposable Set

Step 1:

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

Remove protective cover from spike, and insert spike into spike adapter of formula container (Figure 2-1).

- **If you are using the 100 ml, 500 ml, or 1200 ml disposable set:**

Hold bag upright and pour in feeding solution (Figure 2-2). Close cap securely.

NOTE: Blenderized or aggressively mixed solutions may have foam. If using this type of solution, allow it to sit for 10 to 15 minutes before pouring into bag. This will reduce the chance of an alarm due to air in the tubing.

Step 2:

Remove protective cover from barbed adapter. If using pole clamp, protective cover may be inserted into the receptacle on back of clamp (Figure 2-3).

NOTE: If set is to be used with a carry pack, all air must be removed from bag and tubing. **Continue to step 3 for instructions on removing air.** If set is to be hung above pump, i.e. on an IV pole, **you may skip to step 4.**

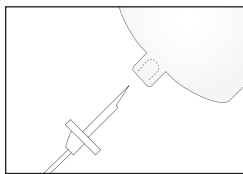


Figure 2-1 Spike Container

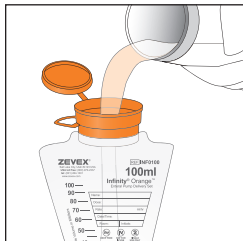


Figure 2-2 Fill Bag

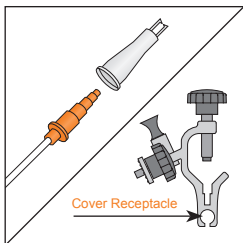





Figure 2-3 Remove Cover from Barbed Adapter / Place Cover on Pole Clamp

Step 3:

Turn bag upside down and gently squeeze. Tilt bag as needed to keep air at tubing port (Figure 2-4).

Step 4:

Gently pinch orange colored tubing **below** the “” symbol. Hold this position until air is removed from tubing. Gently squeeze bag at same time to assist fluid flow. If fluid does not flow, pinch pressure may be too strong. (Figure 2-5).

NOTE: Inside the orange colored tubing, below the “” symbol is the in-line occluder. The in-line occluder is the built-in anti free-flow valve. By pinching tubing gently, the tubing moves away from the in-line occluder allowing fluid to flow (Figure 2-6). It is important to only pinch the tubing below the “” symbol to avoid damaging the in-line occluder.

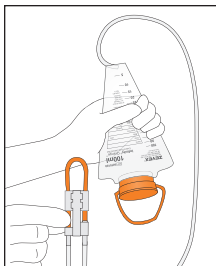


Figure 2-4 Squeeze Bag

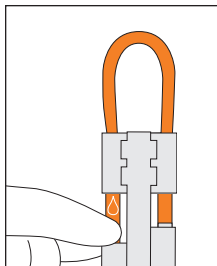


Figure 2-5 Pinch Tubing

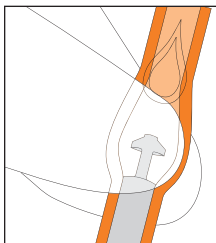


Figure 2-6 Tubing Segment Being Pinched



Figure 2-7 Tubing Segment Being Punctured by Fingernail

NOTE: Be extremely careful to pinch tubing using only the flat, soft part of your finger. Do not use fingernails when pinching tubing; doing so may puncture the delivery set (Figure 2-7). If you suspect that the delivery set has been punctured, please discard and use a new set.

NOTE: Air may also be removed from tubing using the pump prime feature. See step 7 for instructions on using the pump prime feature.

Step 5:

Loop silicone tubing around pump wheel stretching lightly. Seat cassette into pump (*Figure 2-8*). **Close pump door** (*Figure 2-9*).

NOTE: If 1200 ml set is to be used with Mini Back-pack, load set into back section of pack and thread cassette through port in bottom corner of pack prior to loading cassette into pump.

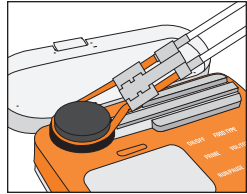


Figure 2-8 Seat Cassette

Step 6:

Press and hold **ON/OFF** key for 1.5 seconds to turn pump on. While pump runs through a self test, display will light and an audible alarm will sound as pump displays the nine digit serial number three digits at a time for one second each. The display will then show the letter 'N' followed by a number, which is the software revision.

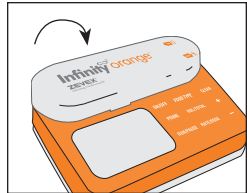


Figure 2-9 Close Pump Door

Next, all segments of display will be shown for 2 seconds. **Verify all display segments and symbols are active.**

The self test is complete and pump will then display last programmed rate and will be in pause mode.

If any air is still in the tubing, continue to Step 7 to use pump prime feature.

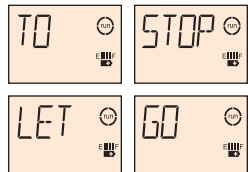


Figure 2-10 Priming Indication

Step 7:

Press and hold **PRIME** key. Alarm will sound once and pump will begin pumping at the maximum rate of 332 ml/hr. Display will read "TO STOP LET GO" (*Figure 2-10*). Once all air is removed from tubing, release key. Pump will stop, display will revert to last programmed rate, and pump will be in pause mode.

Operating the Pump

A Single Feeding Example

If you want to deliver 50 ml of enteral feeding solution at a rate of 100 ml/hr and then stop the pump:

Key Sequence for "A Single Feeding Example"



Step 1:

Prepare the disposable set with enteral feeding solution as described in the Priming and Loading the Disposable Set instructions (Page 7).

Step 2:

Hang feeding bag or container so that the bottom of bag is at or above the level of the pump door.

OR - If an Infinity brand carry pack is to be used, load pump and feeding bag into the proper compartments, securing pump, bag and tubing with the pack's straps (Page 31).

Step 3:

Turn pump on by pressing the ON/OFF key. After running the self test, display will show last programmed rate.

Step 4:

Press the **+** or **-** key to change the rate to 100 ml/hr. Hold down either key to change rapidly (Figure 2-11).



Figure 2-11 Program Rate to 100 ml/hr

Step 5:

Press the RATE/DOSE key to display dose. Press the **+** or **-** key until a dose of 50 ml is displayed (Figure 2-12).

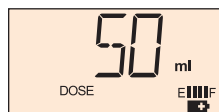


Figure 2-12 Program Dose to 50 ml

Step 6

Confirm food type to be delivered (formula or human milk) before starting pump by pressing the **FOOD TYPE** key. Press the **+** or **-** key to change between formula and human milk.

Step 7

Connect barbed adapter to the patient's enteral feeding tube.

Step 8

Press the **RUN/PAUSE** key. Pump will begin running. Display will show programmed rate and the arcs around the run symbol will rotate (Figure 2-13).

While pump is running, the following may be viewed by pressing the appropriate key: rate, dose, and food type.

To view the amount delivered in the current feeding, press the **VOL/TOTAL** key (Figure 2-14). This counter will reset to 0 when the previously programmed dose has been completed and a new feeding is started. This counter will also reset to 0 if a feeding is interrupted and rate or dose is changed, or if the pump is turned off and then back on again.

To view the amount delivered over the course of several feedings press the **VOL/TOTAL** key a second time. Display will read TOTL then the amount. This counter never resets itself. It can only be reset by the user (Figure 2-15).

While pump is running, the settings cannot be changed and the Prime feature is disabled.

If you want to stop pump at any time, press the **RUN/PAUSE** key. Display will show rate, and pump will be in pause mode. Pump will save the memory of where it was in the feeding before being paused. Or, turn pump off by pressing the **ON/OFF** key.



Figure 2-13 Pump is Running



Figure 2-14 Amount Currently Delivered



Figure 2-15 Total Amount Delivered

To restart pump when in paused mode, press the **RUN/PAUSE** key. The pump will restart the feeding at the point where it was paused.

NOTE: If pump is turned off and turned back on again, the volume delivered counter resets to 0 and food type resets to formula. Rate, dose, and food type must be confirmed before restarting the pump with a new feeding.

NOTE: Any changes to pump settings (except food type) during a feeding cycle will cause pump to start a new feeding; it will not start where it left off. Rate, dose, and food type must be confirmed by viewing each parameter before restarting the pump.

Feeding Completion:

When the dose has been completely delivered, pump will stop running, and display will read DOSE DONE. Pump will be in a pause mode until it is turned off or feeding is restarted. To clear DOSE DONE, press and hold the **ON/OFF** key for 1.5 seconds to turn pump off, or press the **RUN/PAUSE** key to put pump in pause mode. Adjustments to settings can be made at this time, or press the **RUN/PAUSE** key a second time to start another feeding using same rate, dose, and food type settings. Confirmation of rate, dose, and food type is required before beginning another feeding.



Figure 2-16 DOSE DONE

If you would prefer the alarm to sound when the dose is complete, you can change the pump dose complete alarm setting to BEEP WHEN DONE. See the User Preference Settings section (Page 16) for instructions to change this setting. When set to BEEP WHEN DONE, the pump will stop at the end of the feeding, beep intermittently, and display will read DOSE DONE (Figure 2-16). To silence alarm when the dose is complete, press and hold the **ON/OFF** key for 1.5 seconds to turn pump off, or press the **RUN/PAUSE** key to put pump in pause mode.

Next Feeding:

Turn pump on. Previous settings for rate and dose will be saved in memory. Confirm that rate, dose, and food type are correct by viewing each parameter, making necessary adjustments, and restarting the pump with a new feeding.

NOTE: If pump is turned off and turned back on again, the volume delivered counter resets to 0 and food type resets to formula. Rate, dose, and food type must be confirmed before restarting the pump with a new feeding. If dose and food type are not viewed prior to pressing the **RUN/PAUSE** key, pump will alarm and display CON FIRM DOSE AND FOOD TYPE.

NOTE: Rate, dose, and food type settings can be locked so that changes cannot be made. See the User Preference Settings section (*Page 16*) for instructions to change these settings.

The Battery

Running on Battery Power

Infinity Orange will run for 24 hours at a rate of 125 ml/hr. A fully depleted battery takes approximately 6 hours to fully charge.

When pump is running on battery power the battery symbol will appear in the display (*Figure 2-17*).



Figure 2-17 Battery Power Indicator

The segments or blocks between E and F represent the fuel gauge of the battery. Each block represents approximately 6 hours of charge. When each bar is half spent, it will begin to flash, indicating approximately 3 hours of charge is left for that bar. When the last block is gone, the battery symbol will blink to indicate there is approximately 30 minutes of charge left. Display will flash LOW BATT every 3 seconds and pump will beep every 2 seconds to remind user of low battery condition. When battery is fully depleted pump will turn off automatically.

NOTE: The battery life is an approximation based on a fully charged battery and a flow rate of 125 ml/hr. Higher flow rates will run the battery down faster, while lower flow rates will allow the battery to last longer. Battery life degrades over time.

The Battery

Charging the Battery

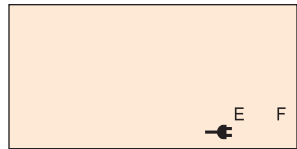
To charge the battery, insert plug from AC Adapter/Charger into port on the left side of pump. Plug charger into a wall outlet.

Pump will charge whether it is turned off or running.

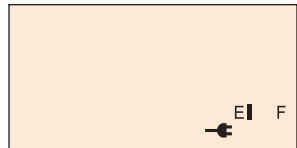
When charger is plugged in and charging, the plug symbol will appear in the display and the fuel gauge will display four bars scrolling from E to F. This pattern continuously repeats while pump is charging (Figures 2-18a through 2-18e). When bars stop scrolling pump is done charging.

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

NOTE: If pump shut down due to low battery, charging less than 10 minutes may result in an ER99 alarm. Fully charge battery if depleted (see page 20 to clear alarm).



a



b



c



d



e

Figure 2-18 Fuel Gauge

User Preference Settings

There are six user preference settings. These settings can be changed to fit the user's needs.

Alarm Volume:

The alarm has two volumes, high or low. Pump default is low (*Figure 2-19*).



Figure 2-19 Alarm Volume Settings BEEP LOW and BEEP HIGH

Settings Lock:

This allows user to set a rate, dose, and food type and then lock those settings so they cannot be changed unintentionally. This will also lock the volume counters from being unintentionally cleared. Pump default is unlocked (*Figure 2-20*).

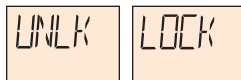


Figure 2-20 Settings Lock UNLK and LOCK

Dose Done:

There are two settings for the DOSE DONE alarm: MUTE WHEN DONE or BEEP WHEN DONE. Pump default is MUTE WHEN DONE (*Figure 2-21*).



Figure 2-21 Dose Done Settings BEEP WHEN DONE and MUTE WHEN DONE

Backlight:

To conserve battery life, the backlight will turn off automatically 10 seconds after the last key has been pressed. However, while pump is connected to an A/C current the backlight settings can be adjusted. The light can be set to ON or OFF. With the ON setting the backlight will remain on the entire time pump is plugged in to a live power outlet. With the OFF setting, the backlight will turn on when a key is pressed and turn off 10 seconds after the last key has been pressed. Pump default is ON (*Figure 2-22*).



Figure 2-22 Backlight Settings LITE OFF and LITE ON

NOTE: Regardless of setting, the backlight will always turn off 10 seconds after pump is turned off.

Max Rate:

Rate range is 0.1 ml/hr up to 300 ml/hr. However, the rate may be programmed to limit how high the rate can be set. The limits are 50, 100, 150, 200, and 250 ml/hr. Rate is not limited if user preference setting is programmed to NO MAX. Pump default is NO MAX (Figure 2-23).

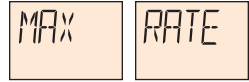


Figure 2-23
MAX RATE Settings

Max Dose:

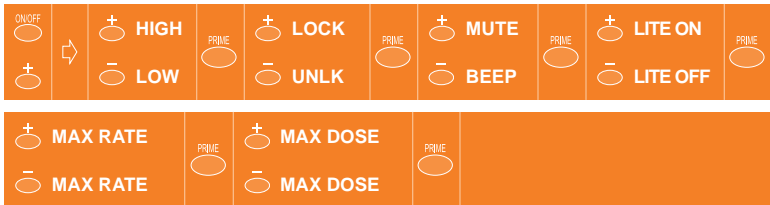
Dose range is 0.1 ml up to 3000 ml. However, the dose may be programmed to limit how high the dose can be set. The limits are 10, 20, 30, 40, 50, 60, 70, 80, 90, 100, and 120 ml. Dose is not limited if use preference setting is programmed to NO MAX. Pump default is NO MAX (Figure 2-24).



Figure 2-24
MAX DOSE Settings

To adjust these settings:

Key Sequence for "Adjusting User Preference Settings"

**Step 1:**

With pump turned off, press and hold for 1.5 seconds the **+** and the **ON/OFF** keys at the **same time**. Pump will beep and then display the words BEEP HIGH or BEEP LOW.

Press the **+** key to change to HIGH or the **-** key to change to LOW. Pump will give a triple beep when the **+** or **-** keys are pressed and setting will change. If setting is as desired, do not press either key.

Step 2:

Press the **PRIME** key. Display will read UNLK (unlocked) or LOCK (locked).

Press the **+** key to change to LOCK (locked) or the **-** key to change to UNLK (unlocked). If setting is as desired, do not press either key.

Step 3:

Press the **PRIME** key again. Display will read MUTE WHEN DONE or BEEP WHEN DONE.

Press the + key to change to BEEP WHEN DONE or the - key to change to MUTE WHEN DONE. If setting is as desired, do not press either key.

Step 4:

Press the **PRIME** key again. Display will read LITE ON or LITE OFF.

Press the + key to change to LITE ON or the - key to change to LITE OFF. If setting is as desired, do not press either key.

Step 5:

Press the **PRIME** key again. Display will read MAX RATE followed by NONE or a maximum rate value such as 100 ml/hr.

Press the + or - key to scroll between settings until the desired value is displayed. If setting is as desired, do not press either key.

Step 6:

Press the **PRIME** key again. Display will read MAX DOSE followed by NONE or a maximum dose value such as 20 ml.

Press the + or - key to scroll between settings until the desired value is displayed. If setting is as desired, do not press either key.

Step 7:

Press the **ON/OFF** key to turn pump off. Setting changes will be saved automatically.

NOTE: Once user has changed the desired user preference setting, it is not necessary to view the remaining user preference settings. Each change will be automatically saved as it is made.

NOTE: Pump will turn off automatically after 2 minutes in the User Preference Settings if the user does not turn it off before then.

ALARMS, MESSAGES, AND INDICATIONS

Following is a list of all alarms, display messages, and indications that are used by the Infinity Orange enteral feeding pump. Each alarm, message, or indication is described in detail on the following pages:

Figure	Description	Page
	Alarms	
3-1	ER01 - ER99	20
3-2	LOAD SET	20
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Should any of these alarms or indications continue after troubleshooting, contact your healthcare provider for pump service.

Alarms

ER01 - ER99 (Figure 3-1)

Pump will sound a continuous beep and display will read ER followed by a two digit number to indicate a self-test has failed.

To clear alarm: Turn the pump off and then back on.

WARNING: If an error occurs (ER01 - ER99 will appear in display), all settings and volume counters should be checked and verified before starting a feeding.

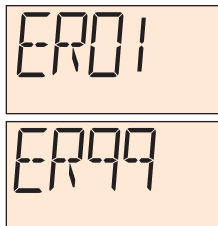


Figure 3-1
ER01 - ER99 Alarm

LOAD SET (Figure 3-2)

Pump will sound a dual tone beep repeatedly and display will read LOAD SET.

Why: This alarm will sound when pump attempted to run with the set improperly loaded or missing.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode, then check the following:

1. An Infinity brand disposable set is loaded into pump properly and door is closed.
2. Check cassette receptacle for cleanliness, especially around pressure sensors. If cleaning is necessary, refer to *CHAPTER 5 - CLEANING* (Page 29).

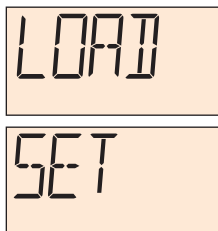


Figure 3-2
LOAD SET Alarm

LOW BATT (Figure 3-3)

When 1 hour or less of battery life is available, display will flash LOW BATT every 3 seconds and pump will beep every 2 seconds to indicate battery is low and pump will soon stop running.

To correct the problem: Plug in AC Adapter/Charger to recharge battery.

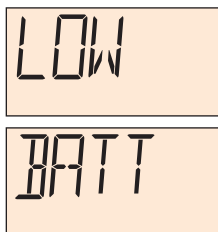


Figure 3-3
LOW BATT Alarm

NO FLOW IN (Figure 3-4)

Pump will sound a dual tone beep repeatedly and display will read NO FLOW IN.

Why: This alarm has occurred because pump has detected blockage in the set between pump and bag.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode, then check the following:

1. Check tubing for kinks or formula clumps. Correct blockage.
2. Check cassette receptacle for cleanliness, especially around the pressure sensors. If cleaning is necessary, refer to *CHAPTER 5 - CLEANING* (Page 29).

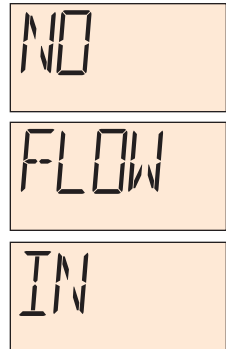


Figure 3-4
NO FLOW IN Alarm

NO FLOW OUT (Figure 3-5)

Pump will sound a dual tone beep repeatedly and display will read NO FLOW OUT.

Why: This alarm has occurred because pump has detected a blockage in the set between pump and patient.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode, then check the following:

1. Check tubing for kinks or blockages. Remove kink or blockage.
2. Check cassette receptacle for cleanliness, especially around pressure sensors. If cleaning is necessary, refer to *CHAPTER 5 - CLEANING* (Page 29).
3. Back pressure from patient may also cause this alarm. Discuss with physician.

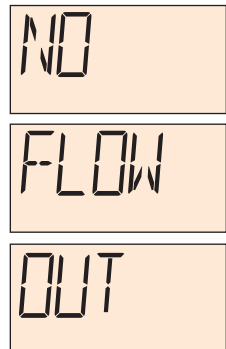


Figure 3-5
NO FLOW OUT Alarm

NO FOOD (Figure 3-6)

Pump will sound a dual tone beep repeatedly and display will read NO FOOD.

Why: This alarm has occurred because pump has detected air in the tubing. It takes approximately 1 ml of air, which is approximately 5 inches (12.7 cm) in length entering the orange colored tubing to cause an alarm.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode, then check the following:

1. Check feeding bag for food. If it is empty, refill bag and prime the set to remove air from the bag and tubing.
2. Check tubing for air bubbles. If bag is full but air is present in the tubing, disconnect set from patient, press and hold the **PRIME** key until air bubble has moved to the end of the tubing.
3. Check cassette receptacle for cleanliness, especially around the air sensor. If cleaning is necessary, refer to *CHAPTER 5 - CLEANING* (Page 29).
4. Check that an Infinity brand disposable set is loaded into pump properly and door is closed.
5. Check disposable set for worn tubing. If it is worn, replace with a new set.

NOTE: Blenderized or aggressively mixed solutions may have foam. Small foam bubbles may collect in the air sensor area and must be cleared in order to avoid a NO FOOD alarm. Allowing foamy solutions to sit for 10 to 15 minutes after mixing and prior to pouring into the bag will reduce the amount of foam.

PUSH RUN TO FEED (Figure 3-7)

Pump will sound a dual tone beep repeatedly and display will read PUSH RUN TO FEED.



Figure 3-6
NO FOOD Alarm



Figure 3-7 PUSH RUN TO
FEED Alarm

Why: This alarm has occurred because pump has been in pause mode for 2 minutes.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode again. Program and use pump or press the **ON/OFF** key to turn it off.

SHUT DOOR (Figure 3-8)

Pump will sound a dual tone beep repeatedly and display will read SHUT DOOR.

Why: This alarm has occurred because the pump door was opened while pump was running.

To correct the problem: Press the **RUN/PAUSE** key to silence alarm and place pump in pause mode then shut the door. Check door is latched securely. If door will not stay closed, check door latch and latch pocket on pump are not broken or cracked.



Figure 3-8
SHUT DOOR Alarm

Messages

DOSE DONE (Figure 3-9)

This message indicates a feeding dose has been delivered.

To clear pump: Either press the **ON/OFF** key to turn pump off, or press the **RUN/PAUSE** key to put pump in pause mode before starting another feeding.

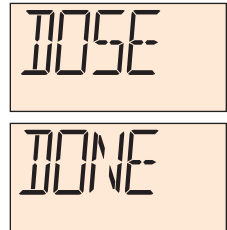


Figure 3-9
DOSE DONE Message

Indications

TO STOP LET GO (Figure 3-10)

When pressing and holding the PRIME key, alarm will sound once, pump will begin pumping at maximum rate of 480 ml/hr and display will read "TO STOP LET GO".

To stop priming: Release the PRIME key.

MAX (Figure 3-11)

If a rate/dose limit has been programmed in the User Preference Settings, pressing the + key when that limit has been met will cause the pump to display MAX.

For example, if the User Preference Setting for maximum rate has been programmed to 100 ml/hr when the user attempts to program a rate higher than 100 ml/hr the rate will stop increasing and each time the + key is pressed the display will read MAX. When released, display will read 100 ml/hr.

To correct the problem: Change limit in User Preference Settings (Page 16).

CON FIRM DOSE AND FOOD TYPE (Figure 3-12)

All feeding parameters must be confirmed before pump will begin running. This message will display if the **RUN/PAUSE** key is pressed prior to viewing rate, dose, and food type parameters.

To correct the problem: View rate, dose, and food type. Change settings where required by using the + or - key.

NOTE: The food type key allows users to select whether they are delivering formula (when selected, screen will read "FORMULA") or human milk (screen will read "HUMAN MILK"). The pump automatically calibrates the air-in-line sensor sensitivity based on what food type setting is chosen.

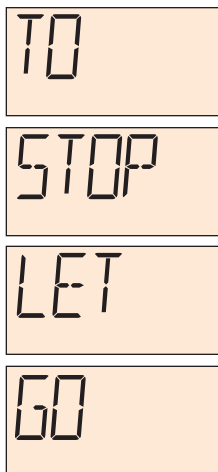


Figure 3-10
Priming Indication

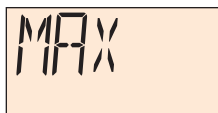


Figure 3-11
MAX Indication



Figure 3-12 CON FIRM DOSE
AND FOOD TYPE Indication

Battery Doesn't Hold Its Charge

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 summer).

To correct the problem: Recharge the battery. If the problem continues during regular use, contact your healthcare provider for service.

Battery Doesn't Charge

If the battery symbol and the E and F of the fuel gauge (Figure 3-13) are flashing while the pump is plugged in, the battery is not charging.



Figure 3-13 Battery Symbol and the E and F of the Fuel Gauge

To correct the problem: Contact your healthcare provider for service.

Charger Installed but No Plug Symbol Visible

If the plug symbol does not display after the AC Adapter/Charger is plugged into pump and a live power outlet, then charger is not charging battery.

To correct the problem: Check the following:

- ▶ Verify that the wall outlet works by plugging in another appliance, such as a lamp.
- ▶ Charger is connected properly.

If this does not correct the problem, pump or charger may be damaged. Contact your healthcare provider for service.

NOTE: There are no user serviceable or replaceable components inside the Infinity Orange.

TROUBLESHOOTING GUIDE

NO FOOD Alarm

If re-priming of the pump delivery set is required, it is advisable to disconnect the enteral adapter from the patient's feeding tube while re-priming.

1. Is feeding bag empty?	YES	Refill bag, re-prime delivery set, and resume feeding.
NO		
2. Is air present in the tubing?	YES	Has all air been removed from bag of pump delivery set?
NO		<div> <p>IF YES: Press and hold the PRIME key to move air in the tubing past pump delivery set cassette and resume feeding.</p> </div> <div> <p>IF NO: Manually prime tubing by turning bag upside down, gently squeezing lower half of bag while pinching the orange colored tubing just below the drop symbol. Hold this position until all air is removed from bag and tubing.</p> </div>
3. Is formula blenderized or aggressively mixed?	YES	Let formula sit for 10 - 15 minutes before preparing pump delivery set for feeding. If foam is present in tubing, flush by priming pump delivery set either manually or with the pump and resume feeding.
NO		
4. Are air bubbles trapped inside the cassette?	YES	Remove tubing from pump and manually prime tubing by turning bag upside down, gently squeezing lower half of bag while pinching the orange colored tubing just below the drop symbol. Hold this position until all air has passed through the orange segment of tubing.
NO		
5. Has the appropriate food type setting on the pump been selected for this feeding?	NO	Pause pump and change food type by pressing FOOD TYPE key and either + or - to change between formula and human milk.
	YES	If alarm continues, contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 for assistance.

LOAD SET Alarm

1. Is door closed securely?	NO / UNSURE	Turn pump off. Unload and reload delivery set cassette. Make sure door is closed securely. Turn pump back on.
YES		
2. Is door cracked or tab on inside of door broken?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to receive a new door.
	NO	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 for assistance.

NO FLOW IN or NO FLOW OUT Alarms

- ▶ **NO FLOW IN** - Occlusion between delivery set and pump.
- ▶ **NO FLOW OUT** - Occlusion between pump and patient.

1. Is delivery set tubing pinched, kinked, or clogged?	YES	Check delivery set for obstructions or kinks in tubing. Correct blockage and resume feeding.
NO		
2. Is tab on inside of door broken?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to receive a new door.
NO		
3. Is pressure sensor region of cassette receptacle clean?	NO	Clean pressure sensor area with a cotton swab, soft cloth or dampened sponge, or wash entire pump under running water. Do not use abrasive materials or harsh chemicals.
YES		
4. Are there visible signs of damage to pressure sensors area?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to return pump for service.
	NO	Disconnect from patient and fill a new delivery set with food. Prime set and start pump. If alarm continues, contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 for assistance.

ER01, ER02, or ER03 Alarms

1. Was pump door open while pump was turned on or while running?	YES / UNSURE	Turn pump off. Unload and reload delivery set cassette. Make sure door is closed securely, then turn pump back on.
	NO	If alarm continues, contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 for assistance.

Charging Problems

1. Is A/C adapter charger plugged into wall outlet and pump properly?	NO / UNSURE	Check connections for both wall plug and pump adapter. Green indicator light on charger wall plug should be illuminated and pump display should have plug symbol with scrolling bars between E and F of fuel gauge. When pump is fully charged, bars will stop scrolling.
YES		
2. Is wall outlet functioning properly?	NO / UNSURE	Plug another device into outlet to verify outlet is functioning properly.
YES		
3. Does the charger adapter appear to have any damage?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to receive a new charger.
NO		
4. Does the charger port appear to have any damage including bent or missing pins?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to return pump for service.
NO		
5. Is Battery Symbol and E and F of fuel gauge flashing?	YES	Contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to return pump for service.
	NO	If condition continues, contact your healthcare provider or ZEVEX Customer Service at (800) 970-2337 to return pump for service.

CLEANING

WARNING: To avoid electrical shock, never clean pump or Infinity Orange AC Adapter/Charger with charger plugged into an outlet or pump turned on.

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

To clean the Infinity Orange enteral feeding pump:

Pump may be cleaned with warm soapy water (standard dish soap) and a non-abrasive sponge or soft cloth. Use a cotton swab to clean pathways of cassette receptacle and to remove orange silicon residue from pump wheel roller pins.

OR - Apply one of the following solutions for approximately 10 minutes, then wipe pump clean with a damp cloth or sponge:

- ▶ 5% bleach and water solution
- ▶ Multipurpose household disinfectant cleaner

Rinse pump by holding under a stream of warm water. Then, dry with a clean cloth.

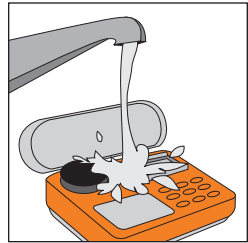


Figure 5-1 Rinsing Pump Under Stream of Water

NOTE: Avoid harsh cleaners/disinfectants. They may cause damage to pump surfaces and may affect pump functionality. ZEVEX has tested the following disinfectants for acceptability for cleaning/disinfecting the Infinity Orange pump. These cleaning products are categorized below:

Acceptable	Unacceptable
Metrex CavaCide	Ball Ruthless
MetriCide 28	Wex-Cide 128
5% Bleach and Water Solution	Alcohol
Warm Soapy Water (Standard Dish Soap)	Vesphene Ilse

To clean the Carrying Packs:

The Infinity brand packs are machine-washable. Use cold water and gentle cycle, whenever possible. Hang to dry.

To clean the AC Adapter/Charger:

Infinity Orange 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 AC Adapter/Charger while it is disconnected from the wall outlet.

ACCESSORIES

Infinity Brand AC Adapter/Charger

Order Number 23401-001

Plug AC Adapter/Charger into a wall outlet and plug connector into pump to operate on AC power and/or recharge battery (*Figure 6-1*).

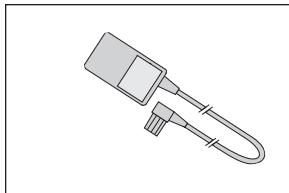


Figure 6-1 AC Adapter/Charger

Infinity Brand Pole Clamp

Order Number Z-11981

Thread bolt into receptacle on the back of pump and tighten gray wheel to mount pump on clamp. If gray wheel is slightly loosened, pump can be rotated to snap into different positions. Retighten gray wheel when pump is in the desired position. Tighten black wheel to mount clamp on a pole (*Figure 6-2*).

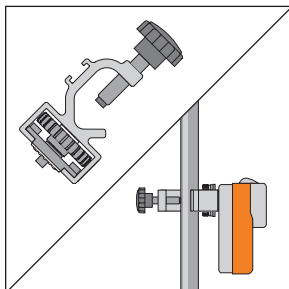


Figure 6-2 Pole Clamp / Pole Clamp with Pump Attached to IV Pole

Infinity Brand Adjustable Angle Pole Clamp

Order Number 26772-001

Thread bolt into receptacle on the back of pump and tighten knob to mount pump on clamp. If knob is slightly loosened, pump can be rotated to snap into different positions. Retighten knob when pump is in the desired position. Tighten black wheel to mount clamp on a pole. Pull pin to adjust angle (*Figure 6-3*).

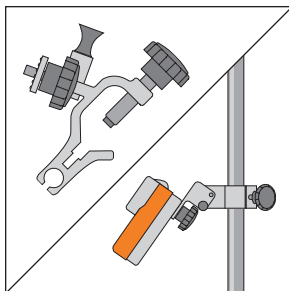


Figure 6-3 Adjustable Angle Pole Clamp / Adjustable Angle Pole Clamp with Pump Attached to IV Pole

Infinity Brand Mini Backpack

Order Numbers PCK1001 (red), PCK1002 (light green and gray), PCK1003 (black and gray), PCK1004 (specialty pack: call for current colors)

Pack holds Infinity pump with a 100 ml or 500 ml bag in the front section or can accommodate a 1200 ml bag in the rear section. Pump is secured with a Velcro® strap. A Velcro strap secures the neck of the bag. The tubing is loaded into pump and any excess length of tubing can be secured with a Velcro tab. The downstream tubing then feeds through a port at bottom of pack (either side). Also included in this pack is a pocket that may be used to hold an ice pack. *Dimensions: 13" H x 8" W x 4.5" D. Approximate weight when loaded with pump and 500 ml delivery set filled with 500 ml of water: 2.9 lbs.; 1200 ml delivery set filled with 1200 ml of water: 4.5 lbs.*



Figure 6-4 Mini Backpack

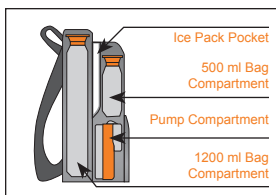


Figure 6-5 Mini Backpack (Cutaway View of Internal Compartments)

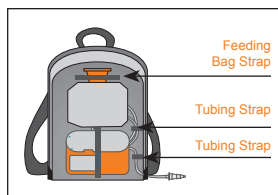


Figure 6-6 Mini Backpack (Cutaway View of Internal Straps)

Infinity Brand Super-Mini Backpack

Order Numbers PCK2001 (black), PCK2002 (light green and gray), PCK2003 (Specialty Pack: call for current colors)

Pack holds Infinity pump with a 100 ml or 500 ml bag. Pump is secured with a Velcro strap. A Velcro strap secures the neck of the bag. The tubing is loaded into pump and any excess length of tubing can be secured with a Velcro tab. The downstream tubing then feeds through a port at bottom of pack (either side). *Dimensions: 9.5" H x 8" W x 4" D. Approximate weight when loaded with pump and 500 ml delivery set filled with 500 ml of water: 2.3 lbs.*



Figure 6-7 Super-Mini Backpack

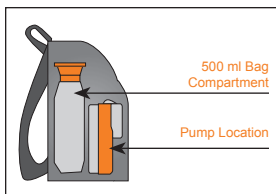


Figure 6-8 Super-Mini Backpack (Cutaway View of Internal Compartments)

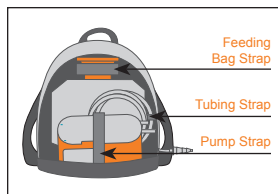


Figure 6-9 Super-Mini Backpack (Cutaway View of Internal Straps)

Infinity Brand Waist Pack

Order Numbers PCK3001 (black and gray)

Pack holds Infinity pump with a 100 ml or 500 ml bag. Pump is secured with an elastic strap. A Velcro strap secures the neck of the bag. The tubing is loaded into pump and any excess length of tubing can be secured with a Velcro tab. The downstream tubing then feeds through a port at bottom of pack (either side).

Dimensions: 7" H x 11" W x 3" D

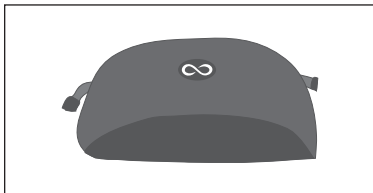


Figure 6-10 Waist Pack

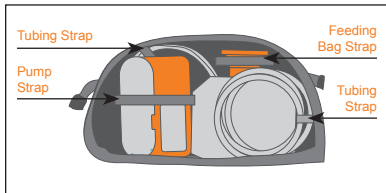


Figure 6-11 Waist Pack (Cutaway View of Internal Compartment and Straps)

Infinity Brand Backpack

Order Numbers PCK4001 (black and gray)

Pack holds Infinity pump with a 100 ml, 500 ml, or a 1200 ml bag. Pump is secured with a Velcro strap. A Velcro strap secures the neck of the bag. The tubing is loaded into pump and any excess length of tubing can be secured with a Velcro tab. The downstream tubing then feeds through a port at bottom of pack (either side). Also included in this pack is a pocket that may be used to hold an ice pack.

Dimensions: 17" H x 8" W x 4" D



Figure 6-12 Backpack

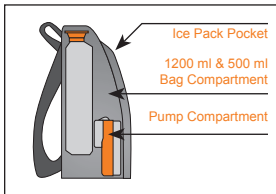


Figure 6-13 Backpack (Cutaway View of Internal Compartments)

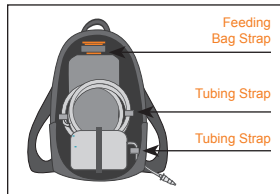


Figure 6-14 Backpack (Cutaway View of Internal Straps)

SPECIFICATIONS

SIZE	Pump Dimensions: 1.95" H x 5.65" W x 4.05" D Pump Weight: 14.4 oz (411.0 g)
BATTERY	Type: Lithium Ion Life: 24 hours @ 125 ml/hr Charge Time: Approximately 6 hours Charge Level Indicator Compact Wall Charger
DISPLAY	Backlit LCD
OPERATING ORIENTATION	Any
FLOW RATE	Range: 0.1 - 300 ml/hr Increment: 0.1 ml/hr from 0.1 ml/hr to 9.9 ml/hr 1 ml/hr from 10 ml/hr to 300 ml/hr Accuracy: $\pm 5\%$ or .050 ml/hr, whichever is greater (see page 40)
DOSE	Range: 0.1 ml to 3000 ml Increment: 0.1 ml from 0.1 - 9.9 ml 1 ml from 10 - 3000 ml
VOLUME DISPLAY	Current Dose Status Accumulated
PROGRAM MEMORY RETAINED	When Pump is on or off
PEDIATRIC USE	Yes
PRIME	Yes
DISPOSABLE SET FEATURES	Automatic Free-flow Protection No Drip Chamber DEHP-free

7. SPECIFICATIONS

ALARMS	ER01 - ER99	Self-test error
	LOAD SET	Set not loaded properly
	LOW BATT	Battery Low
	NO FLOW IN	Upstream occlusion -5 psi (-34 kPa) \pm 3psi (21 kPa) psi (pounds per square inch) kPa (kilopascals)
	NO FLOW OUT	Downstream occlusion, 12 psi (83 kPa) \pm 3psi (21 kPa) and 30 sec. delay before alarm 15 psi (103 kPa) \pm 2psi (14 kPa) and 5 sec. delay before alarm 18 psi (124 kPa) \pm 2psi (14 kPa) and 1 sec. delay before alarm
	NO FOOD	Air in tubing - bag or set may be empty
	PUSH RUN TO FEED	Pump is on in 'pause' mode for 2 minutes
	SHUT DOOR	Door opened while pump was running
ACCESSORIES	AC Adapter/Charger Multi-position Pole Clamp Adjustable Angle Pole Clamp Multi-purpose Infinity brand Custom Carry Packs	
WARRANTY	2 years	
OPERATING ENVIRONMENT	Temperature: 41 °F to 104 °F (5 °C to 40 °C) Humidity: 30% to 95% noncondensing	
STORAGE ENVIRONMENT	Temperature: -4 °F to 149 °F (-20 °C to 65 °C) Humidity: 10% to 95% noncondensing	
CLASSIFICATION INFORMATION	Infinity Orange Enteral Feeding Pump with internal battery – Type BF Applied Part Infinity Orange AC Adapter / Charger – Class II	

IMPORTANT PEDIATRIC CONSIDERATIONS

Infinity Orange can be used on pediatric patients if the specifications of pump meet delivery requirements of the patient. The specifications of primary importance are:

- ▶ The flow rate range of Infinity Orange is 0.1 ml/hr to 10 ml/hr in 0.1 ml/hr increments and 10 ml/hr to 300 ml/hr in 1 ml/hr increments.
- ▶ The Infinity Orange pump delivers the dose at the specified rate within $\pm 5\%$ or .050 ml/hr (whichever is greater) volumetric flow rate accuracy under the following conditions:
 - ▶▶ utilizing ZEVEX Infinity brand disposable sets
 - ▶▶ fluid head height at +6.0 inches \pm 0.3 inches (+15.24 cm \pm 0.76 cm) with respect to center of rotor.

NOTE: For rates less than 1 ml/hr, place pump level with patient.

NOTE: Head height effect on accuracy is shown below (Figure 8-1).

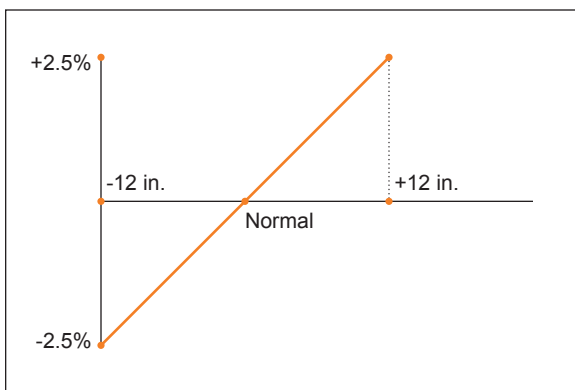


Figure 8-1 Head Height Effect on Accuracy

If these specifications meet the required feed regimen, Infinity Orange can be used to deliver enteral formulas to pediatric patients. ALWAYS VERIFY RATE, DOSE, AND FOOD TYPE BEFORE PROCEEDING TO FEED.

ADDITIONAL TECHNICAL INFORMATION

Electromagnetic Emissions/Interference

Electromagnetic emissions may affect the operation of any electronic medical device, including enteral feeding pumps.

The Infinity Orange will not be affected by electromagnetic emissions in most environments. However, some electromagnetic fields produced by personal communication equipment, household appliances, or occupational tools may cause electromagnetic interference (EMI) which can affect the pump.

Possible sources of electromagnetic interference with electronic medical devices include, but are not limited to: cellular phones, cordless telephones, microwave ovens, anti-theft/security systems, blenders, and high-powered tools (i.e. drills, saws, chain saws). If electromagnetic emitting devices are operated within one yard/meter of the Infinity Orange, the pump may automatically shut off and settings may return to their default values. Check the pump regularly if operating near sources of electromagnetic emissions.

The Infinity Orange can safely be operated on commercial aircraft and is designed in accordance with EN 60601-1-2, EN 60601-1-4 and RTCA DO160D standards for electromagnetic emissions and immunity.

Guidance and manufacturer's declaration - electromagnetic emissions

The Infinity Orange is intended for use in the electromagnetic environment specified below. The customer or the user of the Infinity Orange should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Infinity Orange uses energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	The Infinity Orange is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Infinity Orange Disposable Set Displacement

Infinity Orange Disposable Set displaces approximately 6 ml of fluid when primed. Approximately 3.5 ml of air is drawn into the tubing before the enteral pump detects bag is empty. Therefore, approximately 2.5 ml of fluid remains in the disposable set when pump stops feeding.

Routine Maintenance

There are no user serviceable parts or routine calibration or adjustment procedures required for Infinity Orange. All service requests should be referred to ZEVEX technical service.

WARRANTY

Solely for the benefit of the original buyer, ZEVEX INCORPORATED (“ZEVEX”), warrants all new Infinity Orange 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, or other location designated by ZEVEX, any Infinity Orange 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, 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 Infinity Orange 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 Infinity Orange pump is opened or tampered with in any way without prior authorization from ZEVEX, Inc.

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WHO TO CALL

Additional Information:

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YOUR PHYSICIAN:

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NOTES



OPERATOR'S MANUAL

Also available in other languages

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Covered under one or more of the following US Patent No's 5,267,983, 6,523,414, 6,531,708, 6,595,950, 6,623,447, 6,659,976, 6,685,670, 6,750,468, 6,852,094, 6,907,788, 6,923,785, D455,489, D501,924, D503,799, D503,978, D504,506, D505,199 and D507,647 and Foreign Patent No's 40108978.9, 40209539.1, 40302879.5, ZL 01338370.1, ZL 02369422.4, 03306228.5, 015998, 701976-701985, 16,112, 2104612, 3012123, 3010564, 129,165, 129,630 and 241366. Other US and Foreign patents pending.
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