

12. Electromagnetic Conformity

| <p>The S-2000 Enteral Feeding Pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Sentinel Enteral Feeding Pump should assure that it is used in such an environment.</p> | | |
|--|------------|---|
| Emissions Test | Compliance | Electromagnetic environment |
| Radiated Emissions (CISPR 11) | Group 1 | S-2000 Enteral Feeding Pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment. |
| Radiated Emissions (CISPR 11) | Class B | S-2000 Enteral Feeding Pump 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. |
| Harmonic Emissions EN61000-3-2 | Class A | |
| Voltage Fluctuation/Flicker EN61000-3-3 | complies | |



SENTINEL □
Enteral Feeding Pump

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SYMBOLS REFERENCE



Warning. Attention, read manual before use.



Type of protection against electrical shock



Warning, potential hazard of personal injury, the conditions indicated in the associated text must be understood before proceeding.

10. ACCESSORIES



Use only OST MEDICAL approved enteral delivery sets.



Use of unapproved enteral delivery sets may result in performance that does not meet specifications.



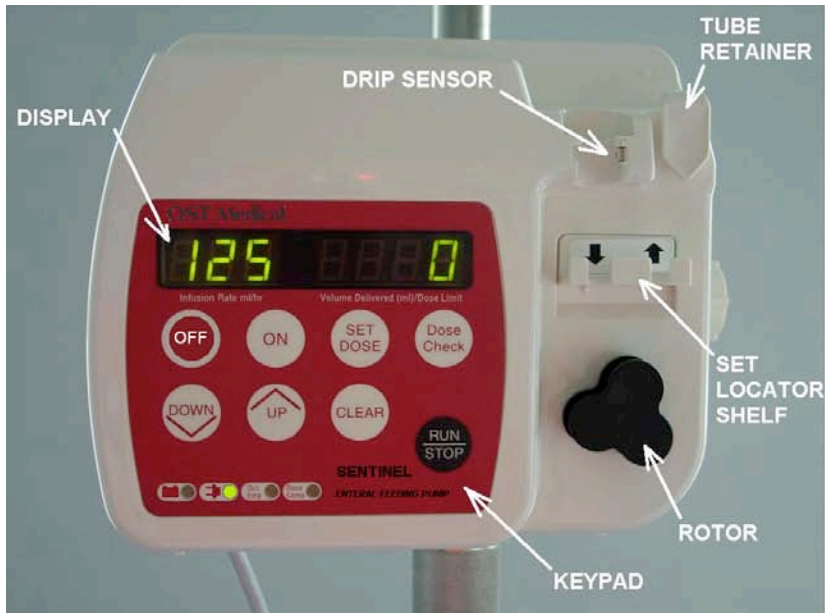
Always dispose of consumables according to local regulations.

11. Indication for Use



The SENTINEL Enteral Feeding Pump can be used for patients who are able to tolerate feeding rates in the range of 5 to 295 ml/hr with an accuracy of $\pm 10\%$ and a maximum occlusion pressure of 15psi.

CAUTION:
FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON ORDER OF A PHYSICIAN, REGISTERED DIETICIAN, REGISTERED NURSE OR OTHER LICENSED PRACTITIONER.

FRONT HOUSING PARTS LOCATION




7. SPECIFICATIONS

| | |
|-------------------------------|---|
| TYPE OF DEVICE: | Enteral feeding pump |
| MECHANISM: | Rotary peristaltic |
| OPERATING RANGE: | 5-295 ml/hour in 1 ml/hr increments |
| DOSE LIMIT: | 1-2000 ml in 1 ml increments 2000-9999 in 5 ml increments |
| DOSE ACCURACY: | ± 10% of selected flow rate |
| OCCLUSSION PRESSURE: | Does not exceed 15 psi |
| BATTERY: | 12v, 1.3AH sealed lead acid Automatically recharges when connected to an AC outlet. Recharge time is 10 hours from complete discharge to full recharge Operating time 6 hours at 125 ml/hr |
| DIMENSIONS: | 19cm H x 23cm W x 13cm D |
| WEIGHT: | 2.45kg |
| CASE MATERIAL: | High strength plastic |
| POWER REQUIREMENT: | 115VAC ±10%, 60Hz ±5%, 12 VA |
| OPER. CONDITION: | +16 to +40°C, 10 to 90% RH |
| TRANSPORT and STORAGE: | -10 to +50°C, 10 to 90% RH |
| SHOCK PROTECTION: | Class II, Type BF  AC plug ground pin is functional earth conductor  |
| WATER INGRESS: | IPX1 |

8. SERVICE

 THERE ARE NO USER SERVICEABLE PARTS IN THE PUMP.

 TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE BACK COVER. SERVICE BY QUALIFIED PERSONNEL ONLY.

For Service Contact: OST Medical, Inc.
11 Knight St. #F-23
Warwick, RI 02886




Tel - 800 495 5270

9. WARRANTY

OST Medical, Inc. warrants all new pumps of its manufacture to be free from defects in material and workmanship. OST Medical will replace or repair at its factory in Warwick, RI, or other location designated by OST, any defective pump within one year of original purchase date. Such repair or replacement shall be at no charge. Purchaser will be responsible for packaging and shipment to OST. This warranty is valid for the original purchaser only. Product which has been subject to abuse, alteration, misuse or which has not been properly maintained is not covered by this warranty. This warranty is void if product has been repaired by anyone other than an OST authorized service representative.

THIS IS THE EXTENT OF WARRANTY PROVIDED BY OST. NO WARRANTY IS IMPLIED FOR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, OR ANY CONSEQUENTIAL DAMAGE ARISING OUT OF THE USE OF THE PRODUCT. OST WILL BE LIABLE, IN ANY EVENT, FOR THE PURCHASE PRICE OF THE PRODUCT.

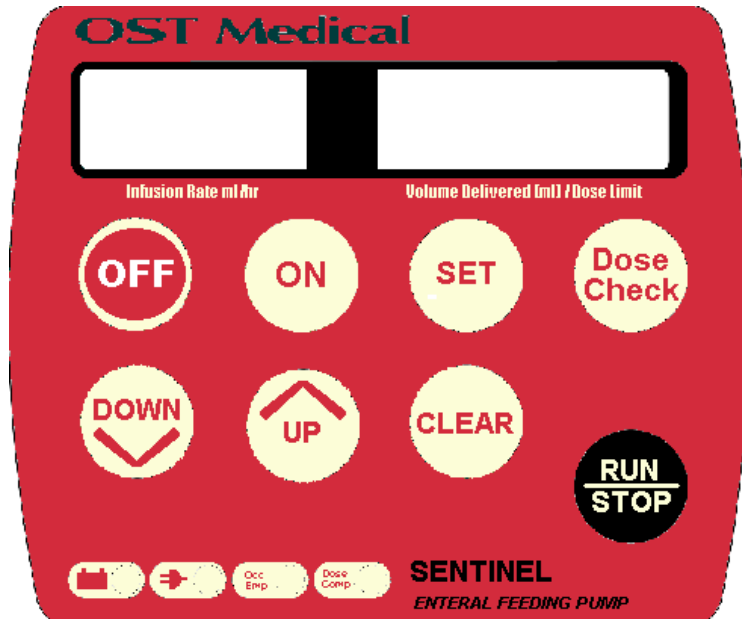
1. INTRODUCTION

-  USE the mains disconnect to remove power from the pump. This connection should remain clear of obstacles and be readily accessible.
-  AVOID operating pump near radio transmitting devices, or heavy electrical equipment.
-  AVOID placing pump where it is subject to high temperature, such as next to heat ducts.

The *Sentinel* is an easy-to-use enteral feeding pump that can deliver all enteral feeding formulas. The pump is easy to program, and many of its functions can be activated with a single touch. Reliable and accurate, the *Sentinel* is designed to give the user easy access to its many useful features.

- Programming directions are located directly on the pump.
- Built-in pole clamp allows patient mobility.
- Pump is easily loaded with one hand.
- Clear, large dual display windows can be read from a distance.
- Dose Check keeps a record of the accumulated amount of formula delivered over several feedings.
- The Clear button clears all displays, except total accumulated dose, with one, four-second touch.
- Audible and visible alarms are readily differentiated. User is alerted when battery is low, when the formula container is empty, or the line is occluded, when the dose is complete, and in the event of formula excess flow.
- The smooth, plastic case is easily cleaned with mild soap and water.
- Memory is not erased in a power failure or when unit is turned off.
- Dose Limit can be set in 1 ml increments up to 2000 ml, then in 5 ml increments up to 9999 ml.
- Special cap holder for administration set, keeps caps convenient and helps prevent contamination.
- Adjustable display brightness. For day or night operation.

2. CONTROL PANEL



DISPLAYS

Left **Infusion Rate:** Shows rate of delivery.

Right **Volume Delivered:** Shows formula volume since display was last cleared
Dose Limit: After displaying volume delivered, displays preset volume limit.

BUTTONS

ON: Turns pump on

OFF: Turns off pump; power to battery charger remains on.

UP: Increases infusion rate and/or dose limit.

DOWN: Decreases infusion rate and/or dose limit.

SET: Displays dose limit (doS / SEt alternately). Sets dose limit when used with UP or DOWN.

Dose Check: Displays the total accumulated delivered volume (tot) since this memory was last cleared.

RUN/STOP: Pressing alternately switches pump from stand by (StoP) to operating mode.


CLEAR: Clears Infusion Rate (cLr), Volume Delivered, Dose Limit, and total accumulated volume (when pressed immediately following Dose Check.)

5. MAINTENANCE

BATTERY

- Battery is provided for back-up due to power outage or for short term use during patient movement only.
- To keep battery charged, always connect pump to AC power.
- Do not store pump with a discharged battery.
- When storing for extended periods, recharge battery every 6 months.


CLEANING AND DISINFECTING THE PUMP

- DO NOT AUTOCLAVE.
- DO NOT USE STERILIZING SOLUTIONS.
- DO NOT IMMERSE PUMP.
- DO NOT USE DISINFECTANTS CONTAINING PHENOL.
- PROLONGED EXPOSURE TO ALCOHOL, HOUSEHOLD DETERGENTS, OR STRONG CLEANERS MAY DAMAGE THE PUMP HOUSING.
-  ALWAYS DISCONNECT THE PUMP FROM THE AC OUTLET BEFORE CLEANING TO AVOID ELECTRICAL SHOCK.

With warm soapy water, dampen a cloth or sponge. Clean the pump housing and rotor. Clean the drop sensor parts with soft cotton swabs dipped in isopropyl alcohol.

When a pump has come in contact with biohazardous material, clean as above, using 70% isopropyl alcohol, or a disinfectant safe for plastics, instead of soapy water.

Follow other official procedures that may differ among institutions.

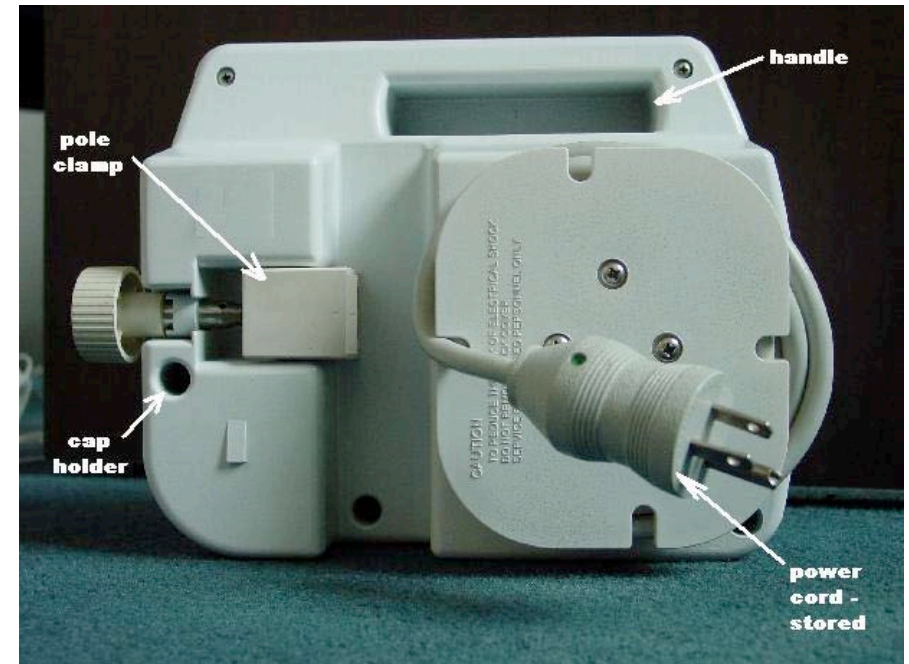
-  DO NOT use cleaners that will degrade polycarbonate.

6. TROUBLESHOOTING GUIDE

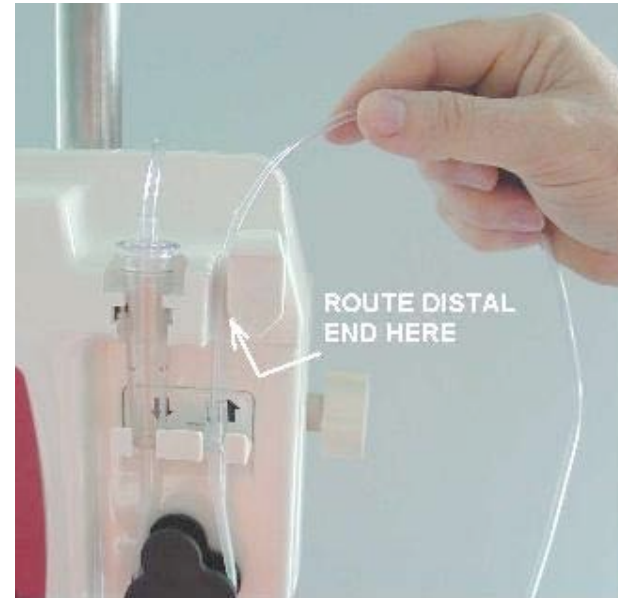
The *SENTINEL* Enteral Feeding Pump is a reliable, electromechanical device. As with any electromechanical device, problems may occur. The following tips will help you correct minor problems.

| SITUATION | POSSIBLE CAUSE | SOLUTIONS |
|---|--|---|
| Battery light flashes. After 15 minutes, pump stops, displays flash, & alarm beeps. | Battery charge is below performance level. | Plug cord into AC outlet for 10 hrs for full recharge. |
| OCC/EMP alarm activates. Pump stops, alarm sounds, displays flash. | Container is empty. | Replace or refill. |
| | Occlusion is restricting flow. | Find point of occlusion: kinked tubing or closed roller clamp in pump set; feeding tube; container. |
| | Drip chamber not properly placed in locator shelf; drops not being sensed. | Place properly. |
| | Pump is on standby (STOP) more than 2½ minutes. | Press RUN/STOP or OFF. |
| Alarm sounds when attempting rate change. Pump does not stop. | UP, DOWN, or CLEAR will only work when pump has been stopped. | Press RUN/STOP once. Change rate. Press RUN/STOP again to restart |
| DOSE COMP alarm sounds. Displays flash. | Pump has delivered set dose. | Increase dose limit. Press RUN/STOP. Pump will run until dose is complete again. |
| | | If feeding has been completed, press OFF. If feeding incomplete, set the dose limit to zero. |
| FLO FASt alarm sounds. Displays flash. | Pump set is dislodged. Tubing off of rotor. | Stop excess flow. Check set placement on rotor. Restart pump. |
| | Drop sensor blocked due to formula on drip chamber walls. | Clear drip chamber or replace pump set. |
| | Drop sensor blocked due to overfilled drip chamber. | Invert and reinstall drip chamber. |

REAR HOUSING PARTS LOCATION



PREPARING PUMP




TUBE SET INSTALLED



4. INDICATORS AND ALARMS



: When plugged into AC power, this indicator is always on indicating the battery is being charged. The light remains on even when pump is turned off. The pump should be plugged into an AC outlet whenever possible.

 : When operating on battery, this indicator lights. Approximately 15 minutes before the battery is discharged, this light will flash, an alarm will sound. The pump will not restart if stopped at this time.

Note: When light is flashing, plug the pump into an AC outlet to continue normal feeding and recharge the battery. It is advisable to avoid frequent battery discharge.

OCC/EMP: When the pump is running, this alarm indicator is activated if:

- the feeding container is empty,
- an occlusion has stopped delivery,
- the pump is left on **STOP** for more than 2½ minutes,
- the drip chamber is improperly installed.

DOSE COMP: This alarm sounds when the quantity of formula delivered reaches the dose limit setting. There will be four beeps with a flashing indicator. This is repeated every five minutes until action is taken.

EXCESS FLOW: A three-tone beep sounds if the pump tubing is not on the rotor when the pump is running (with drip chamber properly installed), or if the drop sensor is blocked for more than six seconds. The alarm sounds at maximum loudness, and the display flashes **FLO FAST**.

3. OPERATING INSTRUCTIONS

NOTE: During normal operation, the pump rotor turns intermittently and, at regular intervals, pauses for a longer period, approximately ½ minute.

NOTE: Prefill and cap liquid containers away from pump to avoid spillage.

1. Plug the power cord into a 115VAC, 60 Hz three-wire, grounded outlet.
2. Press ON. Alarm sounds briefly. Volume Delivered display flashes.
3. Press UP or DOWN until desired infusion rate is displayed.
4. Close roller clamp on feeding set.
5. Insert the drip chamber into the sensor opening and then down onto the left side of locator shelf so that chamber is seated.
6. Open roller clamp. Remove cap from connector. Expel air from pump set by allowing liquid down the tube. Close roller clamp.
7. Bring the tube under the rotor. Seat the plastic tube adapter into the locator shelf above the rotor. Wrap tube around tube retainer.
8. Insert the colored connector of the administration set into the feeding tube. The connector cap can be kept in the cap holder on the back of the pump.
9. To set dose limit, press SET, then press UP or DOWN until desired dose is displayed. **Note:** If Dose Limit is not set (display = 0), the pump will run until the container is empty or the pump is stopped.
10. Open roller clamp.
11. Press RUN/STOP to begin feeding.
12. To change infusion rate, press RUN/STOP to stop pump. Press UP or DOWN to make necessary adjustment. The infusion rate is retained in memory. If UP or DOWN is pressed without stopping the pump, an alarm will sound and the pump will continue running and there will be no change in infusion rate.
13. To clear a memory, first press RUN/STOP to stop pump. To prevent accidental loss of memory, CLEAR will only function when the pump has been stopped. If CLEAR is pressed while the pump is operating, an alarm will sound, and the pump will continue to run whenever CLEAR is pressed.
 - To reset Volume Delivered to 0 - Press and hold CLEAR. Pump will beep once, pause, beep twice, and display clears.
 - To reset Dose Limit to 0 - Press SET, then press and hold CLEAR within three seconds. Pump will beep once, pause, beep twice, and display clears.
 - To reset total accumulated volume delivered to 0 - Press Dose Check, then press and hold CLEAR within three seconds. Pump will beep once, pause, beep twice, and display clears.
 - To clear Volume Delivered, Dose Limit and reset Infusion Rate to 5 – Press and hold CLEAR for four seconds (7 beeps).
14. To view the total accumulated volume delivered, press Dose Check (if pressed while running, pump stops momentarily).
15. Display brightness: press/hold UP and SET to change bright or dim.
16. To Lock/Unlock keypad, while pumping, press/hold UP and DOWN (no dose).
17. To turn the pump off at any time, press OFF.