SENTINEL®

Enteral Feeding Pump

OPERATOR'S MANUAL

AMSINO

Advancing Healthcare Worldwide®

Table of Contents

SYMBOLS REFERENCE

	**Warning. Attention, read manual before use**
	**Type BF equipment (degree of protection against electrical shock)**
	**Warning, potential hazard of personal injury, the conditions indicated in the associated text must be understood before proceeding.**
	**Class II equipment**
	**Functional earth (ground)**

CAUTION/WARNINGS

⚠ 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.

 [CRS Q.36] Warning: Not for intravenous use. Do not use for intravenous infusion into a patient. Intravenous infusion of enteral fluids can result in serious complications up to and including death.

 [CRS Q.1] DO NOT USE PUMP IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

 [CRS Q.20] Danger: Strangulation Hazard. Avoid leaving power CORD wires, feeding set tubing or other choking hazards where infants or young children can become caught. If these objects get wrapped around a child's neck, strangulation and death can occur.

 [CRS Q.21] Danger: The pump and disposable feeding set all contain small parts which could become detached and pose a choking hazard. Some of these components could be inhaled or swallowed by a small child, toddler, or infant, which could result in suffocation and death. Keep all small components out of reach of small children

 [CRS Q.26] Caution: The power CORD, feeding set tubing, and pump accessories may cause a tripping hazard. Avoid leaving cords or tubing in a pathway where a person could trip on them and sustain an injury

 [CRS Q.30] Caution: This pump is not intended to be used in MRI environments or in the presence of strong magnetic fields. Do not use these devices in any areas with strong magnetic fields. The pump contains metal components which could cause unintended movement. This unexpected movement could cause harm due to falling objects or collisions.

 [CRS Q.31] Caution: There are significant hazards associated with accidental misconnections with other infusion devices, which could lead to patient harm or death. For more information about hazards and risk reduction strategies associated with misconnections, see the following: The Joint Commission Sentinel Event Alert Issue 36 - April 13, 2006

 [CRS Q.32] Do not use the pump for delivery of any fluids or substances that are not enteral solutions prescribed by qualified medical personnel.

 [CRS Q.34] This device is designed for use on a conventional IV pole. As with any medical device, it is possible for the weight of the pump to cause the IV pole to tip over. This could result in injury to a patient or operator. When attaching the pump to the IV pole, take precautions to ensure the IV pole remains stable while in use.

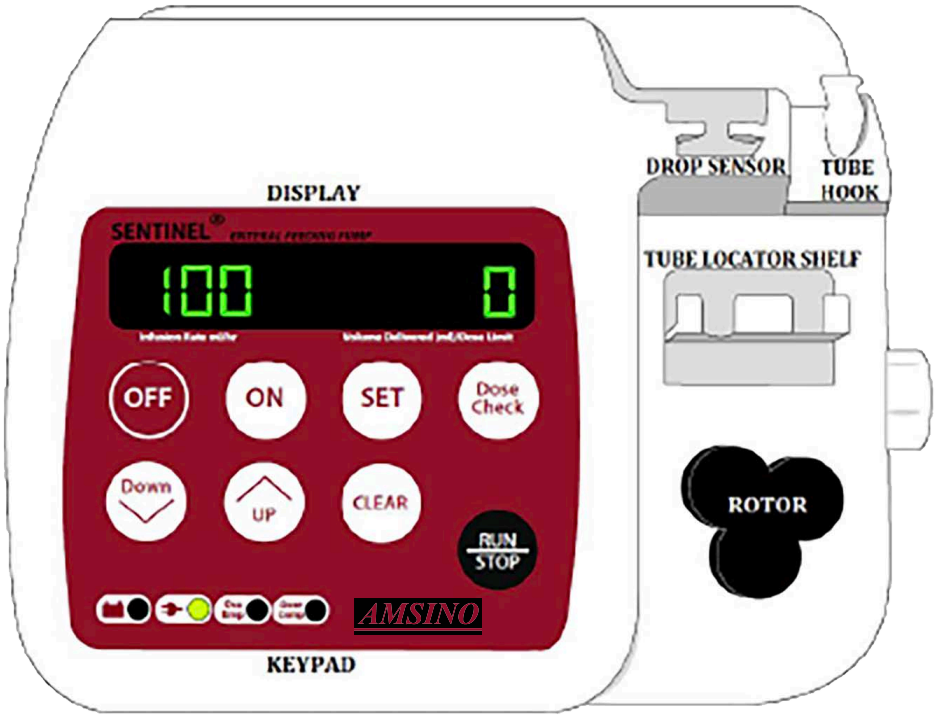
 [C.2.22b] If pump is dropped, inspect and return damaged pump for service.

INTRODUCTION

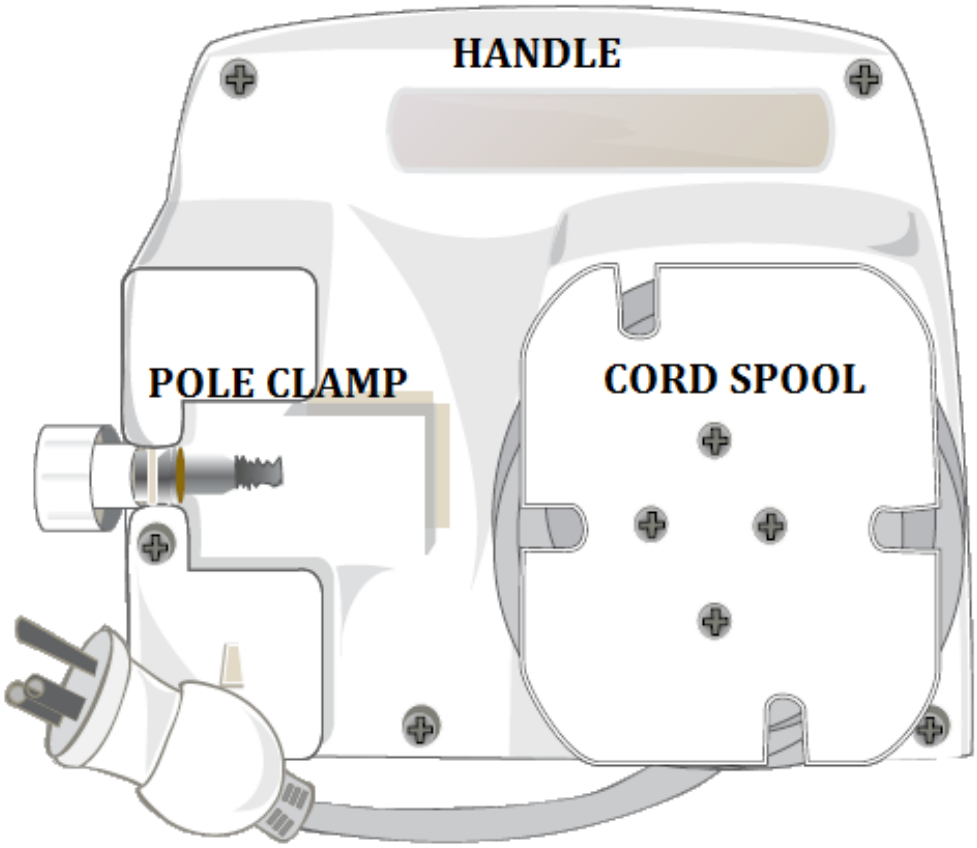
The SENTINEL® is an easy-to-use enteral feeding pump that can deliver all enteral feeding formulas. The pump is easy to program, and many of its functions can be activated with a single touch. Reliable and accurate, the SENTINEL is designed to give the user easy access to its many useful features.

- 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.
- Adjustable display brightness. For day or night operation.

FRONT HOUSING PARTS LOCATION



REAR HOUSING PARTS LOCATION



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 does limit when used with UP or DOWN
Dose Check	Displays the total accumulated delivered volume (tot) since 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)

OPERATING INSTRUCTIONS

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

NOTE: Always plug the power cord into a 115VAC, 60 Hz three-wire, grounded Outlet.

1. Attach pump to IV pole and [Q.13] hang formula container approximately 12 in. above pump. Close roller clamp on attached feeding set.

2. Insert the drip chamber into the sensor opening and then down onto the left side of locator shelf so that chamber is seated, see Tube Set Installation on page 8.

3. Open roller clamp. Remove cap from connector. Expel air from pump set by allowing liquid down the tube. Close roller clamp.

4. Bring the tube under the rotor. Seat the plastic tube adapter into the locator shelf above the rotor.

[Q.13] Do not overstretch silicone tube. Wrap tube around tube retainer, see Tube Set Installation on page 8.

5. 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.

6. Press ON. Alarm sounds briefly. Volume Delivered display flashes.

7. Press UP or DOWN until desired infusion rate is displayed.

8. 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.

9. Open roller clamp.

OPERATING INSTRUCTIONS

10. Press RUN/STOP to begin feeding.

11. To change infusion rate, press RUN/STOP to stop the pump. Press UP or DOWN to make necessary adjustment then press RUN/ STOP to resume. The infusion rate is retained in memory. If UP or DOWN is pressed without stopping the pump, an alarm will sound, the pump will continue running and there will be no change in infusion rate.

12. 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 approximately 10 seconds (7 beeps total).

13. To view the total accumulated volume delivered, press Dose Check. If pressed while running, pump stops momentarily.

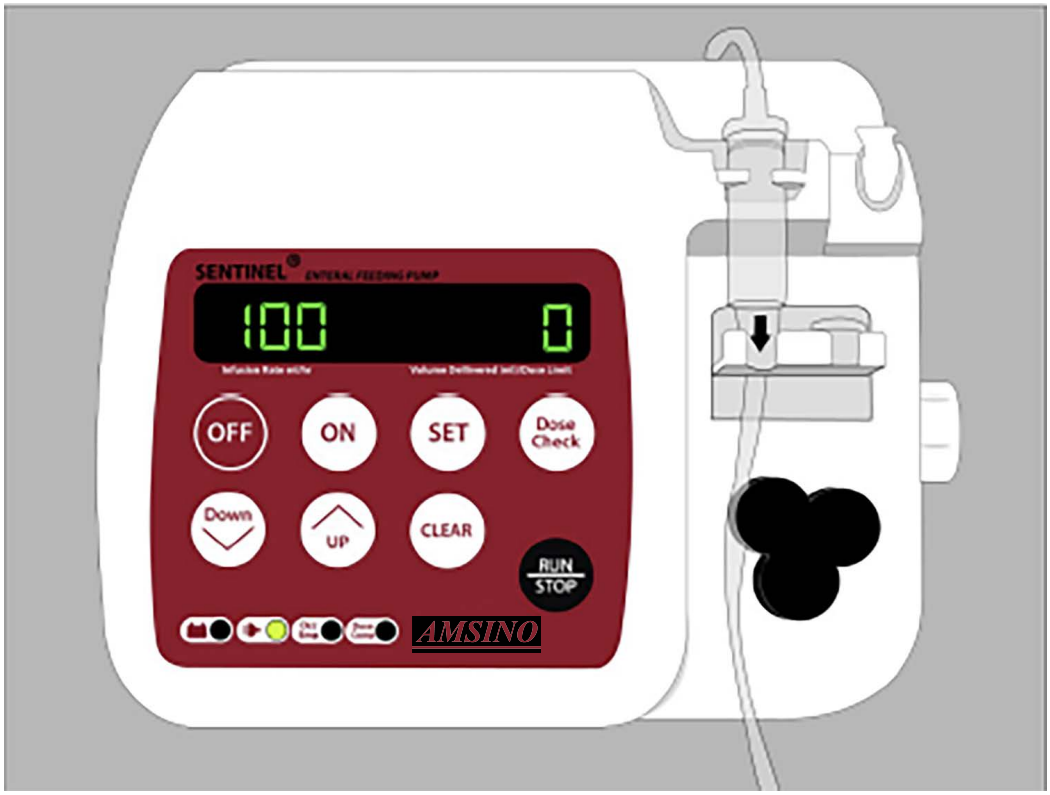
14. To adjust **Display Brightness**, press and hold UP and SET at the same time to change bright or dim.

15. To **Lock/Unlock** keypad, while pumping, press and hold UP and DOWN at the same time (no dose).

16. To turn the pump off at any time, press OFF.

TUBE SET INSTALLATION

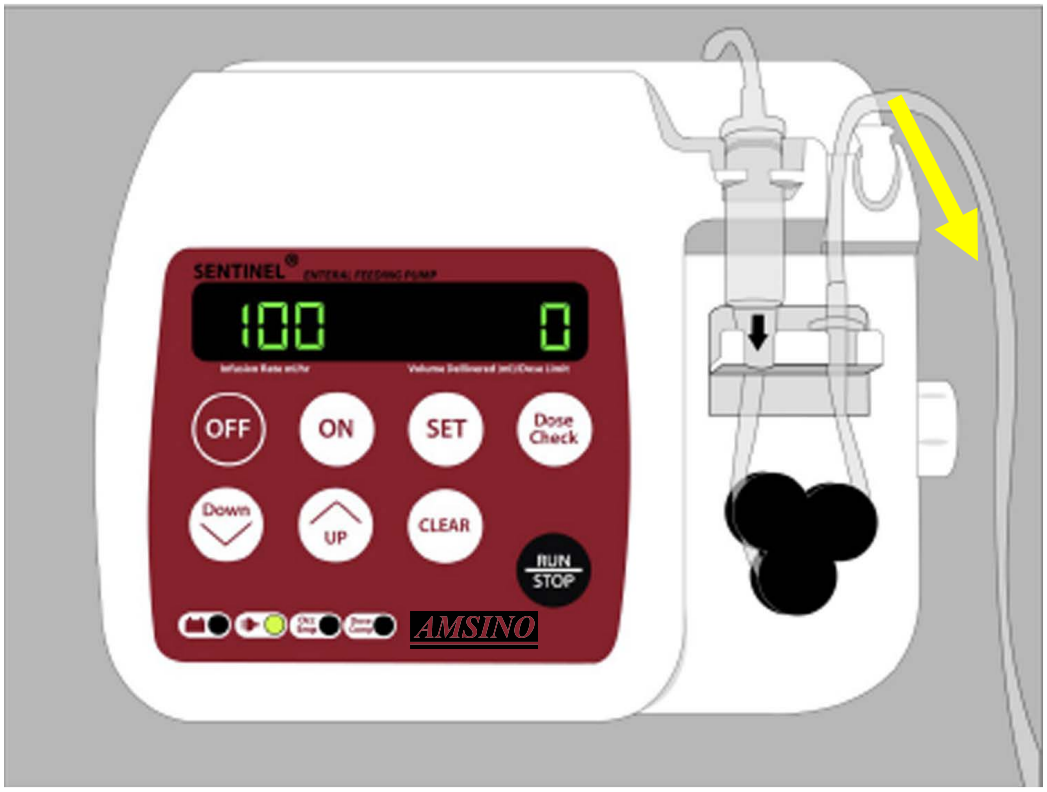
Step 1



Step 2

TUBE SET INSTALLATION

Step 3



Step 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. **Avoid frequent battery discharge cycles**.

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

MAINTENANCE

CALIBRATION

The SENTINEL® Enteral Feeding Pump does not require any routine calibration or adjustment procedures with its use. All functions of formula delivery rate and alarms are software controlled and not adjustable through any service or normal activity. Ultimate pump performance is dependent on the continued use of Amsino International, Inc. approved enteral delivery sets.

BATTERY

- It is recommended the battery be charged for 10 hours prior to first use.
- Battery is provided for back-up due to power outage, or for short term use during patient movement only.
- Always connect pump to AC power to keep battery charged.
- Do not store pump with a discharged battery.
- When storing for extended periods, recharge battery every 6 months.
- [C.2.18c] Contact Amsino Technical Service, if battery fails to charge.

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 [C.2.9c] such as formula spills or patient effluence, clean as above, using 70% isopropyl alcohol, or a disinfectant safe for plastics, instead of soapy water.

⚠ DO NOT use cleaners that will degrade polycarbonate.

⚠ [Q.9] Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.

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 hours 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.

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 with Amsino sets
OCCLUSION PRESSURE:	Does not exceed 15 psi
BATTERY:	12v, 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
POLE CLAMP RANGE: POWER	[C.2.22a] ½" TO 1" DIA.
REQUIREMENT: OPER.	115VAC ±10%, 60Hz ±5%, 14 VA
CONDITION:	+16 to +40°C, 10 to 95% RH [C2.15c] INDOOR USE ONLY
TRANSPORT and STORAGE:	-10 to +50°C, 10 to 95% RH
SHOCK PROTECTION:	Class II, Type BF  AC plug ground pin is functional earth Conductor 
WATER INGRESS:	*IPX1*

SERVICE

[C.2.23b] The only routine service required is between patient use. Inspect pump for damage and clean, refer to MAINTENANCE section.

⚠ THERE ARE NO USER SERVICEABLE PARTS IN THE PUMP. [C2.1] IF PUMP FAILS TO OPERATE, CONTACT AMSINO CUSTOMER SERVICE.

 TO REDUCE THE RISK OF ELECTRIC SHOCK, DO NOT REMOVE BACK COVER.

SERVICE BY QUALIFIED PERSONNEL ONLY

For Service Contact: Amsino Medical Group Co Ltd.
708 Corporate Center Drive Pomona,
CA 91768 USA
P: +1 800.632.6746
F: +1 909.626.3888
info@amsino.com

WARRANTY

Amsino International, Inc. warrants all new pumps of its manufacture to be free from defects in material and workmanship. Amsino International, Inc. will replace or repair at its factory in Smithfield, RI, or other location designated by Amsino International, Inc., 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 Amsino International, Inc. 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 Amsino International, Inc. authorized service representative.

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

ACCESSORIES

⚠ Use only Amsino International, Inc. approved enteral delivery sets.**

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

⚠ Always dispose of consumables according to local regulations.

INDICATIONS 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 ±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 PRACTIONER.

ELECTROMAGNETIC CONFORMITY

The SENTINEL® 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.

Emissions Test	Compliance	Electromagnetic environment
Radiated Emissions (CISPR 11)	Group 1	SENTINEL 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	SENTINEL 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	

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