




Work Instruction

Date Effective: 2 August 2007

Reviewed: _____

Confidential Information

- 1.0 Scope: This specification applies to the SENTINEL enteral feeding pumps for US facilities.
- 2.0 Purpose: To provide a test procedure to comply with JCAHO standards for OEM specifications.
- 3.0 Application: Testing, according to this procedure, is to be performed either annually or when the pump has delivered more than 350 liters (Item 10, History Data Sheet, EP1) since the last test.
- 4.0 PUMP CHECK: Any step below that fails to operate as expected shall be noted and the pump will removed from use and held for authorized service.
- 4.1 INITIAL CHECK: *Performed after pump has been plugged into AC outlet for minimum 10hr.*
- 4.1.1 While unit is unplugged, press “ON” button.
 - 4.1.2  amber battery LED should be illuminated.
 - 4.1.3 Press and hold CLEAR for seven beeps.
 - 4.1.4 “Infusion Rate” display should show “5”.
 - 4.1.5 “Volume Delivered” display should show a blinking “0”.
 - 4.1.6 Plug unit in.  LED should go out; and green  LED should be on.
 - 4.1.7 Check the pump housing for cracks or missing tube hook.
 - 4.1.8 Unit must be cleaned before proceeding to 4.2.
Refer to SENTINEL Operating Manual, part # OM2001, rev. 4, page 10, sec. 5 under Maintenance.
- 4.2 OPERATIONAL TEST:
- 4.2.1 Press the “UP” button a few times to make sure rate value increases. Press and hold the “UP” button for a more rapid pace until you reach 20. Wait a few seconds to make sure the value is retained.
 - 4.2.2 Press the “DOWN” button a few times to make sure the rate decreases. Press and hold the “DOWN” button for a more rapid pace until you reach 10. Wait a few seconds to make sure the value is retained.
 - 4.2.3 Press and hold the “UP” button until the “Infusion Rate” reaches “295”.
 - 4.2.4 Press the “RUN/STOP” button . Observe that rotor turns in counterclockwise direction. Occlusion/Empty alarm should sound when volume delivered reaches 2 milliliters.
 - 4.2.5 Press the “RUN/STOP” button to put the unit in STOP mode, then press and hold the “CLEAR” button. **cLr** appears on the left display and after 7 beeps the milliliters/hour reset to “5” and the volume infused to “0”.
 - 4.2.6 Press “OFF” button.

5.0 DOSE CHECK OPERATION:

- 5.1 Press "Dose Check" button; **tot** should appear on left display. Note the total accumulated volume on the right display.
- 5.2 Set Infusion Rate to 295 ml/hr.
- 5.3 Press the "RUN/STOP" button until the pump alarms and indicator LED "Occ Emp" illuminates. The volume infused display should be at 2 milliliters.
- 5.4 Press "RUN/STOP" to silence alarm.
- 5.5 Press "Dose Check"; **tot** should appear in left display. The volume in the right display should have increased by 2 ml.

6.0 KNOB/POLE CLAMP:

- 6.1 Turn pump so that back of pump is facing you and observe Pole Clamp. On the right side of Pole Clamp, the V-shaped notch should face to the right.
- 6.2 Turn knob so the clamp extends and cannot move any further. Knob should turn without requiring excessive force while clamp moves.
- 6.3 Turn knob in the opposite direction, until the clamp returns to its original position. Knob should have turned easily while clamp moves.
- 6.4 If clamp appears damaged, note this on History Data Sheet.

7.0 Excess flow alarm CHECK:

- 7.1 Press "ON" button.
- 7.2 Set infusion rate at 295 ml/hr.
- 7.3 Place a finger into drip chamber mounting position.
- 7.4 Press "RUN/STOP".
- 7.5 In approximately 5 seconds pump should sound alarm and display **FLO FAST**.
- 7.6 Press "RUN/STOP" to silence alarm.

8.0 RUN TEST:

- 8.1 Install a compatible bag set with distal end placed into spout for recirculating operation.
- 8.2 Press "ON" button.
- 8.3 Set infusion rate to 295 ml/hr.
- 8.4 Press "RUN/STOP".
- 8.5 Allow pump to run until volume infused display shows 20 milliliters.
- 8.6 Press "RUN/STOP".
- 8.7 Press and hold the "CLEAR" button for 7 beeps.

9.0 CLEAR ALL MEMORY:

- 9.1 Press “ON” button.
- 9.2 Press and hold the “CLEAR” button for 7 beeps.
- 9.3 Press “Dose Check” button, and within 2 seconds, press the “CLEAR” button for 3 beeps.

10.0 FINAL CHECK:

- 10.1 Check pump to make sure the following labels are present:

Front: Arrow Label (XL4)
 Danger Label (XL3)

Rear: Serial Number Label (XL2)
 ETL Control / Double Insulated Label (XL6)

Left Side: Direction Label (XL1)
 To View Dose Set Label (XL9)

Bottom: QC Inspection Label (XL7)

- 10.2 Place hands securely on sides of pump. Lift and shake vigorously. There should be no evidence of loose or unattached parts inside of pump.
- 10.3 Check Cord Wrap Plate to make sure it is not loose.

11.0 DELIVERY HISTORY:

- 11.1 Place pump in test mode as follows: Set the rate to 295. Press and hold the “UP” button for approximately 8 seconds. The unit will go into test mode. Release the “UP” button.
- 11.2 Press and hold the “UP” button, then press the “DOWN” button and release both. **EP1** should be in left display. The right display should read the total amount delivered in liters. Record the total amount delivered on the History Data Sheet.
- 11.3 Press the “UP” button and **EP2** should appear in left window. In right window, the total volume delivered on battery appears. Record the total volume delivered on battery on the History Data Sheet.
- 11.4 Press the “UP” button and **EP3** should appear in left window. In right window, the number of times unit ran on battery appears. Record the total number of times unit ran on battery on the History Data Sheet.

HISTORY DATA SHEET

	Pass	Fail
4.0 Pump Check (4.1.1-4.2.6)	_____	_____
5.0 Dose Check Operation (5.1-5.5)	_____	_____
6.0 Knob/Pole Clamp (6.1-6.4)	_____	_____
7.0 Excess flow alarm CHECK (7.1-7.6)	_____	_____
8.0 Run Test (8.1-8.7)	_____	_____
9.0 Clear All Memory (9.1-9.3)	_____	_____
10.0 Final Check (10.1-10.3)	_____	_____
11.0 Initialize Delivery History (11.1-11.4)	_____	_____

*EP1 = _____ LITERS DELIVERED

**EP2 = _____ LITERS DELIVERED ON BATTERY

**EP3 = _____ NUMBER OF TIMES UNIT RUN ON BATTERY

EP4= _____ (for OST use only)

EP5= _____ (for OST use only)

MODEL: SENTINEL

Serial Number of unit tested: _____ Date: _____ By: _____

OST Medical, Inc.

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Written: P. Sacchetti

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* Every 900 liters delivered, refer pump to factory-trained technician.

** Unless otherwise required, change battery when value of EP2 exceeds 900 and value of EP3 exceeds 550.