BELMONT FMS/RI-2 PREVENTATIVE MAINTENANCE

Prior to performing the battery run test, plug the system into an AC wall outlet for at least 8 hours to fully charge the batteries.

Material Required:

- FMS2000 Disposable Set
- Manometer (2 mm Hg resolution)
- Pressure source
- Digital Thermometer
- Graduated cylinders
- Timer

1. Visual Inspection

a. Door Open/Right Hand Side:

- Check that air and fluid out detectors are clean and there are no gaps between the detectors and the Support Housing. If there are gaps, fill the gap with RTV108.
- Check that all the plastic push pins on the door are in-place.
- Check that the valve pincher set screw is tight.
- Check that there are no cracks in the ferrite on either the door or the right hand side.
- Check that the pressure transducer diaphragm has no tears or rips.
- Check that each pump roller spins freely. If not, remove and clean.
- Check that the door is pushed all the way down and there are no dried blood or fluid inside or around the hinges.

b. Back:

- Check that the AC connector (IEC connector) is clean. If there is some saline residue, clean.

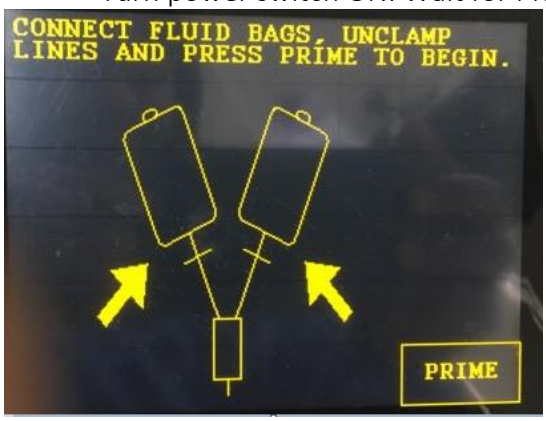
c. Verify Latch/Unlatch Mechanism:

- Check the rubber pads on the pole clamp assembly. If they feel smooth, clean and scrub with isopropyl alcohol.
- Mount and unmount the system on an IV pole, verify that the latch and unlatch work properly and the system will not move down the pole unexpectedly.

2. System Operational Check-Out

a. PRIME

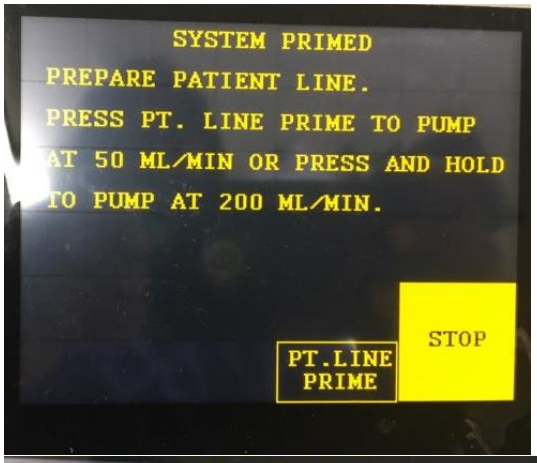
- Install Disposable set.
- Turn power switch ON. Wait for PRIME screen to appear.

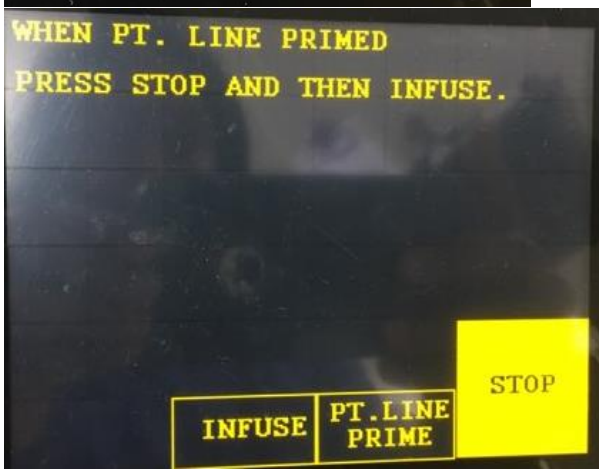


- Close bag clamps. Connect tubing to water source.
- Open bag clamp(s). Press PRIME to prime the system (circulate 100 ml of fluid at 500 ml/min.) Prime volume (100 ml) countdown is displayed on screen. Stop automatically when countdown reaches 0 ml.

b. PT.LINE PRIME

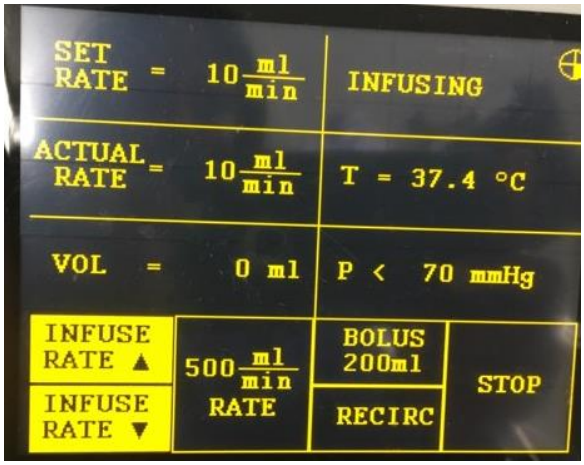
- Press PT. LINE PRIME once to pump at 50 ml/min or press and hold to pump at 200 ml/min. Press STOP when line is free of air bubbles.





c. INFUSE ▲▼

- Press INFUSE to start infusion at 10 ml/min. Press INFUSE RATE ▲▼ to change flow rate.



d. AC to DC switch over

- Remove the power cord. Verify that the system automatically switches to battery when AC is disconnected. BATTERY NO HEATING message displays to indicate the system is now in battery mode and heating is suspended.

e. DC to AC switch over

- Connect back to AC power and verify the operation is uninterrupted.

f. Flow Out Audible Alarm

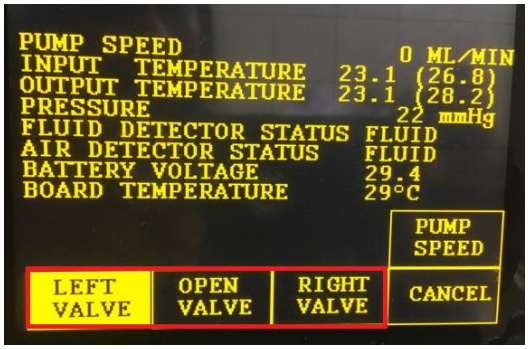
- Adjust the flow rate by pressing INFUSE RATE ▲▼.
- Remove water source, verify that the system stops pumping and sounds an audible alarm with 'FLUID OUT' message displays on screen.

3. Hardware Verification

Prime the disposable set in user mode, turn the machine OFF and turn it ON. Enter SERVICE, before beginning the Hardware Verification process. Enter into service mode. Password: 013192. Select HARDWARE.

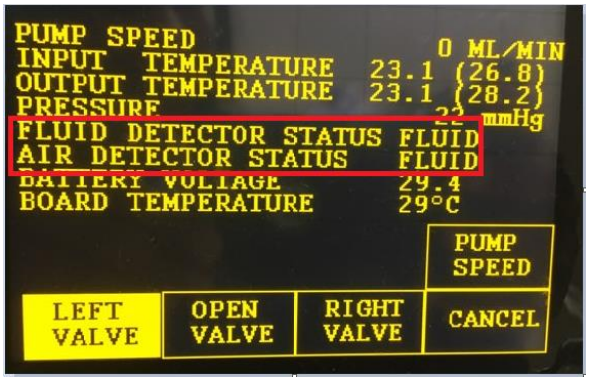
a. Valve Operation

- Press LEFT VALVE, confirm that the valve wand (valve pincher) moves to the left.
- Press OPEN VALVE, confirm that valve wand moves to the middle position.
- Press RIGHT VALVE, confirm that the valve wand moves to the right. Leave the valve into the LEFT VALVE position before continuing to the next step



b. Fluid Out and Air Detectors

- Confirm that the Fluid Out Detector and the Air Detector status lines display FLUID when the system is primed and no air is in the detectors.
- Open the door and pull out the tubing from the detectors. Close the door and confirm that the status line display AIR when the tubing is removed from the sensor.

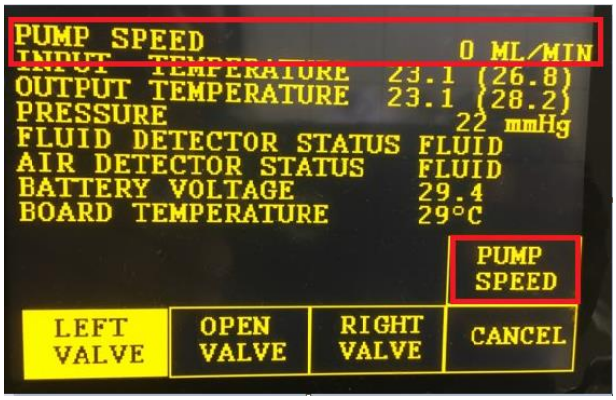


d. Flow Rate

The flow rate can be verified by actually measuring the flow using a graduated cylinder and timer.

Directly measure the flow:

- Make certain the patient line and entire disposable is fully primed before measuring. Set the pump speed to 10 ml/min. Press RIGHT VALVE to set the valve into the infuse position and fill the patient line. Use a graduated cylinder to measure flow at the patient line for ten minutes and verify the average flow rate over that period. The volume collected should be 100 ±25 ml for an averaged flow rate of 10 ±2.5 ml/min.
- Press PUMP SPEED again to change the pump speed to 100 ml/min and measure the flow with a graduated cylinder for one minute. The accepted tolerance is 100 ± 10 ml/min.
- Press once more to change speed to 500 ml/min and repeat the measurement. The accepted tolerance is 500 ±50 ml/min.

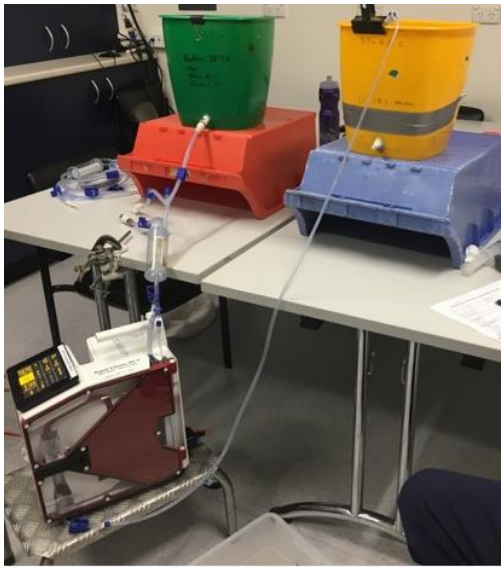


e. Input and Output Temperature Probes

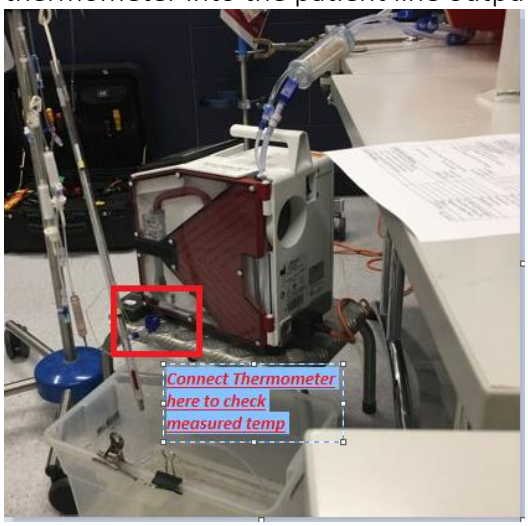
- Prepare 3 buckets of water (0-7degree, 17-23 degree, 37-43 degree)

0-7degree - Approx. 1 cup ice (K1) per 500ml room temperature water

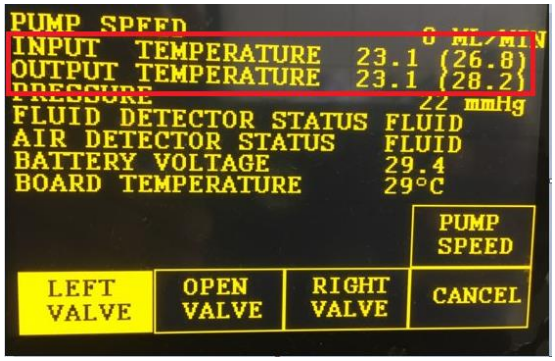
37-43degree - Approx. 1.5L room temp, 500mL hot water



- Connect the three different water buckets to the disposable set. Insert the thermometer into the patient line output.



- Press the RIGHT VALVE key to set the valve to the infuse position. Open the fluid supply and set the pump speed to 500 ml/min.
- Let the temperature stabilize, wait at least 2 minutes. The INPUT TEMPERATURE and OUTPUT TEMPERATURE and measured temperature should be within 2°C of each other for the 0-7°C bucket and 37-43°C bucket. The temperatures should be within 1°C for the 17-23°C bucket.



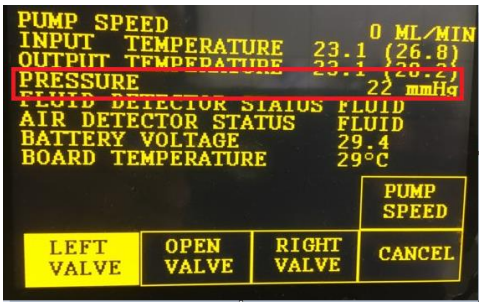
- Press PUMP SPEED to set the pump speed back to 0 ml/min.

g. Pressure Sensor

Connect disposable set to of 37 – 43°C bucket.

- **Inspect the pressure transducer for damage. Make certain the surface of the transducer is not cut or punctured. The pressure transducer must be replaced if the surface is damaged.**

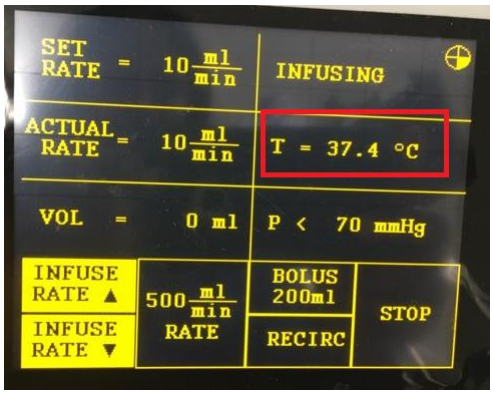
- Make certain the pressure chamber is properly installed and the flow path is not blocked.
- Make certain the fluid is warm (37 - 43°C). The pressure chamber of the disposable is less compliant when it is at room temperature. **Verification must be performed with a warm disposable.** If the fluid is not warm, go to the Main Infuse screen and warm the fluid and disposable by pressing the RECIRC key. Let the fluid recirculated for at least two minutes in AC power before returning to the Hardware mode for verification.
- In the Hardware mode: close the bag clamps and block the air vent on top of the reservoir chamber. Disconnect the patient line and connect the pressure source to the luer fitting at the patient line port of the disposable set and apply pressure using syringe while monitoring the amount of pressure with a manometer.
- Make sure the VALVE is in OPEN VALVE or RIGHT VALVE position.



- Verify the accuracy of the pressure transducer. Apply 300 mm Hg into the disposable. The pressure status line should read 300 mm Hg (±50 mmHg). Repeat the same pressure verification for 200 ±50 mmHg and 100 ±50 mmHg.

f. Temp. when “Over Temp” alarm: On screen

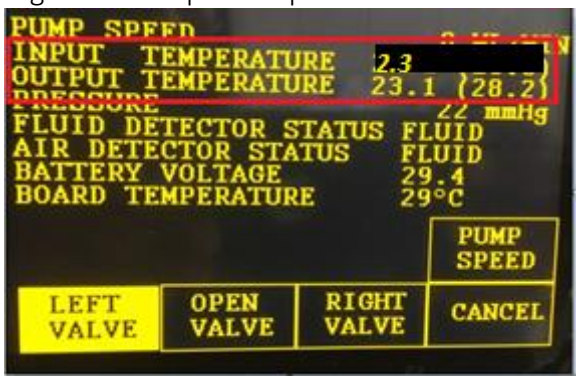
- This test to be performed in user mode. Connect the disposable set to 42°C bucket.
- Perform the prime and Pt.Line prime.
- Connect thermometer to the output. Start infusing 500ml/min.
- The machine should alarm as soon as it reached 42 to 42.5°C and the device screen should show 42°C to 42.5°C.



- The thermometer at the disposable set output should be ±2 degree from screen temp.

4. Operational verification

- Connect disposable set to of 0-7°C bucket, run at three flows 100, 500 and 750 ml/min. Check the output temperature on the screen, it should be at least 26 degrees higher then input temperature on the screen.

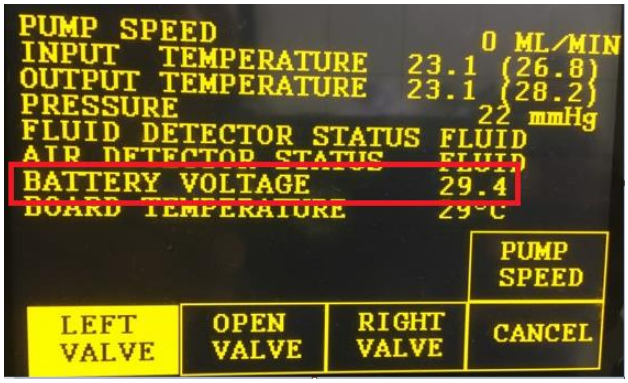


5. Battery Run Time Test

- Prior to performing the battery run test, plug the system into an AC wall outlet for at least 8 hours to fully charge the batteries.
- Disconnect mains power and Infuse at 50 ml/min. Start the timer.
- The system should run for at least 30 minutes with fully charged battery.
- If not, replace the batteries.

6. Battery Voltage

- Unplug the unit from the wall outlet, check ‘Battery voltage’ displayed in HARDWARE screen, should be approximately 24 volts.
- If not, recharge the battery for at least 8 hours and recheck. Plug the unit back into the wall outlet.



7. Electrical safety check

- Perform Class 1 EST test