PREVENTIVE MAINTENANCE AND QUICK OPERATIONAL CHECK OUT PROCEDURE

The Belmont® Rapid Infuser

Belmont Instrument Corporation

Creating a New Standard of Care

780 Boston Road
Billerica, MA 01821, USA

855-397-4547 US/Canada
978-663-0212 Worldwide

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CE 0843

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CAUTION: Federal law (USA) restricts this device to be sold by or on the order of a physician.

P/N 702-00172/REV D

PREVENTIVE MAINTENANCE AND OPERATIONAL CHECK-OUT PROCEDURE

The Belmont® Rapid Infuser, requires minimal service and care. Preventive maintenance should be performed regularly to optimize performance and reduce the likelihood of downtime. Listed below are routine maintenance and operational check out procedure. The instrument does not need regular calibration.

WARNING!
Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately.

WARNING!
Test leakage current routinely to insure against electrical shock hazard.

CAUTION:
Turn the system to STANDBY and unplug the power cord before cleaning to avoid electric shock.

CAUTION:
Immediately wipe any spills from the device.

A. ROUTINE MAINTENANCE

1. Clean and/or Disinfect Exterior

Clean the outside surfaces of the system and inside the door.

a. Turn the pump to STANDBY and unplug the power cord.

b. Wipe the surface with a cloth moistened with water or isopropyl alcohol.

Note: Avoid the use of acetone or other solvents that might damage the surface.

c. To remove dried blood and disinfect the pump, clean them with hydrogen peroxide or a mild bleach solution and dry.

d. Also clean around the door hinges, making sure the door is pushed all the way down inside the hinges.

e. Do not spray cleaning liquids into or onto the air vents at the bottom of the system.

2. Fluid Out and In-Line Air Detectors

Clean the fluid out and air detectors with a moistened Q-tip and dry. Air detector surfaces are delicate. Use care when carrying out this procedure.

3. Power Cord

Inspect the power cord along its length and connectors for cuts and breaks. Replace power cord if damaged.

4. Temperature Probes

Clean the probe sensors with a moistened Q-tip and dry. Use care not to damage the sensor surface.

5. Fan Guards

Inspect the fan guards/air filters, on the bottom of the unit, for debris that might impede air flow. Remove guards by unscrewing the 4 retaining screws and clean, with soap and water, if necessary. Make certain the guards are not damaged. Let the fan guards dry before reinstalling.

6. Seals

Inspect the seal around the unit to make certain it is in good condition. Check also the seal around the touch screen and ceramic disks. Use Dow Corning 732 multipurpose RTV sealant or equivalent if needed to maintain fluid resistance.

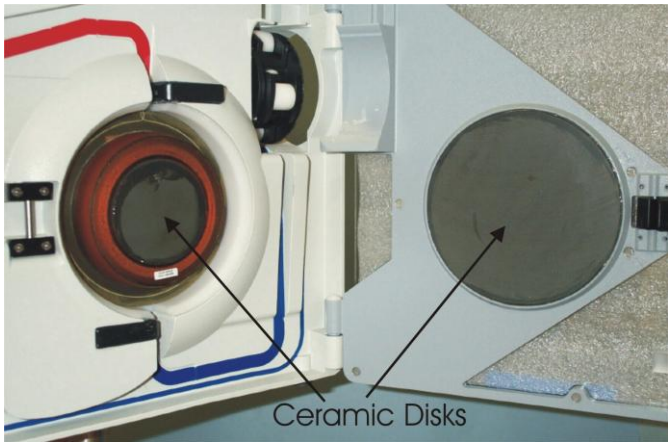
7. Instrument Door and Ceramic Disks

The instrument door must fit properly for the system to operate correctly. The platen part of the roller pump is located on the door. The platen must line up properly with the pump.

a. Check hinges for blood build-up, clean any dried blood from hinge area. Be sure that door is seated completely down on the hinges.

b. Check plastic rivets and door integrity. Make sure that the door frame is not bent. Replace, if bent.

c. Inspect the ceramic disks on the door and in the center of the unit for cracks. Return to manufacturer for replacement if they are damaged.



8. Rubber Feet

Inspect the rubber feet on the bottom of the unit for cracked or missing rubber feet. Replace if necessary.

9. Valve Pincher

Check to make sure that the valve pincher set screw is tight.

10. Pressure Transducer

Make sure that the pressure transducer diaphragm has no tears or rips.

11. Back

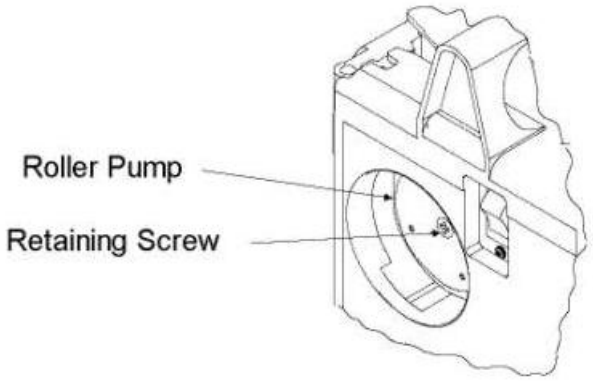
Check that the AC connector (IEC connector), in the back of the unit, is clean. If there is some saline residue, clean.

12. Verify Latch/Unlatch Mechanism

a. Check the rubber pads on the pole clamp assembly. If they feel smooth, clean and scrub with isopropyl alcohol.

b. Mount and un-mount the system on an IV pole, verify that the latch and unlatch work properly and the system will not move down the pole unexpectedly.

13. Clean Pump Head



a. Turn the pump to STANDBY and unplug the power cord.

b. Unscrew the retaining screw that holds the pump head.

c. Remove the pump head and clean with water and soap. Hydrogen peroxide or a mild bleach solution can be used to disinfect.

d. Let pump head dry before replacing and make certain the pump head is securely fastened with the retaining screw.

e. If the pump head squeaks, spray the roller with Teflon spray (Heavy Duty Pure Silicone.)

B. TEST/SYSTEM OPERATIONAL CHECK-OUT

Material Required:

- Rapid Infuser Disposable Set, REF 903-00006
- At least 1 liter of Normal Saline or other crystalloid for testing

1. System Operational Check-Out

a. Install Disposable set.

b. Turn power switch ON. Wait for PRIME screen to appear.

c. Close bag clamps. Hang and spike fluid bag.

d. 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.

e. 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.

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

g. Increase flow rate to 500 ml/min and verify that the output temperature, on the display, is 37.5 ± 1°C.

h. 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.

i. Connect back to AC power and verify the operation is uninterrupted. Adjust the flow rate by pressing INFUSE RATE ▲▼.

j. Infuse until the fluid bag is empty, verify that the system stops pumping and sounds an audible alarm with 'FLUID OUT' message displays on screen.

2. Battery Run Time Test

a. 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.

b. Follow directions in Step 1, a-f. Infuse at 50 ml/min. Remove the power cord and start the timer.

c. The system should run for at least 30 minutes with fully charged battery. If not, replace the batteries.

3. Electrical Safety Test - Leakage Current

Equipment required: Fluke Safety Analyzer, Model 505 or equivalent
2 Liters of room temperature saline

Setup: Plug the Rapid Infuser into AC outlet on the panel of the Safety Analyzer.

> **CAUTION:**
>
> Before applying voltage to Safety Analyzer, make sure input line voltage is correct for the **VOLTAGE OF UNIT UNDER TEST**.

a. **Earth Leakage Currents:**

i. Plug the Safety Analyzer into an appropriate power source, turn Analyzer power ON. Rapid Infuser power switch to Standby.

ii. Switch selector on Analyzer to CHASSIS or LEAKAGE (ΦA). Connect a single red lead to the SINGLE LEAD input jack, and attach large clamp to equipotential ground terminal on the Rapid Infuser.

iii. Record the leakage current displayed for each of the following conditions, with Neutral switch in NORM position. Tests should be performed in the following order.

Polarity - NORM;	Ground – NORM
Polarity - REVERSE;	Ground – NORM
Polarity - REVERSE;	Ground – OPEN
Polarity - NORM;	Ground - OPEN

iv. Repeat the first two (Normal Polarity and Reverse Polarity - Grounded) with Neutral switch in OPEN position.

v. Install the disposable set and prime with saline and proceed to the Infuse screen. Press STOP to set the pump at 0 ml/min, not heating or pumping.

vi. Repeat iii & iv with the Rapid Infuser in ON mode (power switch ON, infuse screen displayed, not pumping or heating).

vii. Repeat iii & iv with the Rapid Infuser, infusing and heating at maximum rate.

viii. All measurements should be <300 ΦA (for 120 V unit) and <500 ΦA (for 230 V unit).

b. **Patient Leakage Current:**

i Install the disposable set and prime with saline and proceed to the Infuse screen.

ii. Attach 12 to 16 gauge stainless steel cannula or hypodermic needle tip to the end of patient line and attach the Safety Analyzer large clamp to the cannula or needle tip.

iii. Prime the Rapid Infuser with saline. Make sure that the entire patient line including the cannula has been primed.

iv. Repeat a.iii, and a.iv with the Rapid Infuser in the STANDBY, ON, and pumping at 750 ml/min modes.

v. Maximum leakage allowable is as follows:

With NORMAL NEUTRAL

Normal Polarity - Grounded (10 ΦA)

Reverse Polarity - Grounded (10 ΦA)

Reverse Polarity - Not Grounded (50 ΦA)

Normal Polarity - Not Grounded (50 ΦA)

With OPEN NEUTRAL (Note: the system automatically switches to battery at 50 ml/min.)

Normal Polarity - Grounded (50 ΦA)

Reverse Polarity - Grounded (50 ΦA)

CHECKLIST

Rapid Infuser S/N:	Tested By:	Date:

	Results	
1. Clean and disinfect exterior		√ **if OK**
2. Clean the fluid out and air detector		
3. Check and /or clean power cord		
4. Clean temperature probe sensors		
5. Inspect and clean fan guards/air filters		
6. Inspect seal around the unit		
7. Inspect instrument door and ceramic disks		
8. Inspect rubber feet, replace if needed		
9. Inspect the valve pincher		
10. Inspect the pressure transducer		
11. Back; Inspect and clean the AC connector		
12. Verify Latch/Unlatch mechanism		
13. Clean pump head		
Test/System Operational Check-Out		√ **if OK**
a. PRIME		
b. PT. LINE PRIME		
c. INFUSE ▲▼		
d. Verify the output temperature (37.5 ± 1°C)		
e. AC to DC switch over		
f. DC to AC switch		
g. FLUID OUT audible alarm		

Electrical Safety Test - Leakage Current Results Sheet

Rapid Infuser S/N:	Tested By:	Date:
Equipment Used:	Safety Analyzer S/N:	Cal Due Date:

a. **Earth Leakage Currents** (all measurements are in µA)

Unit in STANDBY	Polarity - N; Ground - N	Polarity - R; Ground - N	Polarity - R; Ground - O	Polarity - N; Ground - O
$ Neutral - NORM				
$ Neutral - OPEN				
Unit in ON, not pumping				
▪ Neutral - NORM				
▪ Neutral - OPEN				
Unit in ON, infusing @ 750 ml/min.				
< Neutral - NORM				
< Neutral - OPEN				

b. **Patient Leakage Currents** (all measurements are in µA)

Unit in STANDBY	Polarity - N; Ground - N	Polarity - R; Ground - N	Polarity - R; Ground - O	Polarity - N; Ground - O
< Neutral - NORM				
< Neutral - OPEN				
Unit in ON, not pumping				
< Neutral - NORM				
< Neutral - OPEN				
Unit in ON, infusing @ 750 ml/min.				
▪ Neutral - NORM				
▪ Neutral - OPEN				