OPERATIONAL CHECK OUT MANUAL

The Belmont® Rapid Infuser, FMS2000

Belmont INSTRUMENT LLC

780 Boston Road
Billerica, MA 01821, USA

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

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OPERATIONAL CHECK OUT MANUAL

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 702-00133/REV G

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Table of Contents

PARAMETERS SETTING AND PREVENTIVE MAINTENANCE

The Belmont® Rapid Infuser, FMS2000, 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 (as needed), periodic maintenance (at least once a year), and parameters setting. 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.

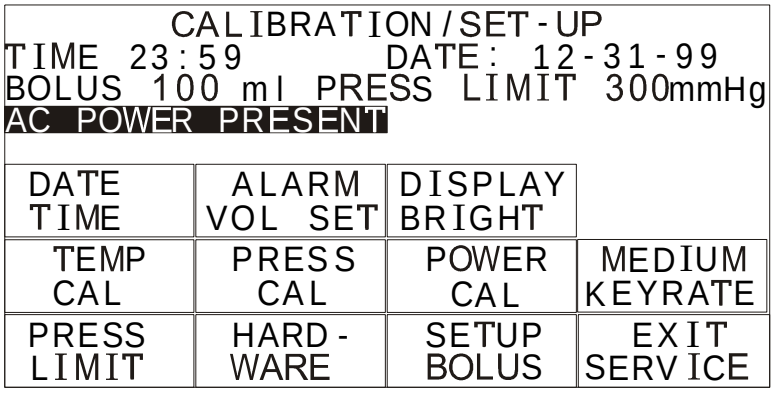
A. SYSTEM SETUP

Changes in system setup can be made to:

- Date and time
- Audible alarm volume
- Display brightness
- Key Rate
- Bolus delivery volume
- Pressure limits for High Pressure alarm

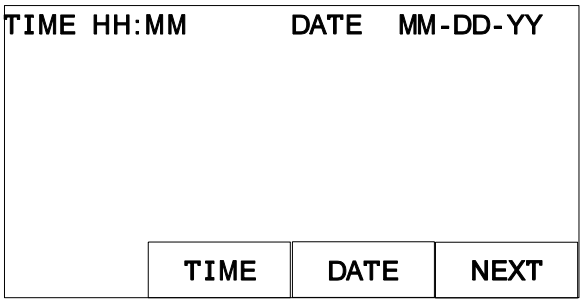
Parameter Setup changes is performed in the Service mode.

Pressing the SERVICE key accesses the Calibration/Set-up mode. This key appears on the BELMONT logo screen only at system powered-up. This screen remains active for 4.5 seconds before the system enters the Prime mode.



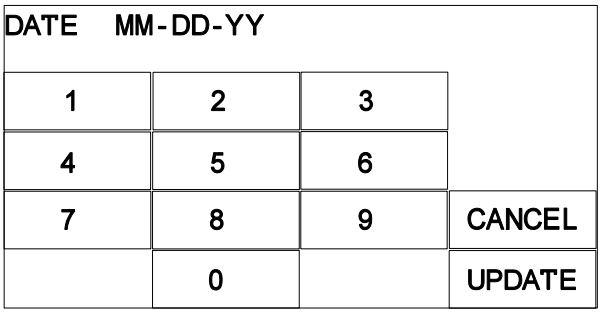
1. Date/Time

Press DATE TIME in the CALIBRATION/SET-UP screen to set the time and date. Press either the TIME or DATE key.

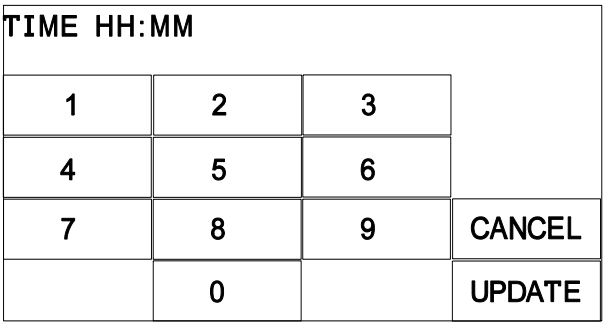


Screen after pressing DATE TIME key

A numerical keypad will be displayed. Enter the appropriate time or date information. Enter the appropriate time in 24-hour clock format (i.e. 1:00 PM = 13:00). CANCEL will erase the entered value and return to the previous Date Time screen. Press UPDATE to save the new value and return to the previous DATE TIME key screen. **Press NEXT to return to the Calibration/Set-Up screen.**



Screen after pressing DATE



Screen after pressing TIME

2. Alarm Volume

ALARM VOL SET is used to set the volume level of the audible alarm. There are seven levels of alarm volume. Each time the key is pressed, a tone will sound to indicate the present alarm volume level.

3. Display Brightness

There are nine levels of display brightness. Press DISPLAY BRIGHT to change the present level of brightness to the next level.

4. Key Rate

The key rate sets up the sensitivity of the touch keys. There are three different levels of sensitivity; FAST, MEDIUM and SLOW. The current level of sensitivity is indicated on the key itself. The FAST setting requires the least amount of time for a key to respond. The MEDIUM setting requires more time and the SLOW key requires the most time and makes the touch keys least sensitive. **The key sensitivity is set at factory to Medium**.

Note that this key changes the time required to depress a key for stroke to be recognized. The pressure required is not affected.

5. Bolus Volume

The bolus volume can be set from 100 to 500 ml and can be changed by 50 ml each time SETUP BOLUS is pressed. The current bolus volume is indicated at the BOLUS status line in the Calibration/Setup screen. The bolus volume is also displayed within the BOLUS key in the Infuse screen (see Chapter 2 under Main Infuse screen).

Bolus Volume Option (1000 ml/min System Only)

The bolus volume can be set from 100 to 1000 ml and can be changed from 100, 200, 400, 500, and 1000 ml each time SETUP BOLUS key is pressed.

6. Pressure Limit

The user can set the maximum allowable in-line pressure. The possible setting ranges from 100 to 300 mm Hg. The current pressure limit value is displayed on the PRESS LIMIT status line on the Calibration/Set-Up screen. Press and hold the key to change the limit in increments of 50 mm Hg. During infusion, the system keeps the pressure in the line under the pressure limit by reducing the infusion rate as the in-line pressure approaches the pressure limit. **The pressure limit is automatically reset to 300 mm Hg each time that the system is powered on.**

B. SERVICE AND PREVENTIVE MAINTENANCE SCHEDULE

Schedule 1

To be performed by either the Clinical User or a Biomedical Technician (BMET).

Routine Maintenance	Interval		
	Before or After Each Use	Every Month	Every 6 Months
1. Clean and/or Disinfect Exterior, if necessary.	●		
2. Clean Fluid Out and In-Line Air Detector.	●		
3. Check the Power Cord.	●		
4. Clean Temperature Probes	●		
5. Check/Clean the Fan Guard.		●	
6. Check the System Seal.			●
7. Check Instrument Door and Ceramic Disk.			●
8. Check Rubber Feet.			●

Schedule 2

To be performed by either a BMET or other qualified service personnel.

Required Test/Verification	Interval	
	Every 6 Months	Every Year
1. Perform Visual Inspection.	●	
2. Perform System Operational Check-Out, including the Audible Alarm Test.	●	
3. Check the battery for rated voltage and check battery run time. Replace batteries when operating time is marginal or after 3 years.	●	
4. Perform Electrical Safety Test.		●
5. Hardware Verification.		●
6. Clean Pump Head		●

C. ROUTINE MAINTENANCE

1. Clean and/or Disinfect Exterior

Clean the outside surfaces of the system and inside the door after each use.

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

Keep the fluid out and air detectors clean and dry. If they become dirty or wet, clean 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

Keep the probe sensors clean and dry. If they become dirty or wet, clean with a moistened Q-tip and dry. Use care not to damage the sensor surface.

5. Fan Guards

Inspect the fan guards, 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.

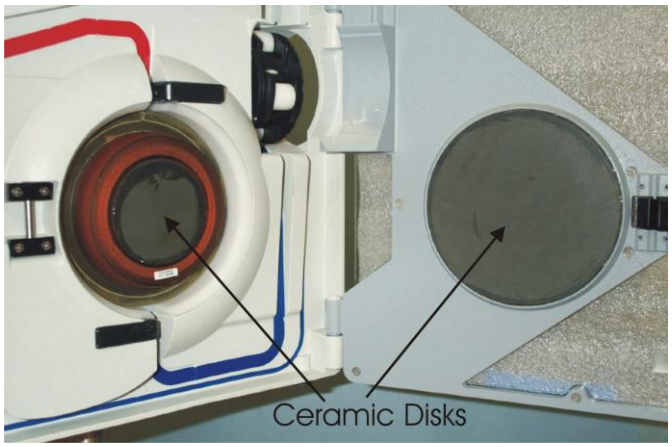
7. Instrument Door and Ceramic Disks

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.

D. TEST/SYSTEM OPERATIONAL CHECK-OUT

The device should be serviced periodically, in accordance to schedule 1 and 2, by a qualified technician.

Material Required:

- FMS2000 Disposable Set, REF 903-00006
- Bio-Tek Safety Analyzer or equivalent
- Saline or other crystalloid for testing
- 2 liters of 35-42ºC fluid
- Manometer (2 mm Hg resolution)
- Pressure source
- Digital Thermometer with thermocouple (0.1ºC resolution)
- Graduated cylinders (ASTM Class B accuracy)
- Timer
- Tachometer (optional)

1. Visual Inspection

a. Door Open/Right Hand Side:

i. Check that air and fluid out detectors are clean.
ii. Check that all the plastic push pins on the door are in-place.
iii. Check that the valve pincher set screw is tight.
iv. Check that there are no cracks in the ferrite on either the door or the right hand side.
v. Check that the pressure transducer diaphragm has no tears or rips.
vi. Check that each pump roller spins freely. If not, remove and clean.
vii. Check that the door is pushed all the way down and there is no dried blood or fluid inside or around the hinges.

b. Back:

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

c. Verify Latch/Unlatch Mechanism:

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

2. 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 ± 1ºC.

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.

3. 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 2, a-g. Infuse at 50 ml/min. Start the timer.

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

4. Electrical Safety Test - Leakage Current

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

Setup: Plug the FMS2000 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. FMS2000 power switch to Standby.

ii. Switch selector on Analyzer to CHASSIS or LEAKAGE (μA). Connect a single red lead to the SINGLE LEAD input jack, and attach large clamp to equipotential ground terminal on the FMS2000.

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 FMS2000 in ON mode (power switch ON, infuse screen displayed, not pumping or heating).

vii. Repeat iii & iv with the FMS2000 infusing and heating at maximum rate.

viii. All measurements should be <300 μA (for Domestic unit) and <500 μA (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 FMS2000 with saline. Make sure that the entire patient line including the cannula has been primed.

iv. Repeat a.iii, and a.iv with the FMS2000 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 μA)

Reverse Polarity - Grounded (10 μA)

Reverse Polarity - Not Grounded (50 μA)

Normal Polarity - Not Grounded (50 μA)

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

Normal Polarity - Grounded (50 μA)

Reverse Polarity - Grounded (50 μA)

5. Hardware Verification

Install and prime the disposable set before beginning the Hardware Verification process.

Hardware mode verifies:

a. Valve operation
b. Fluid Out and Air Detectors
c. Battery voltage.
d. Flow Rate (Pump speed)
e. Input and Output Temperature Probes including “Over Temperature” alarm test, and
f. Pressure sensor.

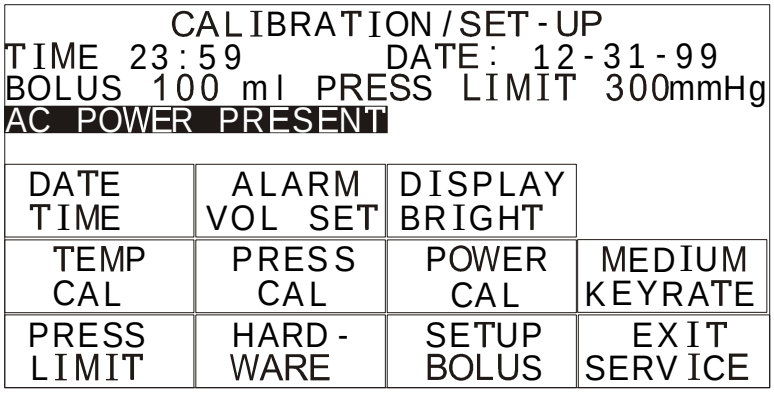
A password is required to access the SERVICE screen, to insure that this mode is not accessed accidentally.

Press the SERVICE key, at power-up, to access the Calibration/Set-up screen. This screen remains active for 4.5 seconds before the system enters the Prime mode screen.

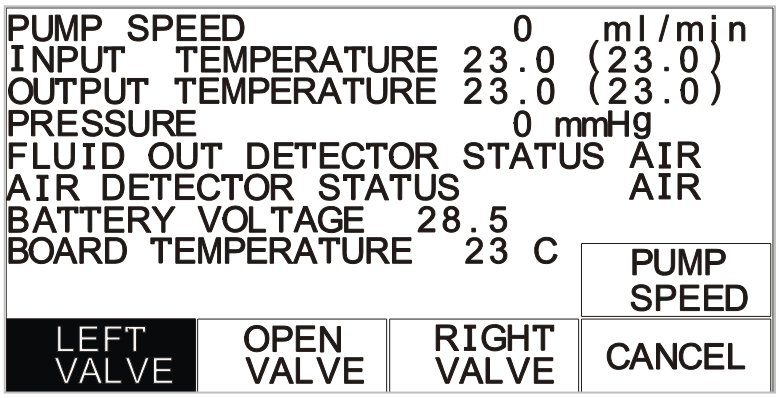
WARNING!

Do not access hardware verification while the instrument is patient connected.

- Press HARDWARE from the Calibration/Set-Up screen.
- Enter the Password 013192.



Calibration/Setup Screen



Hardware Status Screen

Status Line	Reading
Pump Speed	0, 10, 100, 500, 750, and an optional 1000 ml/min
Input Temperature	Temperature in ºC, probe ambient reference in parentheses
Output Temperature	Temperature in ºC, probe ambient reference in parentheses
Pressure	Pressure in mmHg
Fluid Out Detector Status	Air or Fluid
Air Detector Status	Air or Fluid
Battery Voltage	Battery charge level in volts
Board Temperature	Temperature of the circuit board inside the case.

Function Key	Action
PUMP SPEED	Change pump speed.
LEFT VALVE	Move the valve to the left or recirculate position.
OPEN VALVE	Move the valve to the middle or load position.
RIGHT VALVE	Move the valve to the right or infuse position.
CANCEL	Exit Hardware status and return to the Calibration/Set-Up screen.

Hardware Verification:

a. Valve

i. Press LEFT VALVE, confirm that the valve wand (valve pincher) moves to the left.

ii. Press OPEN VALVE, confirm that valve wand moves to the middle position.

iii. Press RIGHT VALVE, confirm that the valve wand moves to the right. Leave the valve in the LEFT VALVE position before continuing to the next step.

b. Fluid Out and Air Detectors

i. 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.

ii. 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.

c. Battery Voltage

Unplug the unit from the wall outlet. '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.

d. Flow Rate

The flow rate can be verified by actually measuring the flow using a graduated cylinder and timer or by using a tachometer. Choose the method that best serves your setup.

Directly measure the flow:

i. 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.

ii. 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.

iii. Press once more to change speed to 500 ml/min and repeat the measurement. The accepted tolerance is 500 ± 50 ml/min.

iv. Press once more to change speed to 750 ml/min and repeat the measurement. The accepted tolerance is 750 ± 75 ml/min.

v. For 1000 ml/min option, press once more to change speed to 1000 ml/min and repeat the measurement. The accepted tolerance is 1000 ± 100 ml/min.

Measure by using a tachometer:

i. Close the door. Set the pump speed to 10 ml/min. Use a tachometer to measure the rotational speed of the pump head. The accepted tolerance is 1.95 rpm ± 25%.

ii. Press PUMP SPEED again to change the pump speed to 100 ml/min. The accepted tolerance is 19.65 rpm ± 10%.

iii. Press once more to change speed to 500 ml/min and repeat the measurement. The accepted tolerance is 97 rpm ± 10%.

iv. Press once more to change speed to 750 ml/min and repeat the measurement. The accepted tolerance is 146 rpm ± 10%.

v. For 1000 ml/min option, press once more to change speed to 1000 ml/min and repeat the measurement. The accepted tolerance is 195 rpm ± 10%.

e. Input and Output Temperature Probes and "Over Temperature" Alarm

Prepare at least 2 liters of 37º - 43ºC fluid

i. Connect the fluid supply to the disposable. Remove the patient line from the luer connector. Insert the thermocouple approximately 2" into the connector previously connected to the patient line.

ii. 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.

iii. Let the temperature stabilize, wait at least 2 minutes. The INPUT TEMPERATURE and OUTPUT TEMPERATURE value readings (the values not between the parentheses) should be within (2ºC).

iv. Compare the numbers displayed, on screen, to the thermocouple reading. The accepted tolerance is 1ºC for fluid temperature between 30ºC to 40ºC and 2ºC outside this range.

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

vi. Press CANCEL to return to the Calibration/Set-Up screen.

vii. Press EXIT SERVICE to return to PRIME screen.

viii. Prime the unit and the patient line with room temperature water.

Prepare at least 2 liters of 43º – 45ºC fluid.

ix. Connect this fluid supply to the disposable. Infuse at 500 ml/min.

x. Compare the numbers displayed, on screen, to the thermocouple reading. The alarm sounds when the screen reads between 42º – 42.5ºC.

xi. Record the temperature when the "Over Temperature" alarm occurs. The accepted tolerance of the temperature between the thermocouple and on the screen should be within 1º to 2º C of each other.

f. Pressure Transducer

> **WARNING!**
>
> Do not apply excessive pressure to the pressure chamber or pressure transducer. The pressure transducer is a precision electromechanical device and can be damaged with excessive force. **Do not use the system if the pressure transducer is damaged**.

i. **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.**

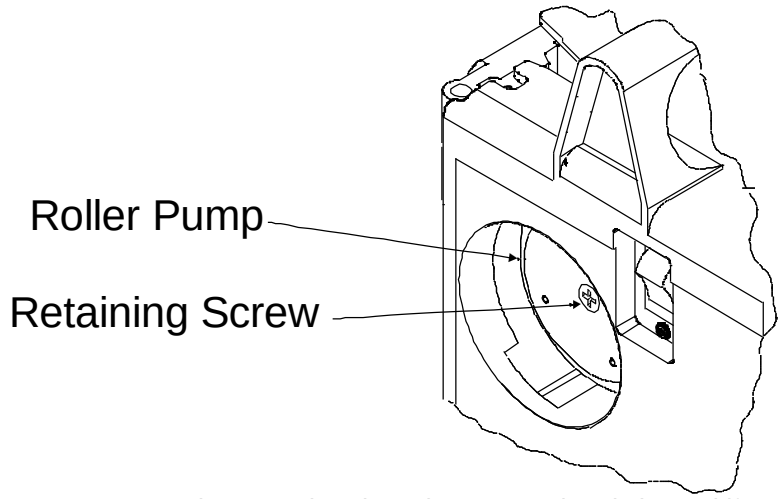
ii. Make certain the pressure chamber is properly installed (see Chapter 2: Installing the Disposable) and the flow path is not blocked.

iii. Make certain the fluid is warm (37 - 42ºC). 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 (Chapter 2: Main Operating Screen: Recirculating Mode). Let the fluid recirculated for at least two minutes in AC power before returning to the Hardware mode for verification.

iv. In the Hardware mode: close the door, 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 while monitoring the amount of pressure with a manometer.

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

6. Clean Pump Head



The pump head can be removed and cleaned if needed.

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 Silicone spray (Heavy Duty Pure Silicone.)

E. CHECKLIST

FMS2000 S/N:	Tested By:	Date:

Equipment Used:	Safety Analyzer S/N:		Cal Due Date:
	Pressure Source S/N:		Cal Due Date:
	Thermometer S/N:		Cal Due Date:
	Tachometer S/N:		Cal Due Date:

	Results	
1. Visual Inspection: a. Right Hand Side b. Back c. Latch/Unlatch		√ **if OK**
2. Operational Check-Out d. PRIME e. PT. LINE PRIME f. INFUSE ▲▼ g. AC to DC switch over h. DC to AC switch i. FLUID OUT audible alarm		√ **if OK**
3. Battery Run Time test		>30 min.
4. Electrical Safety Check (See attached Results Sheet) a. Earth Leakage Current b. Patient Leakage Current		√ **if OK**
5. Hardware verification:		
a. Valve Operation		√ **if OK**
b. Fluid Out and Air Detectors		√ **if OK**
c. Battery Voltage		**approx. 24 V**
d. Flow Rate		√ **if OK**
e. Input and Output Temperature Probes		√ **if OK**
Temp. when "Over Temp" alarm: On screen		**42º to 42.5ºC**
Thermocouple		**1º to 2ºC of screen**
f. Pressure Sensor		√ **if OK**
6. Clean Pump Head		√ **if done**

Electrical Safety Test - Leakage Current Results Sheet

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

	Polarity - N; Ground - N	Polarity - R; Ground - N	Polarity - R; Ground - O	Polarity - N; Ground - O
Unit in STANDBY				
▪ 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)

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