SERVICE MANUAL

The Belmont® Rapid Infuser, FMS2000

Belmont INSTRUMENT LLC

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866-663-0212 US/Canada
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CE 0843

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

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INTRODUCTION

The **BELMONT FLUID MANAGEMENT SYSTEM**, **FMS2000** infuses blood, replacement IV fluids or irrigation fluids warmed to physiologic temperature at user-set rates from 10 to 750 milliliters per minute (ml/min) with 1000 ml/min option. Low infusion rates of 2.5 and 5.0ml/min (150 and 300ml/hr) are also available to keep the venous line open. No heating is provided at these low infusion rates.

The system monitors temperature, line pressure, and air in the fluid path to ensure safe operation and alarms at all unsafe conditions. A hardware override circuit prevents unsafe operation in case of system computer failure. A touch screen displays flow rate, total fluid infused, temperature, line pressure, alarm and status messages and proper procedures to proceed safely after an alarm situation. Keys appropriate to a particular point in the operation are displayed on the touch screen.

Battery backup allows for mobile transport of the patient and system. During battery operation, fluid warming is disabled while pump operation and safety monitoring remain active. Flow rate during battery operation is limited to 50 ml/min.

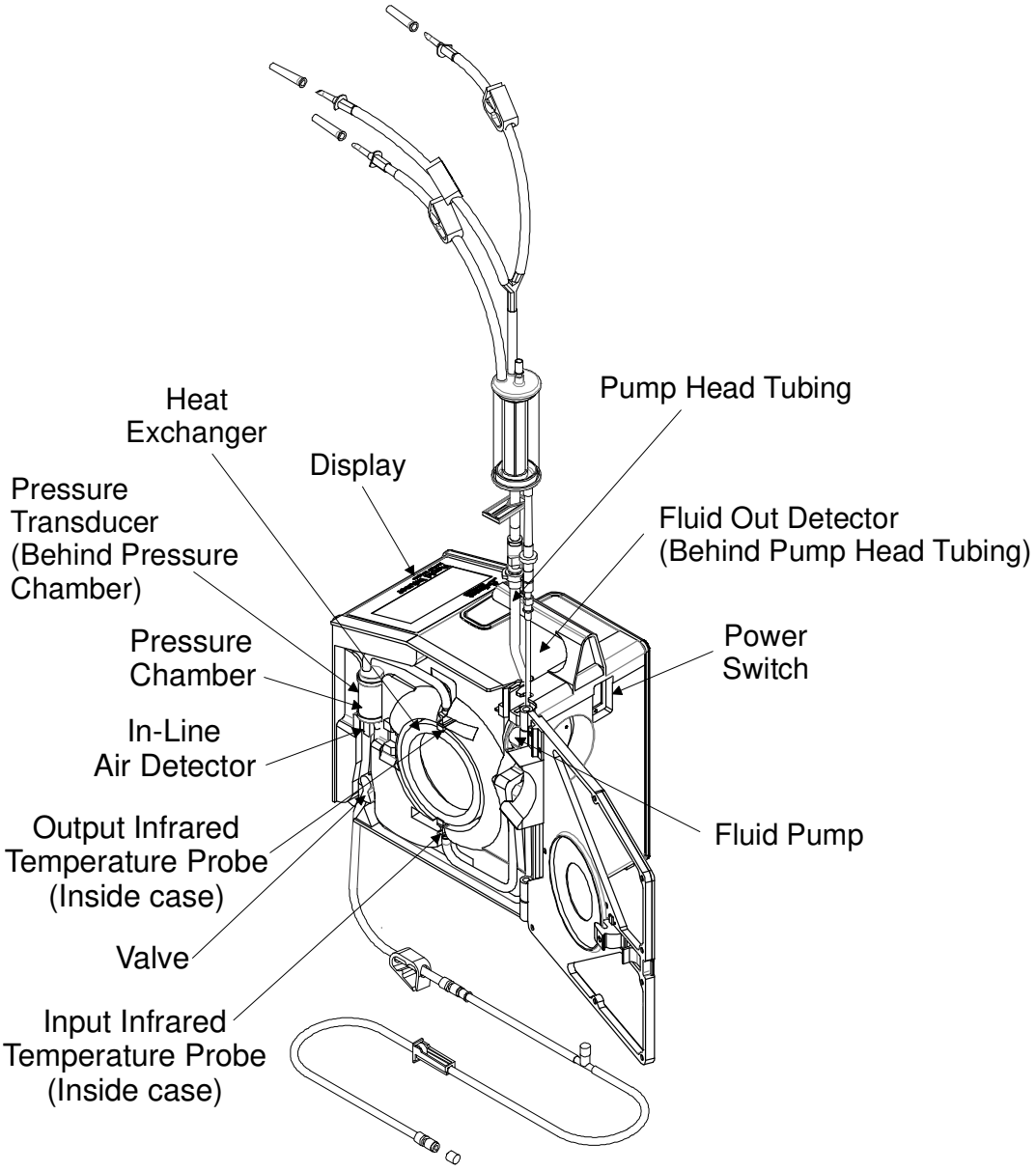
OVERVIEW OF THE BELMONT FMS2000

The complete system consists of the FMS2000 **Control System**, which is mounted on an IV pole, and the FMS2000 **System Disposable Set**.

The **Control System** consists of three major components:

- A high speed fluid pump.
- An efficient fluid warmer.
- A Monitoring/Alarm system for sensing and analyzing:
  - Infusate Flow Rate
  - Fluid Temperature
  - Line Pressure
  - Air Bubbles in the Infusate

The **Disposable Set** is preconnected and has a sterile fluid path. **It is intended for single patient use only**. It connects directly to fluid or blood bags and contains components necessary to pump and warm the infusate, and interfaces directly to temperature, air, and pressure sensors in the Control System. **The** FMS2000 **must be used only with the supplied disposables.**



System Diagram Showing Main Components

FLUID PUMP

The roller type peristaltic fluid pump is designed to obtain low hemolysis, consume low power, is lightweight and very reliable. The pump speed is controlled by the demanded flow rate that is set by the operator. The pump head can be removed for cleaning. The pump is mounted near the top of the Control System just below the “Fluid Out" (Out of Fluid) Detector. The pump tubing is built into the disposable set.

HEATING SYSTEM AND TEMPERATURE MONITORING

Blood or replacement fluid is warmed as it passes through the heat exchanger. The heat exchanger consists of a plastic housing holding stainless steel rings used to transfer the heat to the fluid. Infrared temperature sensors, which are mounted at the entrance and the exit of the heat exchanger, monitor the temperature of fluid as it enters and exits the heat exchanger. The temperature of the heated fluid as it leaves the heat exchanger is displayed on the screen. The system corrects for overheating or underheating and will shut off and alarm at unsafe conditions. The system is capable of heating fluids from 10ºC to 37.5ºC at 750 ml/min and 20ºC to 37.5ºC at 1000 ml/min.

PRESSURE MONITORING

A pressure sensor monitors the line pressure of the infusate. Line pressure is directly influenced by the infusion set used. Larger bore catheters or needles result in lower line pressure allowing for higher flow rates.

If the sensor detects pressure, which exceeds the limit set by the user, the pump automatically slows down to maintain the line pressure below the pressure limit. The pressure limit is set at the factory to the maximum limit of 300 mmHg. If the line pressure suddenly increases, pumping and heating stop. An alarm sounds and "High Pressure" is displayed on the screen. High pressure in the line during infusion cannot be transmitted back to the infusate bag. This high pressure sensing prevents fluid lines from "blowing out" if blocked.

AIR DETECTORS

Air in the system is vented through a hydrophobic filter at the top of the Reservoir Chamber in the Disposable. During infusion, after every 500 ml infused, the system will automatically recirculate any air in main fluid circuit back into the Reservoir Chamber to be vented. In addition, there are two (2) air detectors to monitor for air.

Fluid Out (Out of Fluid) Air Detector: This air detector is located closest to the fluid bag just above the fluid pump. If air is detected, pumping and heating stop. The alarm sounds and the "Fluid Out" warning message is displayed on the screen. A graphic message appears showing the location of the air detector involved, and gives instructions on how to clear the alarm and proceed safely.

In-line Air Detector: This air detector is located above the valve wand (diversion valve). If air is detected, the valve is closed immediately to prevent air from reaching the patient line. Pumping and heating stop. An alarm sounds and the "Air detection" warning message is displayed on the screen. A graphic message appears showing the location of the air detector, which signaled the warning and gives instructions on how to clear the alarm and proceed safely.

DIVERSION VALVE

The diversion valve motor is capable of running in two (2) directions. The diversion valve shuts off the recirculation line when the system is in the infusion mode. When the RECIRC key is set to the recirculation mode, the diversion valve shuts off the infusion line to the patient and recirculates fluid through the system, at a preset flow rate of 200 ml/min. If unsafe conditions occur, the system stops pumping, heating, and reverts the diversion valve to the recirculation mode.

ALARM AND ALARM MESSAGES

An alarm message is displayed on the screen whenever an error condition occurs which may require user intervention. At each alarm condition, the pump is stopped, the heater turned off, and the diversion valve closes, blocking fluid infusion to the patient, and rerouting fluid back to the reservoir.

See Chapter 8: Alarm Messages and Troubleshooting Procedures for complete list of alarms.

CONTROL PANEL: DISPLAY AND KEYS

The control panel consists of the touch screen display, which incorporates a bright graphical display with touch pad keys. The display shows status and alarm messages at the top and middle, and contains the touch keys at the bottom.

CONTROL PANEL SUMMARY

Status Display:

- **Flow Rate in ml/min**
- **Volume Infused**
- **Infusate Temperature in ºC**
- **Pressure in the Fluid Line in mmHg**
- **Bolus Volume (when infusion of a fixed bolus of fluid is desired).**

Function Keys: The keys that control all system functions are displayed on the screen. The screen is changed each time a function key is pressed. Only keys that are relevant to the desired function are presented. The active key is highlighted.
There are three (3) different levels of sensitivity: Fast, Medium, and Slow. The key sensitivity is set at the factory to medium, but can be adjusted by the operator in SERVICE MODE.

See Chapter 6 for 'Key Rate' sensitivity setup.

Alarm Display: Graphical alarm messages indicating where errors have occurred and suggested operator action.

Technical Specifications of the Belmont FMS2000

DIMENSION	
Size	13.5" x 12" x 7.5" (34.29cm x 30.48cm x 19.05cm)
Weight	28 lbs (12.7 Kg)

PORTABILITY	
Hand Carry	Handle on top of unit for easy transport
I.V Pole Mount	I.V pole mountable or free standing. I.V pole diameter range of pole mount: 1" - 1 1/4"

POWER	
AC Input Voltage	115-120 V~ or 230 V~
Fuse	1.25A, 250V, Fast Acting, 5x20mm
Operating Frequency	50/60 Hz
Maximum Power	1440 VA
Line Isolation	1500 V to ground
Earth Leakage	< 300 µA (For Domestic unit) < 500 µA (For 230 V - unit)
Electrical Compliance	IEC 60601-1 + A1 + A2, EN 60601-1 + A1 + A2 + A11 + A 12 + A 13, CAN/CSA-C22.2 - No. 601.1- M90 + S1 + A2
Circuit Breaker	15Amp, 125VAC/10 Amp, 240VAC, 50/60 Hz
Power Cord	U.S: 3 conductors, 14 AWG type SJT Cord with Hospital grade plug
	Outside U.S.: 3 x 1.5 mm^2 International Harmonized Cordage with Hospital grade plug
Battery Type	Rechargeable lead acid
Running Time	> 30 minutes at 50ml/min. without heat
Recharge Time	8 Hours

ENVIRONMENTAL	
Operating Temperature	10ºC to 32ºC (50ºF to 90ºF)
Storage Temperature	-15ºC to 40ºC
Relative Humidity	10% to 90%
Pressure	49 to103 kPa
Shock and Vibration	Meet MIL STD.810E method 514.4 (Basic Transportation)
Electromagnetic Compliance	Meet EN60601-1-2 (2007) and IEC 60601-1-2 (2007)

OPERATING PARAMETERS	
Flow Rate	10-750 ml/min, with 1000 ml/min option, in 10 ml/min steps plus 2.5 and 5.0 ml/min with fluids of viscosity 1 to 8 centipoise (Water and crystalloid fluids through packed red cells) Tolerance: ± 10% from 20 - 1000 ml/min ± 25% for 2.5, 5.0,10 ml/min
Output Temperature	Set to 37.5ºC for flow ≥ 60 ml/min, to 39ºC at 50ml/min or lower.
Heating Capacity	Min. 1400 watts to fluid (20ºC temperature rise at 1000 ml/min)
Line Pressure	0 - 300 mmHg, via pressure transducer
Operating Modes	a) Load disposable set b) Prime system c) Prime patient line d) Infuse at operator controlled rate with warming e) Infuse fixed volume bolus with warming f) Stop system

OPERATING PANEL	
Control Panel and Display	Splash proof touch screen display
Display Area	5" X 2.5" (12.7cm X 6.35cm)
Status Display	Flow rate (ml/min) Total volume infused (ml) Line pressure (mmHg) Output infusate temperature (ºC) Bolus volume (ml) Alarm messages
Functional Keys	Keys are displayed appropriate to the particular point in operation
Character Display	Graphical Alarm Messages - display where errors have occurred

SAFETY AND MONITORING	
Infusate Temperature	Via infra-red sensors at the input and output to the heat exchanger.
Line Pressure	A pressure transducer monitors the in line pressure. If the pressure reaches the threshold set by the user, the pump will slow down until pressure falls below the threshold. If the in-line pressure rises faster than 40 mmHg/ml or exceeds 400 mmHg, an alarm sounds, the "HIGH PRESSURE" message is displayed, the line to the patient is closed and pump comes to an immediate stop.
Air Detection	Two ultrasonic air detectors monitor air in the fluid path. The fluid detector is mounted closest to the fluid bag. It sounds an alarm if there is no fluid entering the system. The other air detector checks for air in the fluid line before it enters the patient line. Out of Fluid criterion: Detect 0.8ml air in input line Air detection criterion: Detect 0.1ml air in fluid line
Diversion Valve	Provides flow path to patient, or recirculation fluid path within the system. The recirculation path is used to prime the system and eliminate air after an air detection alarm or after every 500 ml of fluid infused. The recirculation path is activated at all alarm conditions.

ALARM STATES and CONTROLS	ALARM MESSAGES
Operator Setting, User-correctable	MISSING DISPOSABLE DOOR OPEN FLUID OUT AIR DETECTION HIGH PRESSURE
System Status	LOW BATTERY
System Failures	AIR DETECTOR FAULT PUMP FAULT VALVE FAULT HEATER FAULT LATCH HEAT POWER READ BACK FAULT HEATER OVER POWER FAULT POWER MODULE OVERTEMP HEATING FAULT WATCHDOG OVER TEMP

SAFETY AGENCY APPROVALS & CLASSIFICATIONS	
Type of Protection Against Electric Shock	Class I, or internally powered
Degree of Protection Against Electric Shock	CF defibrillator-proof
Degree of Protection Against Harmful Ingress of Water	IPX2, Drip proof
Method of Sterilization	Disposable delivered sterile, single use
Degree of Safety in Presence of Flammable Anesthetics	Not suitable
Mode of Operation	Continuous
Medical Equipment CLASSIFIED C UL US 49WB UL 60601-1 CAN/CSA-C22.2 No. 601.1 ANSI/AAMI/ES60601-1 (2005) CAN/CSA-C22.2 No. 60601.1 (2008)	Medical – General Medical Equipment As to electrical shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA-C22.2 No. 601.1, ANSI/AAMI/ES60601-1 (2005, 3rd ed.), CAN/CSA- C22.2 No. 60601-1 (2008)
Medical Device Directive: Council Directive 93/42/EEC	Hardware: Class IIb
	Disposable Set: Class IIa

SYMBOLS AND DEFINITIONS	
Symbol	**Description**
CE 0843	Compliance to Medical Device Directive 93/42/EEC
	Alternating current
	Equipotentiality
	Standby
	ON
	Caution
 or 	Consult accompanying documents/refer to manual
	Defibrillator-proof type CF equipment
IPX2	Protected against dripping water
S/N	Serial Number
	Manufactured by
	Authorized European Representative

STEP-BY-STEP SUMMARY OF OPERATING PROCEDURES

The following is a step-by-step summary of the major steps for proper operating the FMS2000; the remainder of the chapter explains each step in detail.

SET-UP

- **Inspect the system**
  - Power cord: use only supplied power cord
  - Reservoir Support
  - Disposable Set
  - 3.0 L Reservoir, if needed
  - Large Reservoir Holder, if needed
- **IV Pole Mounting**
  - IV Pole: 5-wheel (max diameter 1 ¼", min 1")
  - IV Pole Mounting Support Assembly
- **Installing Disposable Set and 3.0 L Reservoir** (if needed)
  - Install reservoir support or large reservoir holder
  - Install disposable set and 3.0 L Reservoir, if needed
  - Close the door
  - Completely close all bag clamps
- **Access Power**
  - Plug power cord into the unit
  - Press circuit breaker to ON. Wait for PRIME screen to appear
- **Installing Fluid Bag**
  - Hang fluid bag on IV pole
  - Remove bag spikes, insert into fluid bag
  - Open bag clamps

PRIMING

- **Priming Main System with solution compatible with blood**
  - Press PRIME - recirculate fluid at 500 ml/min, stop automatically after 100 ml (countdown is displayed on screen)
- **Priming the Patient line**
  - Press PT. LINE PRIME
  - Press once, prime at 50 ml/min. Press and hold, prime at 200 ml/min
  - Press STOP after no air in patient line

INITIATING INFUSION

- **Connect to the Patient**
  - Select an appropriate cannula size for desired flow rate
  - Using aseptic technique, make patient connection without entrapping air
- **Infuse**
  - Press INFUSE to start infusing at 10 ml/min.
  - Adjust flow rate, as needed

MAINTAIN INFUSION

- **Maintain Infusion**
  - Routinely check patient and system parameters, on screen
  - Respond to and correct system alarms

BATTERY OPERATION

- **Battery Operation**
  - Press RECIRC key to preheat fluid in the reservoir
  - Remove power cord from receptacle

END OF PROCEDURE

- **End of Procedure**
  - Clamp off patient line and bag spikes
  - Turn circuit breaker to STANDBY
  - Remove disposable set
  - Dispose of disposable set using hospital policy when handling and disposing the bio-hazardous materials

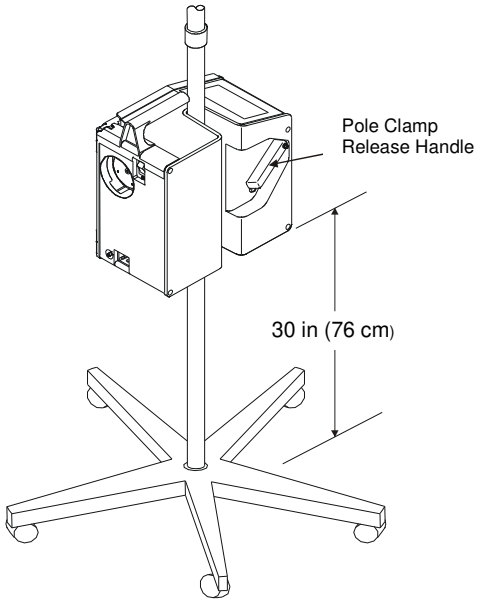
PLACEMENT OF THE SYSTEM – IV Pole Mounting

CAUTION:

Check that the system is securely clamped to an IV pole that can support the system and fluids and will not tip over.

To insure proper ventilation of the system, keep the fan at the bottom of the unit clear.

The operator should take standard precautions applied to all rotating machinery when operating this system.

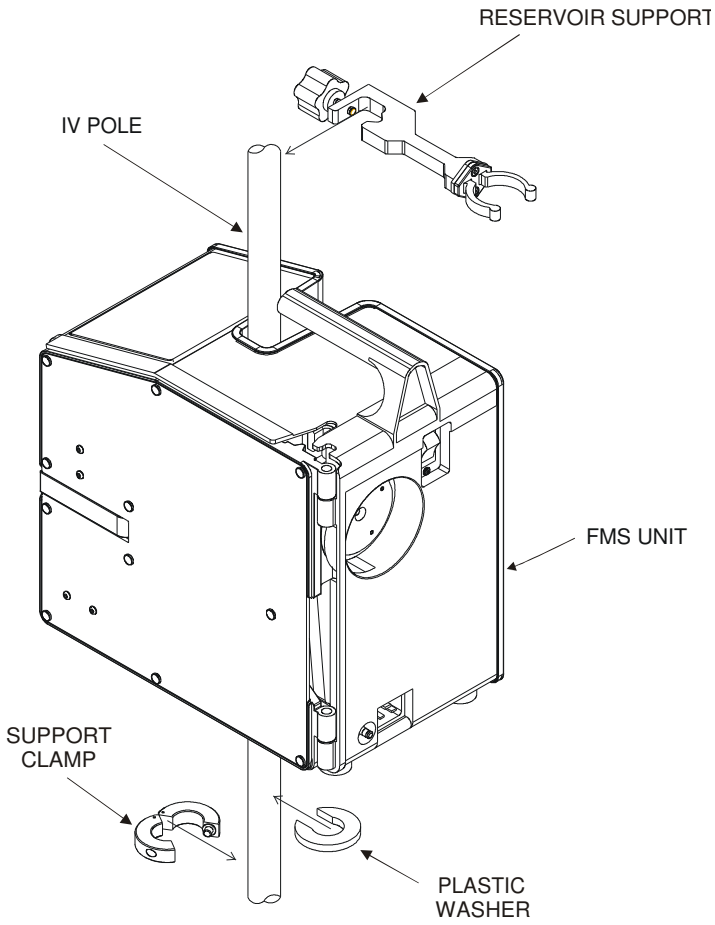


1. Mount the FMS2000 on a 5-wheel IV pole with a maximum pole diameter of $1^{1}/_{4}$ inches (3.18 centimeters) and a minimum base diameter of 24 inches (61 centimeters) capable of supporting the weight of the machine, 26 lbs (11.8 kilograms) and fluids. The system can be fully spiked with 3 units of fluid. Do not mount the system higher than 30 inches (76 centimeters) off the ground.

2. Continue the installation with the Support Assembly (clamp and washer). Position the support clamp below the FMS2000 with just enough room for the thickness of the plastic washer. Snap the plastic washer onto the IV pole above the support clamp. Tighten the screw in the support clamp with a 3/16 Allen Wrench.

3. Support the FMS2000 by the top mounted handle prior to opening the “Pole Clamp Release Handle”. Lift up on the “Pole Clamp Release Handle” to open. Mount the system onto the IV pole by pushing down on the pole clamp release handle at the desired height. Check that the system is locked in place before proceeding.

4. Clamp the reservoir support onto the IV pole above the FMS2000.



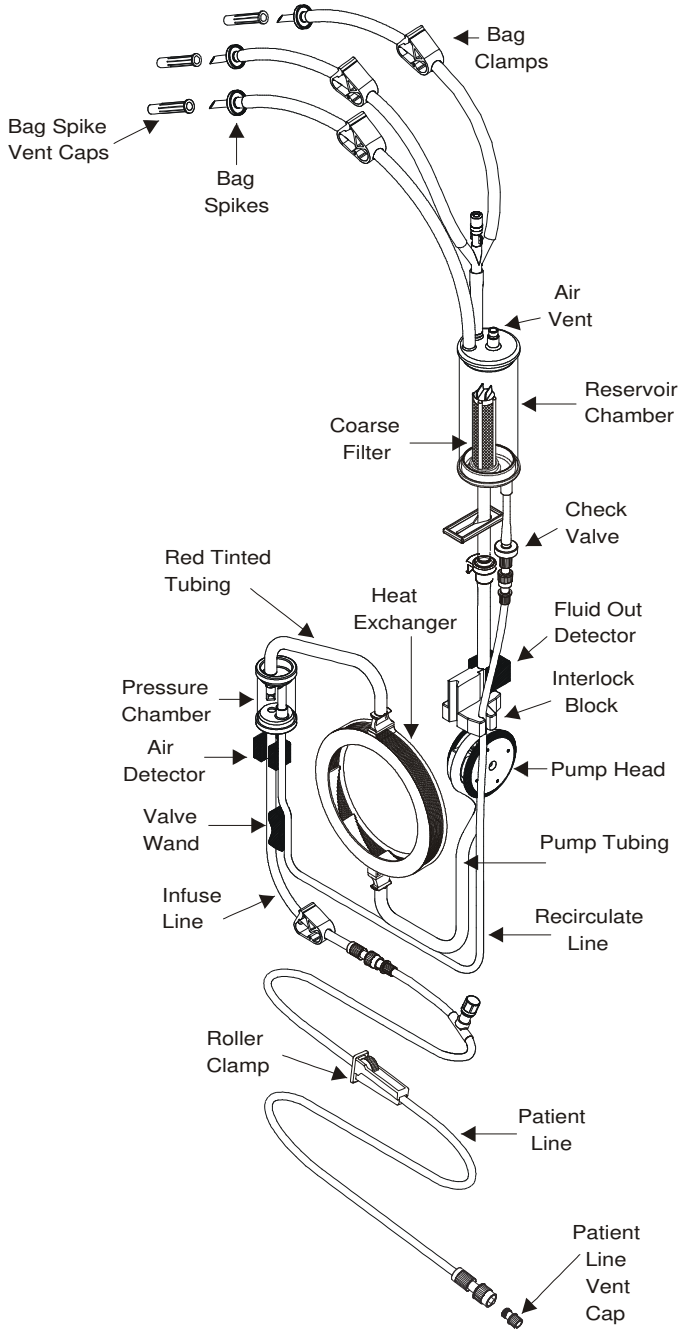
IV mounting of the FMS2000 with support assembly (Clamp and Washer)

5. Make certain that there is nothing obstructing the air vents at the bottom of the system.

6. Do not operate the system while it is lying on its side.

INSTALLING THE DISPOSABLE SET

3- Spike disposable set with key components



WARNING!
Store the disposable set in a dry, well-ventilated area free from exposure to chemical vapors. Always apply the first-in, first-out technique to minimize the length of storage for any unit.

CAUTION:
The disposable set is for single patient use only. **Do not reuse**.

WARNING!
Use only anticoagulated blood products.

WARNING!
Do not mix lactated Ringer's or other solutions containing calcium with citrated blood products.
Use only anticoagulated blood products

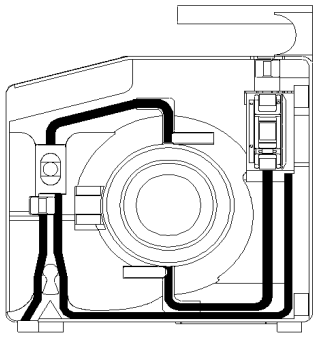
WARNING!
Practice standard precautions when handling blood products. Treat all blood as if it were infected and clean up all spills immediately.

CAUTION:
Keep the windows on the disposable set and the IR probe clean and dry. Avoid touching them. If the windows become dirty or wet, clean with a soft cloth with alcohol and dry.

CAUTION:
Do not alter or change any part of the disposable set, which is specifically designed for use in the FMS2000. Any changes or alterations may endanger the patient or damage the system.

WARNING!
To avoid risk of electric shock, this device must only be connected to supply mains with protective earth.

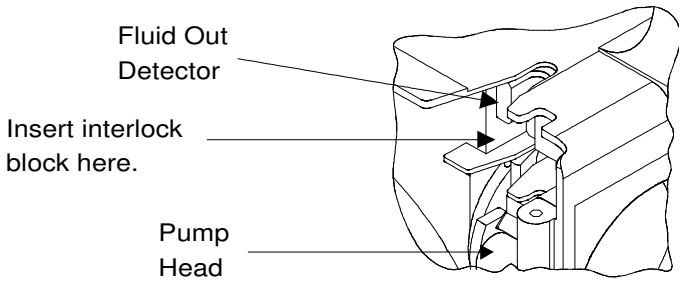
CAUTION:
Immediately wipe any spills from device



Tubing path in the system

1. Remove the disposable set from the tray and lay the reservoir chamber over the top of the machine. Open the door. Insert the heat exchanger with the red arrow pointing up.

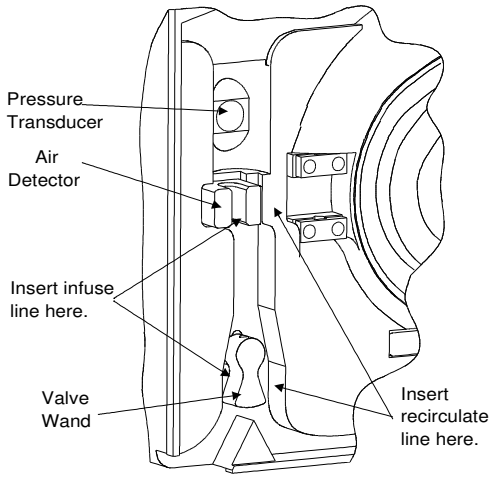
2. Firmly position the interlock block into the fluid out detector.



3. Guide the curved piece of pump tubing over the pump head and position the pump tubing into the groove. Check that the thinner recirculate line is in the groove to the right.

4. Place the pressure chamber into the pressure chamber slot. Move valve wand slightly to the middle. Insert the wider infuse line into the air detector and to the left of the valve wand.

5. Place the thinner recirculate line to the right of the air detector, and to the right of the valve wand.



WARNING!

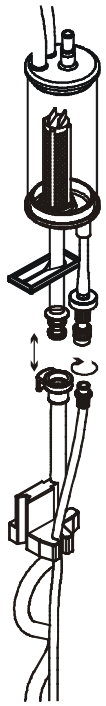
Do not apply excessive pressure to the pressure chamber or pressure transducer. The pressure transducer is a precision electromechanical device and can be damaged with excessive force. Do not use the system if the pressure transducer is damaged.

CAUTION:

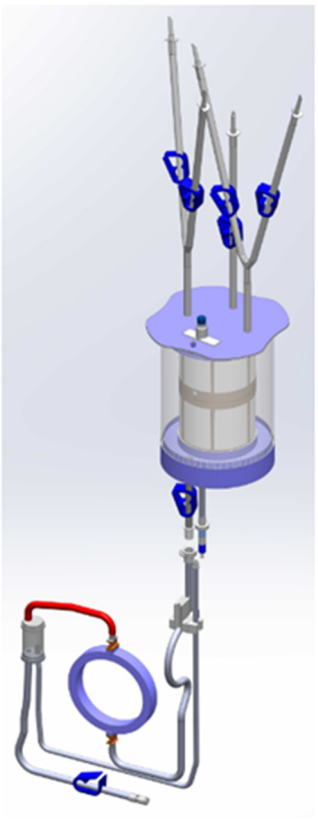
For proper operation, keep the fluid out detector and pump tubing clean and dry. Do not block the air vent on the top of the reservoir chamber.

6. Close the door. Make certain the tubing is not crimped or caught in the door. Connect the patient line.

INSTALLING THE 3.0 LITER RESERVOIR



Disconnect Standard Fluid Supply



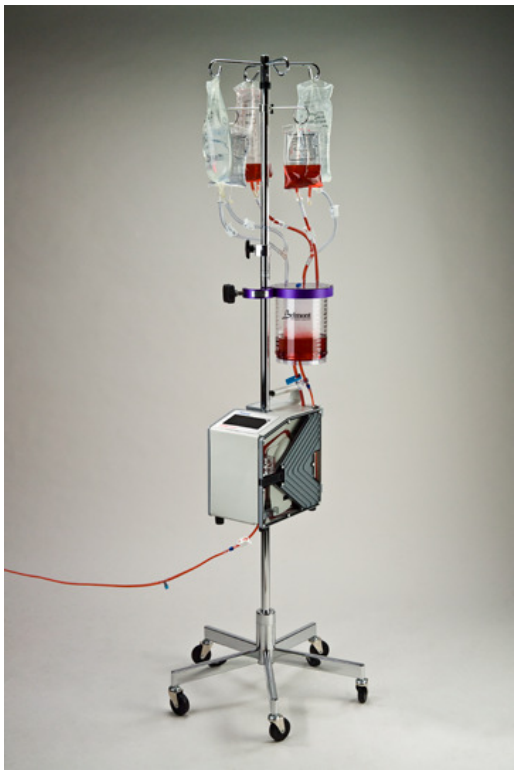
Connect 3.0 L Reservoir to the 3-Spike Disposable Set

1. Using aseptic techniques, remove the standard fluid supply from the 3-spike disposable set by disconnecting the luer connectors.

    - Completely clamp off the larger pump tubing.
    - Disconnect the larger pump tubing by pressing in the luer lock tab and pulling the connector out.
    - Disconnect the thinner recirculate line by unscrewing the connector.

2. Assemble the 3.0 L Reservoir using aseptic techniques by first attaching the three fluid supply tails onto the top of the reservoir.

3. Connect the 3.0 L Reservoir to the luer of the 3-spike disposable set.



4. Attach the reservoir holder onto the IV pole and place the reservoir into the holder.

5. Make certain the two connection leads underneath the reservoir are not stretched or kinked. Stretched or kinked connection leads can cause flow restrictions and frequent Fluid Out alarms.

6. Install the 3-spike disposable set into the FMS2000, as previously shown.

CAUTION:

Do not pressurize or apply a vacuum to the reservoir.

POWERING ON THE SYSTEM

1. Check that the detachable power cable is securely seated in the main power receptacle.

2. Plug the system power cord into an appropriate AC receptacle. Do not use an adaptor for ungrounded outlets.

3. Turn power on by switching the circuit breaker to the ON position. The system will perform a self-check to check the integrity of system parameters.

4. AC POWER PRESENT appears at the logo screen when the system first powers up. Check the power cord and AC receptacle connections if the statement does not appear.

5. PRIME screen, Figure 2, will appear.

    a. If you turn power ON without the disposable set, MISSING DISPOSABLE message and alarm will appear, Figure 1.

    b. Open the door or press MUTE to silence the alarm. Install the disposable set as described earlier.

    c. Press NEXT to go to the PRIME screen, Figure 2.

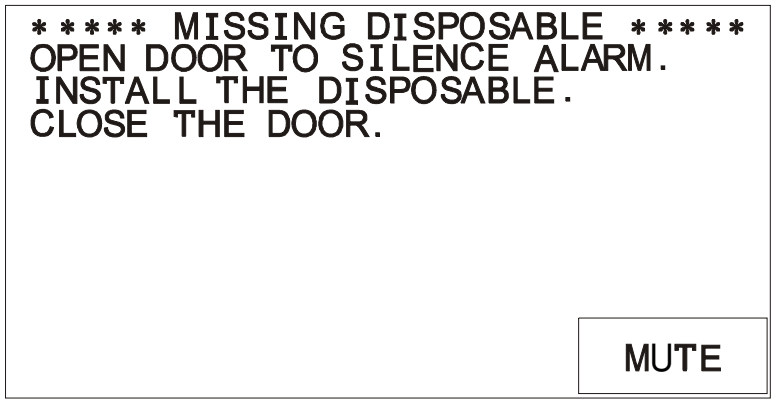


Figure 1. Missing Disposable Set message

PRIMING THE DISPOSABLE SET

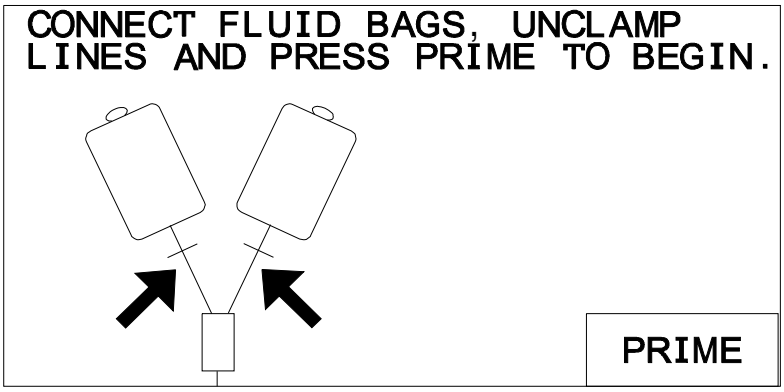


Figure 2. Prime screen 1

We strongly recommend loading and priming the disposable set just prior to the procedure

The system is primed in two steps using solution compatible with blood. **DO NOT USE CALCIUM-CONTAINING SOLUTIONS:**

1. **Prime the Main System.**

   The main system including reservoir chamber, pressure chamber, heat exchanger, and internal tubing is primed automatically for 100 ml at 500 ml/min to remove the air and replace it with fluid.

2. **Prime the Patient Line.**

   The patient line prime is done under user control to remove all air from the patient line.

PRIMING THE MAIN SYSTEM

a. Completely close all bag clamps. Remove the bag spike cap(s) and insert bag spike(s) into the fluid bag(s), pierce it fully to ensure that fluid flows freely. Unclamp bag clamp(s).

b. When hanging the fluid bag above the machine, the pump tubing that is seated in the fluid out detector should not be stretched. Stretching the pump tubing may cause false Fluid Out alarms.

c. The recirculate line must not be kinked or restricted.

d. For optimal system performance, packed red cells should be of good quality.

CAUTION:

Bag port filters may impede flow of viscous fluids. They can clog or trap air, which can block flow.

Use high quality infusate. High amounts of particulates in the blood may clog the bag filter and/or coarse blood filter inside the reservoir chamber. Replace bag filter, reservoir chamber and/or disposable set if filter(s) becomes clogged.

"The filter traps cells, cellular debris, and coagulated protein, resulting in a high protein concentration at the filter surface", AABB 13th Edition*.

Replace reservoir chamber or disposable set when the filter becomes clogged to maintain proper flow. If it becomes occluded the fluid out sensor will activate, an audible alarm will sound, a message "Fluid Out, Check inlet tubing and filter. Add more fluid" will appear and the pump will stop.

CAUTION:

Immediately wipe any spills from the device

e. Prime the system with crystalloid that is under 42EC. Infusing fluids 42EC and over will trigger the Over Temperature alarm. DO NOT PRIME WITH BLOOD.

f. Press the PRIME key to initiate prime, Figure 2. The infuse line is closed off by the valve and fluid is sent through the disposable set at 500 ml/min. The prime volume countdown is displayed on the screen, Figure 3. One hundred milliliters of fluid is circulated to prime the system.

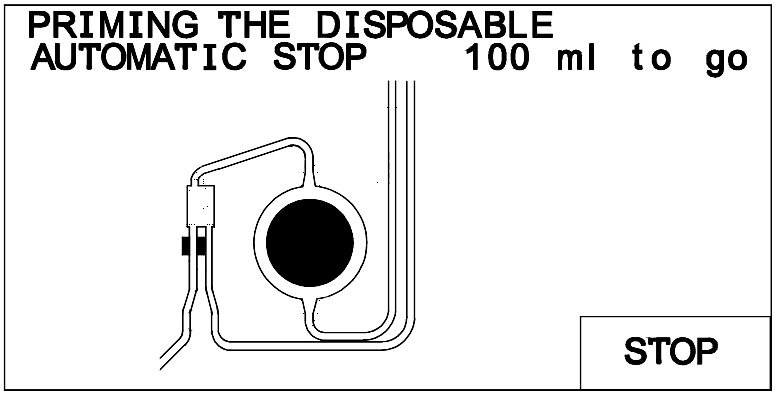


Figure 3. System priming

g. If air is detected during Prime, the volume countdown will be reset to 100 ml again. Air in the disposable set is recirculated back to the reservoir chamber and vented out the hydrophobic filter located on top of the reservoir chamber or back into the fluid bags if both bag spikes have pierced the fluid bag(s) and both bag clamps are opened. Heating occurs during Prime. The prime sequence will stop automatically when countdown reaches 0 ml. If after 30 seconds the countdown does not decrease to at least 87 ml, the system will stop and prompt the user with the Prime screen to unclamp the lines and restart the Prime.

h. If Prime has to be stopped, press STOP. This does not bypass the full prime. The prime volume countdown will remain on the screen. To continue Prime, press RESUME PRIME. When the process is complete, no air should remain in the main system fluid circuit.

CONTROLS	
PRIME	Press the PRIME key to prime the reservoir, heat exchanger, pressure chamber and tubing by recirculating 100 ml of fluid at 500 ml/min through the main flow path. A countdown of volume, from 100 ml to 0 ml completes the prime, appears on the screen. Fluid heating begins when the countdown reaches 60 ml. **THIS STEP IS IMPORTANT FOR PATIENT SAFETY AND CANNOT BE BY-PASSED.**
STOP	Stops the pump and places the system in standby, ready to continue on request. But will not by-pass the full Prime.
RESUME PRIME	Continues the priming process if the STOP key was pressed during Prime.

PRIMING THE PATIENT LINE

a. The patient line must be primed before infusion. The user controls both the speed and duration of the Patient Line Prime. This step primes the patient line with warm fluid.

b. Press PT. LINE PRIME once to prime at 50 ml/min or press and hold the key to prime at 200 ml/min.

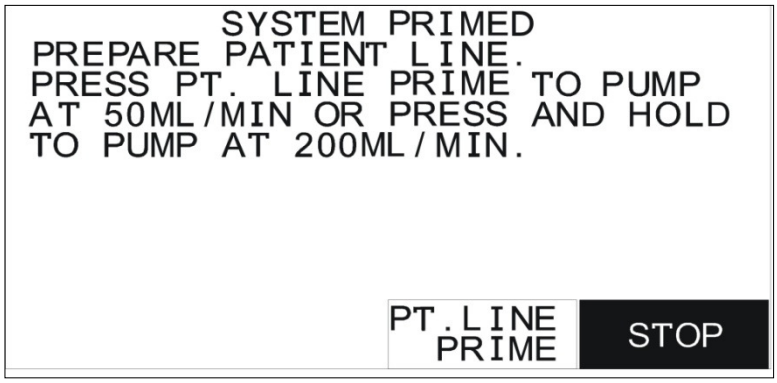


Figure 4. System primed, ready for Patient Line Prime

c. Press STOP or engage the roller clamp first and then press STOP to stop the flow when the patient line is fully primed, Figure 5. Inspect the patient line for air bubbles.

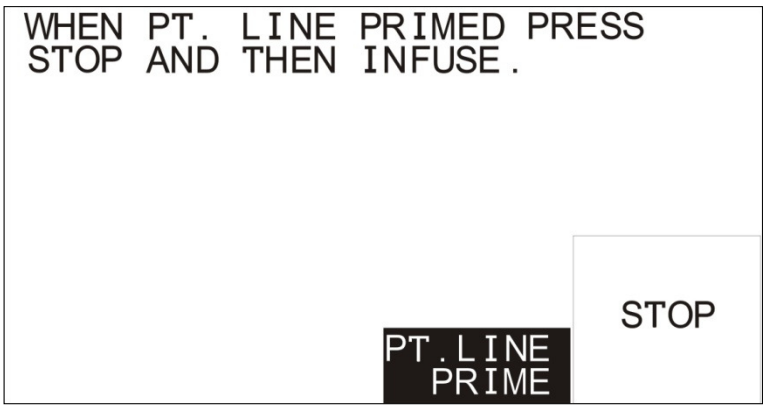


Figure 5. Patient Line Prime

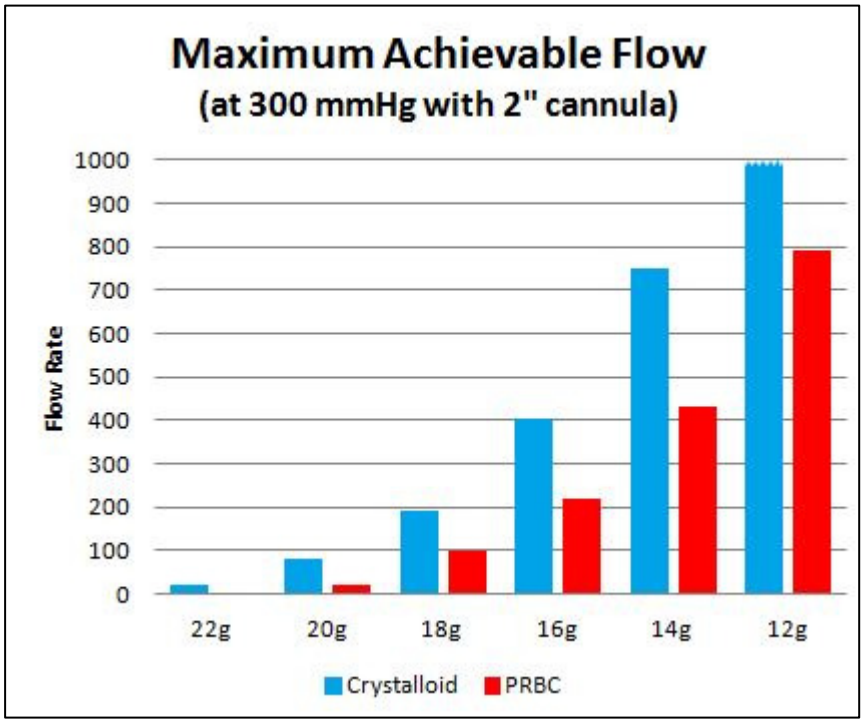
CONNECT TO PATIENT

WARNING!

Before continuing, the operator must inspect and make certain that the patient line is completely primed and free of air. Any air bubbles after the diversion valve in the patient line must be removed before the procedure can be safely continued.

CAUTION:
A single dedicated intravenous access should be used exclusively for infusing blood components and solutions compatible with blood.

1. Choose the appropriate cannula size to match the desire flow rate.



2. Maximum allowable flow rate depends on various factors such as the viscosity of the fluid, the length and diameter of the cannula and patient line. High viscosity, long patient line or small bore cannula will reduce the maximum allowable flow rate.
3. Use aseptic techniques to make the patient connection without entrapping air.
4. Press INFUSE to go to the Infuse screen and start infusing at 10 ml/min. Figure 6.

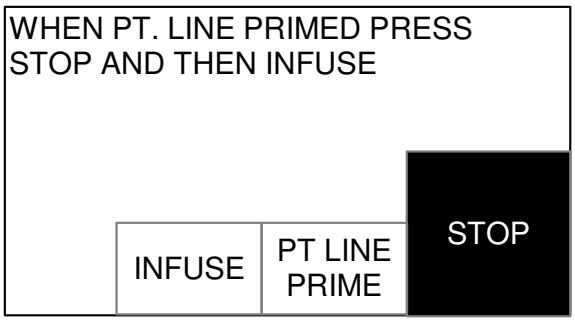


Figure 6. Patient Line Prime

CONTROLS	
PATIENT LINE PRIME	Primes the patient line with warm fluid. Press the key once to prime at 50 ml/min or press and hold the key to prime at 200 ml/min. **WARNING!** The operator must make certain that the entire fluid path is completely primed and free of air before administering fluid to the patient. Failure to do so may result in the introduction of air into the patient.
STOP	Stops pumping and heating. The system is in standby, ready to continue on request.
INFUSE	After properly priming the system, press INFUSE to go to the main operating screen and start infusion at 10 ml/min.

MAIN OPERATING SCREEN

Figure 7. Infuse screen.

CONTROLS	
INFUSE RATE	Start at 10 ml/min when the INFUSE key is pressed. Press INFUSE RATE to increase the infusion rate. Press and hold the key to increase rate more rapidly. The maximum rate is 750 ml/min.
INFUSE RATE	Press INFUSE RATE to decrease the infusion rate by 10 ml/min in the ml/min scale each time the key is pressed. Press and hold the key to decrease rate more rapidly.
500 ml/min RATE	Set the system to the rate of 500 ml/min.
BOLUS	The FMS2000 will pump the volume indicated on the BOLUS key at a rate of 200 ml/min. The bolus volume on the key can be set in the Service mode (see Chapter 6) or by pressing and holding down the BOLUS key while in the Infuse screen. Release the key when the desired BOLUS volume appears in the volume delivered position. The bolus delivery rate can be changed while infusing by either pressing 500 ml/min or by using the INFUSE RATE or INFUSE RATE key. At the end of the bolus volume, the system will beep and return to the previously selected flow rate if the previous rate was 50 ml/min or lower. If the previous rate was higher than 50 ml/min, the flow rate will be set to 50 ml/min.

RECIRC	Sets the system into the Recirculation mode to remove air in the line and to preheat the reservoir chamber and disposable set. The valve shuts off the infuse line to the patient and sends the fluid to recirculate through the system at a preset rate of 200 ml/min. Recirculation will automatically stop and sound a beep after 5 minutes.
STOP	Halt the pumping and heating. Status display continues to be active.

CAUTION:

The system can infuse fluid at rates up to 750 ml per **minute with 1000 ml/min option**. A unit of blood will be emptied in less than one minute at this rate.

CAUTION:

Routinely check patient and system parameters, on screen. Respond to and correct system alarms.

Replace the reservoir chamber or disposable set when the filter becomes clogged. The Fluid Out alarm will occur when the flow through the filter is restricted. If it becomes occluded the fluid out sensor will activate, an audible alarm will sound, a message “Fluid out, Check inlet tubing and filter. Add more fluid” will appear and the pump will stop.

FLUID INFUSION, CONTINUOUS

The infuse rate automatically starts at 10 ml/min when the main operating screen first appears. Adjust the flow rate by pressing INFUSE RATE or INFUSE RATE . Press 500 ml/min RATE to immediately set the infuse rate to the 500 ml/min.

- **Automatic Warming**

  The system automatically warms the fluid to physiological temperature at all flow rates in the ml/min range.

  - For flow rates above 50 ml/min, the fluid will warm to 37.5EC.
  - For flow rates from 10 ml/min to 50 ml/min, the fluid will be warmed to 39EC to help compensate for thermal losses in the patient line under low flow conditions.
  - There is no heating at 2.5 and 5.0 ml/min (150 and 300 ml/hr) settings. Message "LOW FLOW, NO HEATING" flashing on the screen indicates that the system is not heating at low flow rates.

- **Pressure Control**

  Pressure control regulates the pump speed to keep line pressure under the user-set pressure limit. The pressure status line flashes and a periodic beep sounds while the system is under pressure control. Line pressure is mainly due to the small orifice of the infusion set or any occlusions in the line. The pressure limit is set at the factory to the maximum limit of 300 mmHg. To reduce the limit, see Chapter V, Calibration/Set-Up.

  < A larger bore cannula results in lower line pressure and lower line pressure allows higher flow rates. To achieve the desired flow rate, refer to the section, Match the Infusion Set to Flow Rate and Fluid Type earlier in this chapter for the guide to infusion set bore size.

WARNING!

Keep tubing clear of kinks, twists and other restrictions.

- **Automatic Air Purging**

  After every 500 ml of fluid infused, the diversion valve will momentary switch into the recirculate position for a short duration to automatically remove air from the main system fluid circuit into the reservoir chamber. Air in the reservoir chamber may be vented out the hydrophobic filter or back into the fluid bag if bag spikes attached to fluid bags are opened. The RATE status line displays REMOVING AIR during this process. The volume readout (VOL) remains unchanged during automatic air purging and resumes counting when infusion resumes. This process is automatic and requires no operator action.

  - The recirculate rate is temporarily set to 500 ml/min, if the flow rate is set at #500 ml/min. The recirculation rate is set at the actual flow rate, if flow rate is > 500 ml/min, during automatic air purging. When infusion resumes, the system returns to the previously set rate.

BOLUS INFUSION, INFUSE A FIXED VOLUME

- Press BOLUS to deliver the fixed volume indicated on the key at a rate of 200 ml/min. The bolus volume is set at the factory to 200 ml. This can be changed in the Calibration/Set-Up screen (see Chapter V) or by pressing and holding the BOLUS key in the Infuse screen: The new bolus volume will appear in the VOL (volume) status line with the prefix of BOL (bolus). Releasing the Bolus key will start the infusion. To change the flow rate during the bolus infusion, press the RATE ▲, RATE ▼, or 500 ml/min keys. At the end of the bolus volume, the system beeps and returns to the previously selected flow rate if the previous rate was 50 ml/min or lower. If the previous rate was higher than 50 ml/min, the flow rate will be set to 50 ml/min.

RECIRCULATION MODE

- The RECIRC key sets the system into the Recirculation mode. The diversion valve shuts off the infusion line to the patient and recirculates the fluid through the system at a preset rate of 200 ml/min. The infusate in the reservoir chamber and the main system will be warmed and air in the line swept into the reservoir chamber. The system will automatically beep and return to the Stop mode after 5 minutes of recirculation if the operator does not terminate recirculation.

WARNING!

Excessive or prolonged recirculation may damage red blood cells by exposing them repeatedly to the rollers inside the pump head. Limit the time the blood is allowed to recirculate.

PROTECTION FROM ACCIDENTAL POWER OFF

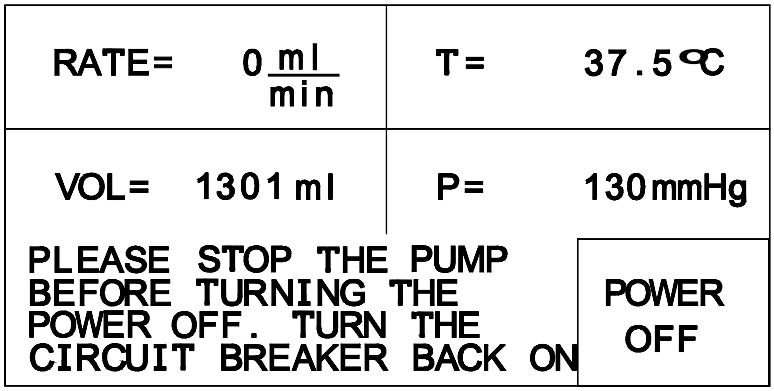


Figure 8. Circuit breaker was turned to STANDBY while pumping.

If the circuit breaker was turned to the STANDBY position while the system is pumping, the system will stop pumping, alarm and display, Figure 8. This message is to protect the system from being accidentally powered down during a procedure. To power down the system, press POWER OFF. To continue with the procedure, turn the circuit breaker back to the ON position and resume operation.

END OF PROCEDURE

Clamp off the patient line and bag spikes at the end of the procedure. Turn the system to STANDBY, using the circuit breaker, first then remove the disposable set from the system. Make certain the patient line is clamped shut when the door of the system is open while the system is powered off to prevent uncontrolled fluid flow. Follow the cleaning procedures outlined in Chapter V to clean and disinfect the system. Practice standard hospital policy when handling and disposing the bio-hazardous materials.

CAUTION:

With fluid in the disposable set and the system not powered on, keep the patient line clamp closed when opening the door to prevent uncontrolled fluid flow.

BATTERY OPERATION

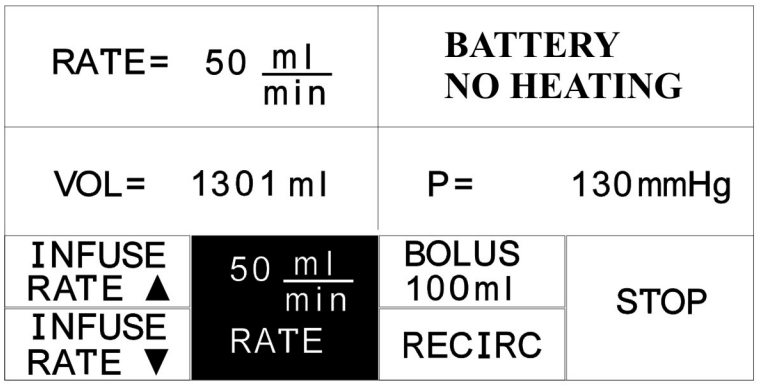


Figure 9. Infuse screen while in battery operation.

The system can operate in battery mode during transport. The built-in rechargeable battery automatically charges whenever the system is connected to line power. The system automatically switches to battery operation when the AC line is disconnected. Battery operation should be used only briefly or at very low flow rates because there is no heating. The maximum flow rate is 50 ml/min. Full safety monitoring remains active. The normal running time in battery operation is at least 30 minutes.

- Press the RECIRC key while the system is in the AC mode to preheat the fluid in the reservoir chamber and main system fluid path.

- Unplug the system, the status line that displays temperature will be flashing BATTERY NO HEATING to indicate the system is now in battery mode, the maximum flow rate is 50 ml/min, and heating is suspended.

- Adjust the flow rate by pressing INFUSE RATE ▲ or INFUSE RATE ▼. Press 50 ml/min RATE key to immediately set the infuse rate to the maximum rate of 50 ml/min or the maximum rate allowable under pressure control, Figure 9.

- When the system is plugged back to the AC outlet, the flow rate stays at 50 ml/min if the previous rate was greater than 50 ml/min. The system will return to the previous rate if the previous rate was 50 ml/min or lower.

LOW BATTERY

- When the battery runs low, the system will display BATT LOW message and sound an audible alarm. The system should be plugged into an AC outlet to continue operation and charge the battery.

- The normal recharge time is 8 hours.

RESTARTING THE SYSTEM

- If the system ever needs to be restarted from power off after the initial startup, follow the same procedure and precautions as the initial startup to restart the system. The Main System Prime and Patient Line Prime cannot be bypassed.

- The volume accounting information on the VOL status line in the Main Infuse screen will be reset to 0 each time the system is restarted after a power down.

CAUTION:

With fluid in the disposable set and the system not powered on, keep the patient line clamped closed when opening the door to prevent uncontrolled fluid flow.

EMERGENCY MANUAL OPERATION

In the event the system is not operational during a procedure, fluid can be infused manually on an emergency basis using pressure or gravity as follows:

1. Bypass the system by switching to STANDBY on the circuit breaker.

2. Open the door.

3. Remove the infuse line from the valve wand. The rest of the disposable set may be left intact in the instrument or may be removed. Opening the door will allow the fluid to bypass the roller pump.

4. Apply pressure at the fluid bag to aid flow. Make certain that the bag clamps and patient line are open. Take care that excessive force is not used on the bag to avoid rupturing the disposable set or damaging blood cells.

WARNING!

In emergency manual operation, all safety features of the system have been bypassed. Monitor the patient line to insure that air is not allowed to enter the patient. Do not apply excessive force on the fluid bag to avoid rupturing the disposable set or damaging blood cells.

Wiring Interconnect Diagram

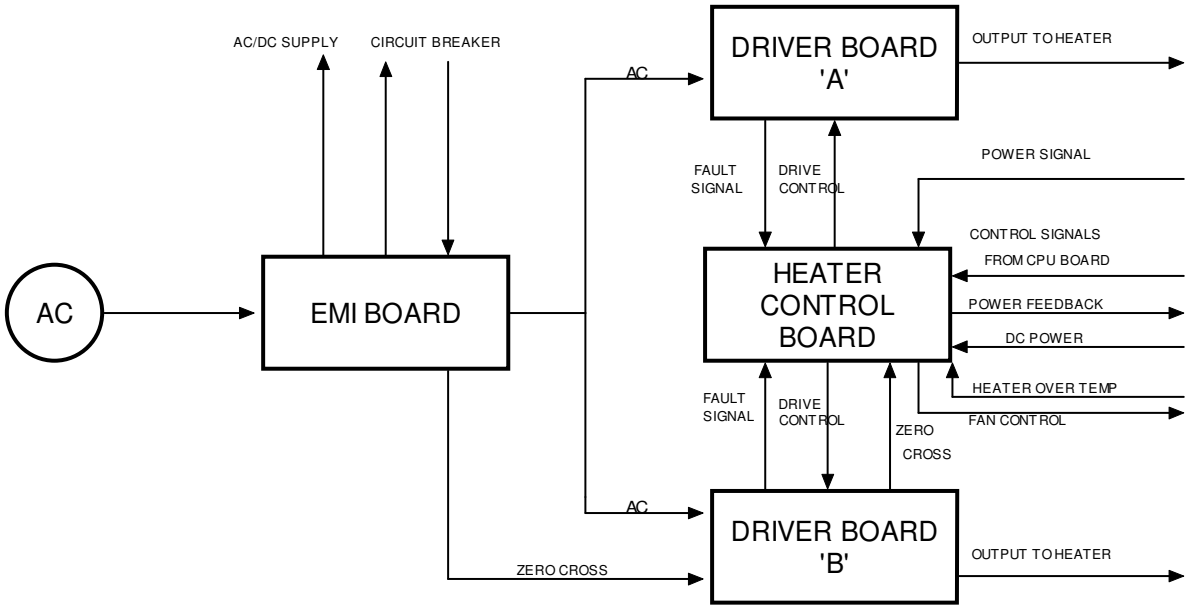
The wiring interconnect diagram shown represents major connection between modules. See drawing 705-00022.

Theory of Operation

The FMS2000 system consists of four (4) main modules: power module, daughter board, computer board, and AC/DC board. In addition to these main modules, there are a membrane panel switch for user interface, roller pump, diversion valve, two (2) temperature probe assemblies, circuit breaker, and a power entry module. The manual is designed to familiarize the service personnel with each module so that troubleshooting and/or replacement can be done on a module level.

1. <u>Power Module</u>:

The power module consists of EMI filter board, Driver 'A', and Driver 'B boards, Heater Control board, and Heatsink Assembly.



Power Module Block diagram

EMI Filter Board:

The EMI filter board provides the necessary filtering for conducted emissions both into and out of the FMS2000. Both common mode and single ended filtering are employed. The board also contains transient protection. AC power enters the system through the EMI board where it is filtered. The filtered voltage then leaves the board to go to the circuit breaker, and to AC/DC power supply board. The voltage then comes back from the circuit breaker and is further filtered and transient protection is provided at this point. This filtered voltage is then applied to the driver boards.

Driver 'A' and 'B' Boards:

The driver boards provide the power to the heat exchanger and isolate the main electronics from the AC line. Each driver board contains two Insulated Gate Bipolar Transistors, IGBT's, which are used as power switches. Driver circuits that monitor for unsafe operating conditions such as over current, IGBT desaturation, and under voltage control these devices. One of the driver boards contains a zero-cross detection circuit that provides a square wave output in phase with the AC power input on the EMI board. The IGBTs are driven with signals derived from the heater control board.

Heater Control Board:

The heater control board contains the following functions: heater driver signal generation, non-volatile memory, power measurement, fan speed control, over temperature for the heatsink, watchdog and system interface.

The heater control board receives control data from the computer board through a serial interface, as well as line phase information and driver circuit fault monitoring signals from driver boards. The computer data determines the frequency at which the heater is to be driven, and the duty cycle at which the power is to be supplied to the heater. The line phase information, supplied by the zero cross circuitry, coordinates the IGBT commutation sequence with the AC line polarity. A Field Programmable Gate Array (FPGA) derives pulse width modulated signals and complementary synchronous rectifier control signals, which drive the IGBT's. The operating frequency of the heater driver, which is determined during factory calibration, is the series resonant frequency of the ferrite core heater winding and resonant capacitors.

The heater control board measures the power that is applied to the heat exchanger. This is accomplished by measuring the magnetic field behind the heat exchanger rings with a "pickup winding". The voltage across the pickup winding squared is proportional to the power induced into the heat exchanger. The pickup winding is loaded to achieve an impedance match, and to convert the induced current to a RMS voltage.

This voltage is applied to a voltage-to-frequency converter, which produces a frequency that is proportional to the output power. A counter then generates a number that is used by the system computer to control the output power under software control, thus closing the control loop. The counter is continuously monitored in hardware for a number that exceeds the maximum power level. If this power level is reached, the system stops pumping and heating, and sounds alarm with 'Over Power Fault' message on screen. The heater control also monitors the AC power supplied to the system. If dangerous levels of noise are present or the line frequency changes the control circuit will stop heating and wait for stable conditions. If stable conditions are not obtained then a fault is generated. When the system is operating in battery mode, the heater does not function, and the system is allowed to pump only at a flow rate of 50 ml/min maximum.

The fan control circuitry supplies three levels of energy to the fan. The speed of the fan is governed by the computer and an over temperature switch mounted on the heatsink. The computer controls the fan speed based on the output power that it requests. If the over temperature switch is activated, the fan will go as fast as possible regardless of the computer command, and the computer is notified of the over temperature condition. If the over temperature condition exists for a fixed period of time, pumping and heating stop. When the power switch is turned off, and the system is plugged into an AC line, the fan will continue running at a low speed to vent the machine during battery charging.

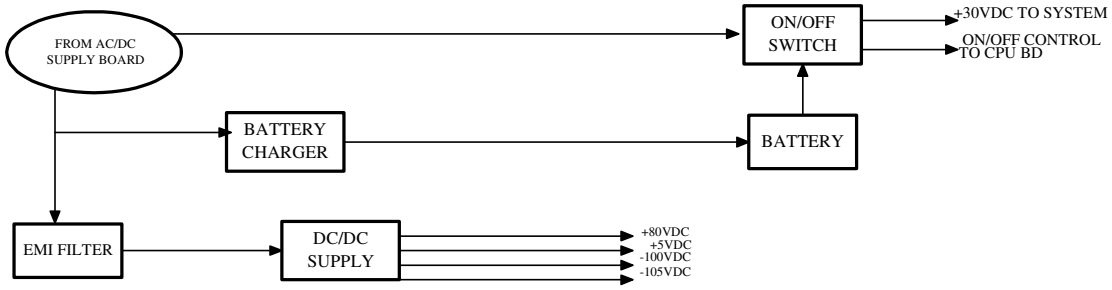
Heatsink Assembly:

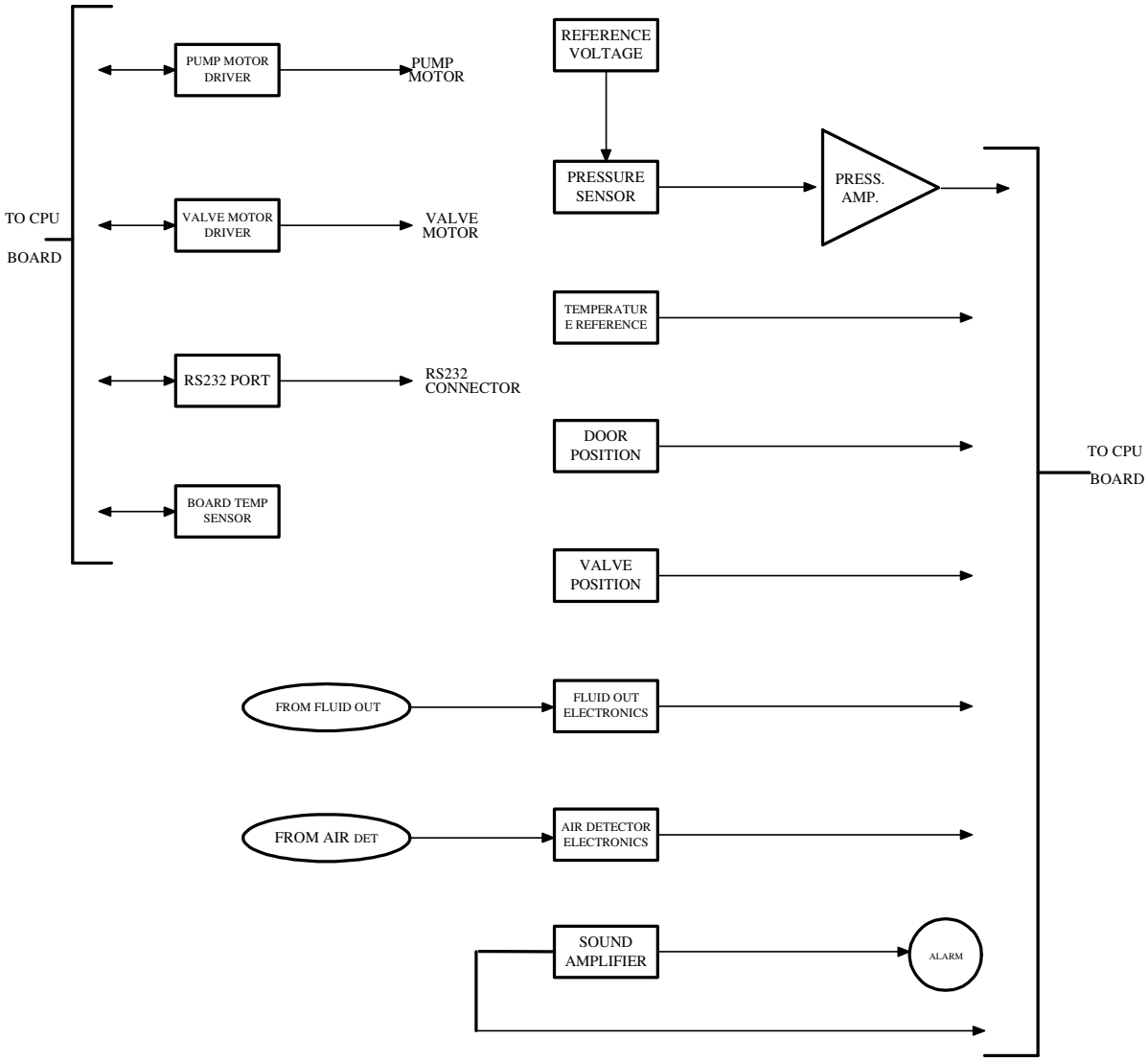
The heatsink assembly contains an aluminum bonded fin heatsink and fan to cool the IGBT's. It also holds the driver boards and heater control board. This entire assembly mounts to the EMI board. The fan bracket and holes on the EMI board are used to mount the module into the system.

OPERATION:

The power module receives information from the computer board via a serial peripheral interface (SPI). A watchdog constantly monitors the flow of information back and forth between the power module and the computer. If the computer detects improper communication, heating and pumping will stop. If the driver boards send any fault information to the heater control board, the heater control board will try to correct the problem. If the problem persists, the board will stop responding to the system commands, stop pumping and heating, and output error information to the display.

2. Daughter Board





The daughter board contains: battery control circuitry, DC/DC power supply, roller pump motor driver, valve motor driver, valve position sensors, pressure transducer and amplifier, RS232 port, air detector electronics, sound transducer, and door position sensor. The temperature probe assemblies, which are mounted on the support housing, are connected to the daughter board by cables. The daughter board mounts directly to the right hand side of the support housing.

OPERATION:

The battery control circuitry charges the battery, maintains the fan running while the system is off, and controls the power flow in the unit including power on/off control.

The DC/DC power supply contains a EMI filter, a DC/DC converter and regulators. The supply outputs +5V, +80V, -100V and -105 V derived from a 20-30 volt input. The +5V and –100V have secondary regulators to ensure that the output voltages remain within the specified tolerance limits. The supply is current limited and contains a thermal fuse.

The pump motor driver consists of a half bridge power driver that allows both acceleration and braking of the pump motor. The driver has an over current sense and independent shutdown control. The pump speed is controlled by a pulse width modulated signal produced by the microcontroller, which is controlled by the demanded flow rate that is set by the operator. The feedback is accomplished by means of an encoder in the motor communicating with the computer board.

The valve motor driver contains two parts, the motor power driver and current monitoring circuitry. The driver consists of four power MOSFETS in a bridge configuration which is capable of driving the motor in both directions. The current monitor circuitry sends a voltage to an analog-to-digital converter (ADC) input of the microcontroller system that is proportional to the motor current, and also has a limit comparator for shutdown in the event of an over current condition.

The valve position sensors are Hall effect sensors that are placed at the proper locations on the daughter board to detect a magnet that is mounted in the valve wand magnet. These signals are sent to the computer module.

A pressure transducer is strategically placed on the daughter board so as to interface with the pressure chamber/air eliminator of the disposable set. The pressure sensor is a Wheatstone bridge strain gauge, incorporating a diaphragm, with diffused or implanted resistors in a bridge configuration. The pressure sensor measures the pressure difference relative to atmosphere, or gauge pressure. When pressure is applied to the diaphragm, the output shifts due to piezoelectric effects created by mechanical strain in the four bridge resistors. The sensor is powered by a constant current source, and an instrumentation amplifier on the daughter board amplifies the signal produced. This signal is applied to an ADC input of the microcontroller. The disposable set pressure chamber must be installed flat to the pressure sensor diaphragm, or pressure sensitivity will be affected.

An RS232 port driver changes the serial data logic level signals to RS232 levels. A ribbon cable carries data to a DB9 connector on the support housing. The RS232 port is used in factory troubleshooting only.

The air detector electronics (OEM circuit boards) are mounted directly to the daughter board. Two (2) detectors are used in the system, one for fluid out detector and one for in-line air detector. They are the same detectors except one has a larger slot to be used with pump tubing and smaller slot for patient line tubing. The new version of the in-line air and fluid out detectors has the built-in electronics so the electronic boards are not needed.

The air detector utilizes the characteristics of high frequency acoustic energy to detect the presence of air, air bubbles, and foam within fluids passing through the tubing. The tubing is pressed into the slot of a sensor containing piezoelectric crystals. The piezoelectric crystals send and receive pulses of ultrasonic energy through the tubing and the fluid. Sound travels at a slower rate through air than it does through liquid. The tubing must be firmly pressed into the slot of a sensor to assure adequate acoustic coupling between tubing and the sensor. The two (2) air detectors are 3/8" OD tubing for fluid out detector and 5/16" OD tubing for patient line air detector.

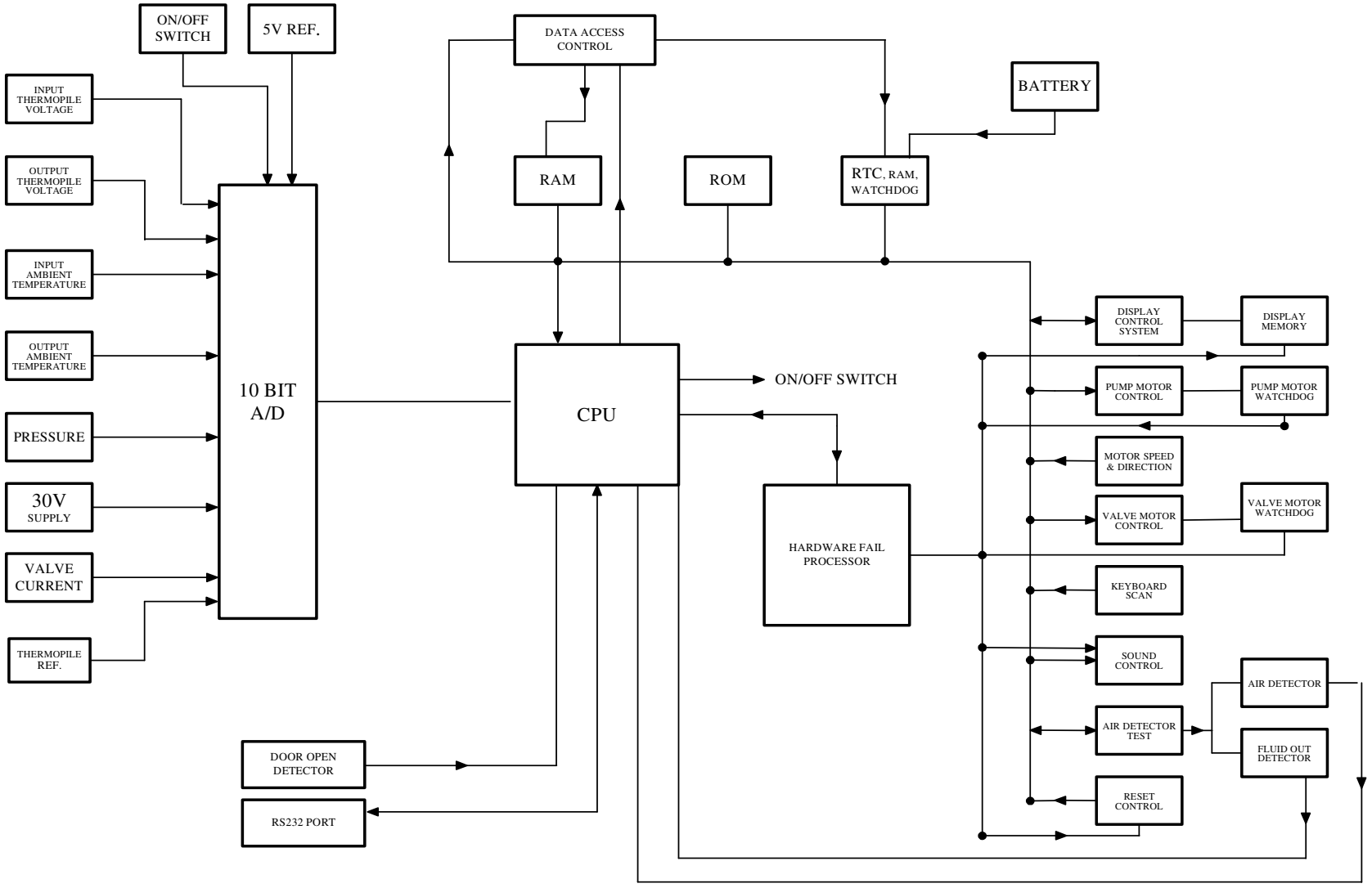
The sound circuit drives a piezoelectric sound sensor with a 30volt pulse signal. The operator can adjust, the pulse width, to increase or decrease the sound amplitude in the service mode.

The door status (latch or unlatch) is sensed by a Hall effect device strategically mounted on the daughter board behind the door handle, which has a magnet embedded in it.

The ambient temperature circuitry measures the ambient temperature of the daughter board. This is accomplished with an LM45 precision centigrade temperature sensor. This device requires no calibration and is accurate to ± 2ºC.

3. Computer Board

Computer Board Diagram



The computer board contains a CPU, memory, system software stored in EPROM, and two (2) Field Programmable Gate Arrays (FPGA's) containing logic for display control, 8 channel 10 bit ADC, valve control, pump motor control, keyboard scan, fault monitoring, watchdog, and serial interface.

The CPU is a 16 bit microcontroller. This device contains a number of on board peripherals that are utilized as follows:

The 8 channel 10 bit ADC measures: input thermopile voltage, output thermopile voltage, input and output ambient temperatures, pressure, 30V supply voltage, diversion valve current, and thermopile reference.

2 pulse width modulators: valve energy and spare.

7 hardware interrupts: power module, display, valve positions (open, middle, close), door position, and spare.

4 input capture timers: only two (2) are used for fluid out detector and air detector.

5 output timers: only one (1) is used: sound beep

1 RS232 logic port

1 serial interface port: communicate with power module

7 programmable chip selects: EPROM, Real Time Clock (RTC), RAM word, RAM lower byte, RAM upper byte, display FPGA, and motor FPGA.

The board contains three types of memory, EPROM, RAM and battery backed up RAM. The EPROM is used to boot the system on power up, and to store the main program when the power is off. The system RAM is used for running the program and temporary constant storage. The battery backup RAM is used for storing calibration constants that are generated during the system calibration. The battery backed up memory also contains a real time clock and watchdog. These constants are compared with the ones stored on the power module to ensure calibration accuracy. If the daughter board is disconnected from the computer board, or if either of the temperature probe assemblies is removed, the memory will be erased, thereby forcing re-calibration. This is a safety feature, since remove the daughter board or the temperatures probes, resulting in alignment change. A jumper can be installed to bypass this function during calibration and troubleshooting.

The display FPGA performs two (2) main functions. The first function is the interfacing of the computer to the display through an independent memory. The second function is to provide a locking method for the battery backed up RAM so that it cannot be modified accidentally.

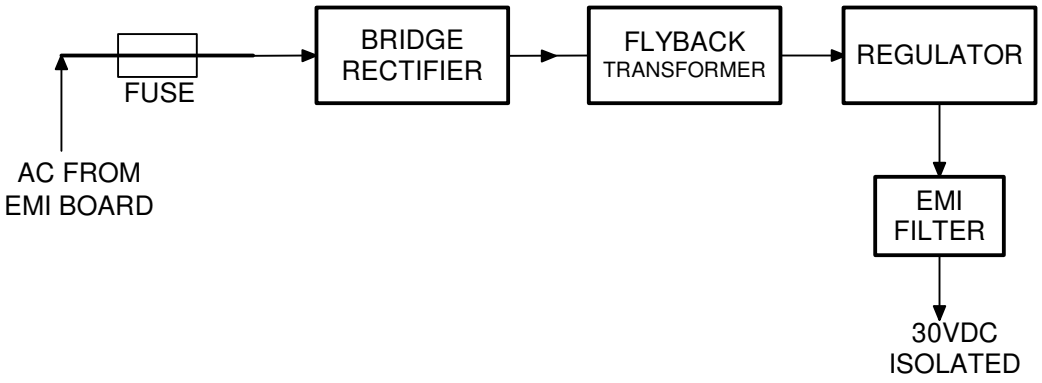
The motor FPGA performs various functions. The main function is to control the speed of the motor and to decode the encoder signals from the back of the motor. It also scans the keyboard, provides valve control, tests the air detectors and watchdog functions.

A display driver circuit provides level shifting for the 0 to 5 volt logic circuits down to –105 to –100 volts.

A buffering circuit provides the necessary driving capacity to drive the cable to the power module.

An array of comparators is used to sense the signals from the keyboard on the touch screen panel.

4. AC/DC Power Supply Board



The AC/DC power supply board converts 85 to 260 volts AC, at 50 to 400 Hz, to 30 volts isolated DC. The supply contains its own EMI filter and provides a regulated output. The supply uses a flyback topology, and is capable of 35 watts continuous power. The supply is used to charge the battery and to provide DC power to run the system electronics.

5. Miscellaneous Modules

The support housing holds all the components/modules. The left side cover holds two (2) 12 volt sealed lead acid batteries and the pole clamp mechanism. The door holds one of the heater assembly ferrite pole pieces. Some of the components are listed below:

The heater components: ferrite pole pieces, bobbin, heater winding and heater housing are arranged in the device so that when the heat exchanger (part of the disposable set) is put in place and the door is closed, the assembly forms a transformer. The magnetic flux, in the transformer, is generated by applying AC voltage to the heater winding which induces flux in the ferrite bobbin. The ferrite bobbin is physically aligned with the ferrite pole pieces, which carry the flux out around the heat exchanger and collimate it so that the rings in the heat exchanger enclose the magnetic field. An electric current is generated in the rings, warming them by virtue of their electrical resistivity. This, in turn, warms the fluid by conduction. The heater winding is electrically isolated from the heat exchanger and the ferrite pieces by solid plastic walls. The housing of the disposable set heat exchanger is also constructed of plastic which insure patient isolation even if the heater winding should crack. One of the ferrite pole pieces mounts to the door and the other piece, along with the bobbin, heater winding, and heater housing are mounted in the support housing.

The membrane panel switch (touch screen), for user interface, contains a transparent area through which the display is viewable, and a 4 x 4 matrix of buttons. The buttons are overlaid on the bottom four-fifths of the screen. A graphic boarder contains the company name and logo, along with the system trade name. An ESD/EMI conductive layer is incorporated into the panel, and is electrically tied to chassis ground.

The roller pump is a peristaltic type using four rollers. Each roller is held into a roller block by a pin upon which it is allowed to roll freely. The roller blocks are mounted to the pump hub that is attached to the shaft of a gear head motor. The roller blocks are mounted with a pin at one end, and are supported at the other end by a spring mounted plunger. The spring applies enough force to the roller so as to completely pinch the tubing. The pump hub is attached to the gear head shaft by a shaft coupler, which allows the pump head to be removed with a single screw for easy cleaning. The 35:1 gear head ratio is used to reduce the speed of the motor and increase torque. The motor is a brushed motor with an optical encoder. The encoder is a two-phase device that allows for both speed and directional sensing. Although the driver circuit can only drive the motor in one direction, the speed and direction measurement circuitry can detect if the motor has been connected backwards.

The diversion valve is used for closing and opening the patient line and recirculation line. It contains a gear head and pincher. Hall effect sensors, on the daughter board, sense a magnet that is mounted in the pincher to locate the pincher position. The tubing is compressed between the pincher and the sidewalls of the support housing. The patient line tubing passes across one side of the pincher and the recirculation tubing on the other side. This allows for three different valve positions; recirculation line open and patient line closed; recirculation line closed and patient line open; and both lines open. The valve motor is driven in both directions by computer commands. Because of the high torque requirement when pinching the tubing, a 370:1 ratio gear head is used to increase the motor torque. A bias current and the friction of the gear head keep the pincher in position during steady state conditions.

The temperature probe assemblies (2) are mounted directly in the support housing. One measures the input fluid temperature and one measures the output fluid temperature of the heat exchanger. These are infrared (IR) sensors that "look" into the fluid path through infrared transparent germanium windows on the devices, and thin plastic film on the disposable set. The temperature probe circuit board within each assembly contains a precision amplifier for the IR sensor output. The voltage generated is proportional to the difference between the temperature of the source and the ambient temperature of the device. Device ambient temperature is measured by an integral thermistor. This data is then manipulated by the computer board using constants arrived at during calibration. The computer algorithm is capable of determining the temperature of the fluid within the disposable set regardless of fluid or device temperature. It is for this reason that the opening on the temperature block must remain clear of debris.

The circuit breaker is designed to protect equipment, sub-system, and components against the potentially catastrophic effects of electrical overload and short circuit.

The power entry module is a 16 A, 250 V, capable of withstanding a 2000 VAC dielectric strength for 1 minute. The AC line power enters the FMS2000 via a removable power cord, which plugs into this connector.

REMOVAL AND REPLACEMENT OF MAJOR COMPONENTS AND MODULES

- Before beginning any Removal and Replacement procedure(s):
    - **FMS2000** Circuit Breaker should be switched OFF and unplug the unit from the wall outlet
- After any Removal and Replacement certain components or module(s), FMS system parameters setting, calibration, and/or operational check should be performed, see Chapter 6 and 7.
- Drawings and Bills of Material (BOM's) are included.
- Proper ESD precautions are required for all electronic assemblies.

REQUIRED MATERIAL & TOOLS

1. Pliers, needle-nosed
2. Screwdriver, #2 Phillips head
3. Allen Wrench, 3/32
4. IC Removal Tool
5. Kapton Tape
6. Teflon Grease or equivalent
7. RTV sealant, Dow Corning 732 silicone or equivalent

A. INSTRUMENT COVER (**Reference Drawing**: 403-00108)

Removal

1. Lay the unit with the door face down.
2. Using an Exacto knife or flat razor blade, cut through the silicone around the perimeter of the instrument cover.
3. Remove the “Warranty Void” seal.
4. Remove 6X flat head Phillips screws attaching Instrument Cover to Support Housing.
5. Using a thin flat Screwdriver, pry the instrument cover away from Support Housing.
6. Pull Instrument Cover away from Support Housing in a bottom-to-top motion while carefully pulling out attached ‘battery to Daughter PCB’ Cable (Do not remove gasket from Instrument Cover.)
7. Unplug battery cable from Daughter PCB, JP13.

Installation

1. Reattach ‘battery to Daughter PCB’ cable to Daughter PCB, JP13.
2. Carefully slide Instrument Cover back onto Support Housing. Do not pinch the battery cable.
3. Reinstall 6X flat head Phillips screws.
4. Apply a thin bead of silicone around entire perimeter of Instrument Cover and allow at least 1 hour for silicone to dry.

B. AC/DC PCB (**Reference Drawing:** 403-00107)

Removal

1. Ground strap must be worn.
2. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
3. Unplug Circuit Breaker Cable, JP2 from Daughter PCB.
4. Unplug 2X lugs, JP1 and JP2, from AC/DC PCB.
5. Remove 3X pan head Phillips screws.
6. Remove AC/DC PCB and store in a static proof bag.

Installation

1. Ground strap must be worn.
2. Align AC/DC PCB in card-guide slots located in the Support Housing and attach with 3X pan head Phillips screws.
3. Reattach Circuit Breaker Cable, JP2 from Daughter PCB.
4. Reattach 2X lugs, JP1 and JP2.
5. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

C. ACTUATOR HANDLE (**Reference Drawing:** 403-00108)

Removal

1. Remove 1, 8-32 x 3/4 button head hex screw, lock washer and flat washer attaching Actuator Handle to Shaft Coupling.
2. Slide Actuator Handle off Actuator Shaft Coupling. (Do not remove 2X Disk Springs. No disk springs in older units.)

Installation

1. If the Disk Springs were removed; reinstall by orienting each disk spring with the arcs facing each other. Figure 1.
2. Reattach Actuator Handle.
3. Reinstall 1X button head hex screw, lock washer and flat washer.

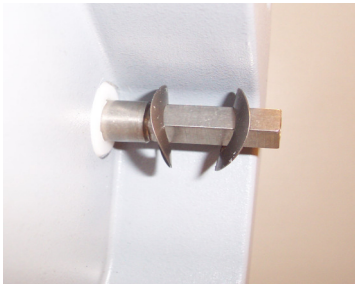


Figure 1: Orient Disk Spring washers as shown.

D. AIR DETECTOR PCB (**Reference Drawing:** 403-00107)

(If P/N 310-00024 is used, this Air detector PCB is not needed)

Removal

1. Ground strap must be worn.
2. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
3. Carefully pinch the top of (2X) Air Detector Sensor Standoffs & gently pull Air Detector PCB off.
4. If P/N 310-00024 Air Detector Sensor is used, discard this Air detector PCB.

Installation

1. Ground strap must be worn.
2. For P/N 310-00009 Only: Place Air Detector PCB over Air Detector Transducer Standoff, aligning pins on the back of the PCB with the mating connectors on Daughter PCB & press down gently until PCB snaps in place.
3. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

E. AIR DETECTOR SENSOR (Reference Drawing **403-00107)**

(For Air detector sensor, P/N 310-00024)

Removal

1. Refer to Step K Removal, to remove the Daughter PCB,
2. Using an Exacto knife, remove the silicone from the detector.
3. Remove the two screws and the spacer from the air detector.
4. Gently push the case through the front of the Support Housing.

Installation

1. Feed the sensor connector through the front of the Support Housing.
2. Align the detector with its mounting holes. Install the spacer (not needed for P/N 310-00024) and fasten the two screws onto the air detector.
3. Apply RTV silicone to entire back surface and screw holes of the air detector.
4. Remove Air Detector Electronic PCB and discard, refer to Step D. Refer to Step K Installation, to reinstall the Daughter PCB. Plug the sensor connector to JP12 on the Daughter PCB.

F. BATTERY (**Reference Drawing**: 403-00108)

Removal

1. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
2. Unplug lugs from battery terminals and slide batteries out of the pockets in the Instrument Cover.

Installation

1. Reinstall 'battery to Daughter PCB' Cable lugs onto batteries. (Note the proper orientation of the lugs.) Figure 2.
2. Slide batteries back into the pockets in the Instrument Cover. The battery should be flush with the pocket edge for proper fit of the instrument cover.
3. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

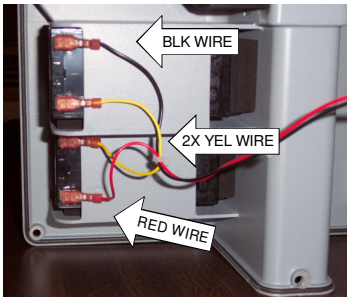


Figure 2: Attach lugs as shown; BLK, YEL, YEL, RED

G. C152 REPLACEMENT (Reference Drawing: 403-00107)

Removal

1. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
2. Ground strap must be worn.
3. Remove CPU PCB. (See Step J.)
4. Locate C152 position. Use a solder pull or solder wick to remove left over solder.

Installation

1. Ground strap must be worn.
2. Position C152 on CPU PCB and solder in place. Figure 3.
3. Reinstall CPU PCB. (See Step J.)
4. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

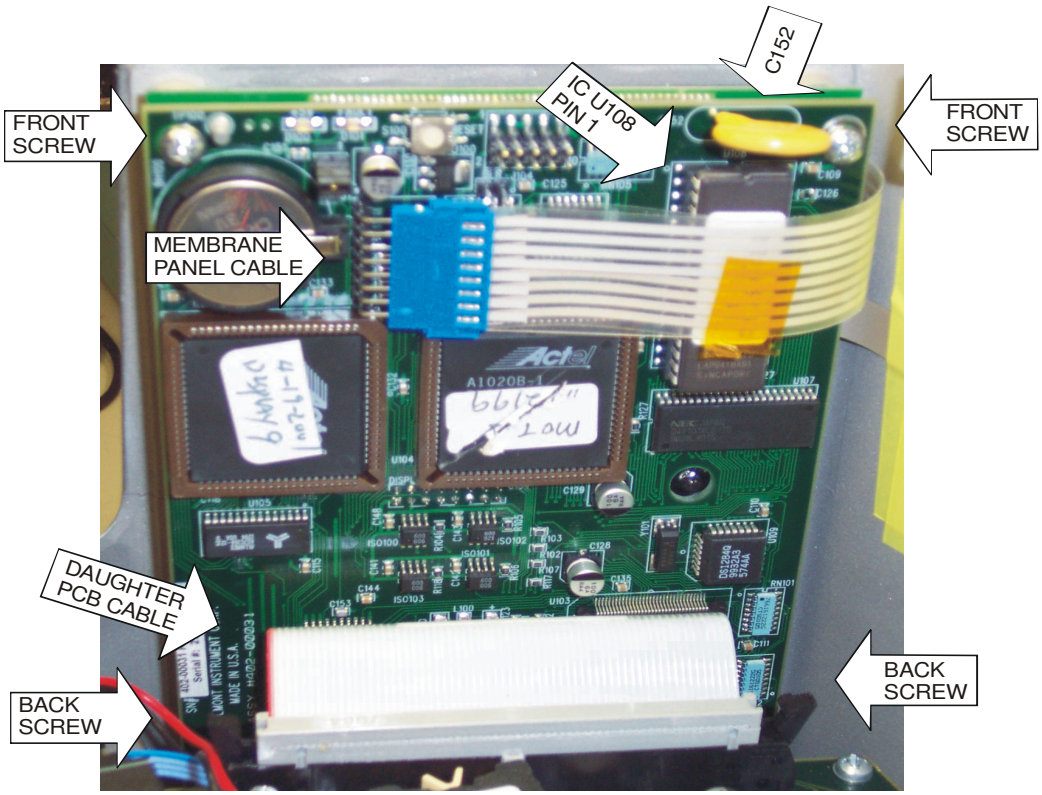


Figure 3: CPU Board

H. CERAMIC DISK (DISH HEATER) (Reference Drawing 403-00109)

Removal

1. Remove Door Assembly from Support Housing, by pulling upward.
2. Place a protective covering over Cover and lay Door Assembly face down on a flat surface.
3. Cut through silicone around Ceramic Disk.
4. Remove Ceramic Disk and Disk Gasket.

Installation

1. Remove one side of the protective covering from Disk Gasket.
2. Press the Disk Gasket onto the center of Ceramic Disk.
3. Remove the other protective covering from the Disk Gasket.
4. Place Ceramic Disk, with the Disk Gasket side down, into the cutout in the Door. (Do not allow the walls of the Door to touch the Ceramic Disk.)
5. Apply a thin bead of silicone around entire perimeter of Ceramic Disk and allow at least 1 hour for silicone to dry.
6. Replace Door Assembly into the Support Housing, making sure the door is pushed all the way down.

I. CIRCUIT BREAKER (Reference Drawing: 403-00107 (for 120V unit) or 403-00270 (for 230V unit)

Removal

1. Remove 4 X 6-32 pan head Phillips screws [(2) ¼" & (2) 1 1/8"] connecting Circuit Breaker to Support Housing.
2. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
3. Refer to Step B to remove AC/DC PCB.
4. Unplug Daughter PCB Cable.
5. Remove 4X lugs from circuit breaker.
6. Remove circuit breaker and the spacer block.

Installation

1. Install spacer block between Support Housing and Circuit Breaker. Reinstall 4 X pan head Phillips screws connecting Circuit Breaker to Support Housing.
2. Reattach Daughter PCB Cable. Figure 4.
3. Reattach 4X lugs to circuit breaker. Figure 4.
4. Refer to Step B to reinstall AC/DC PCB.
5. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

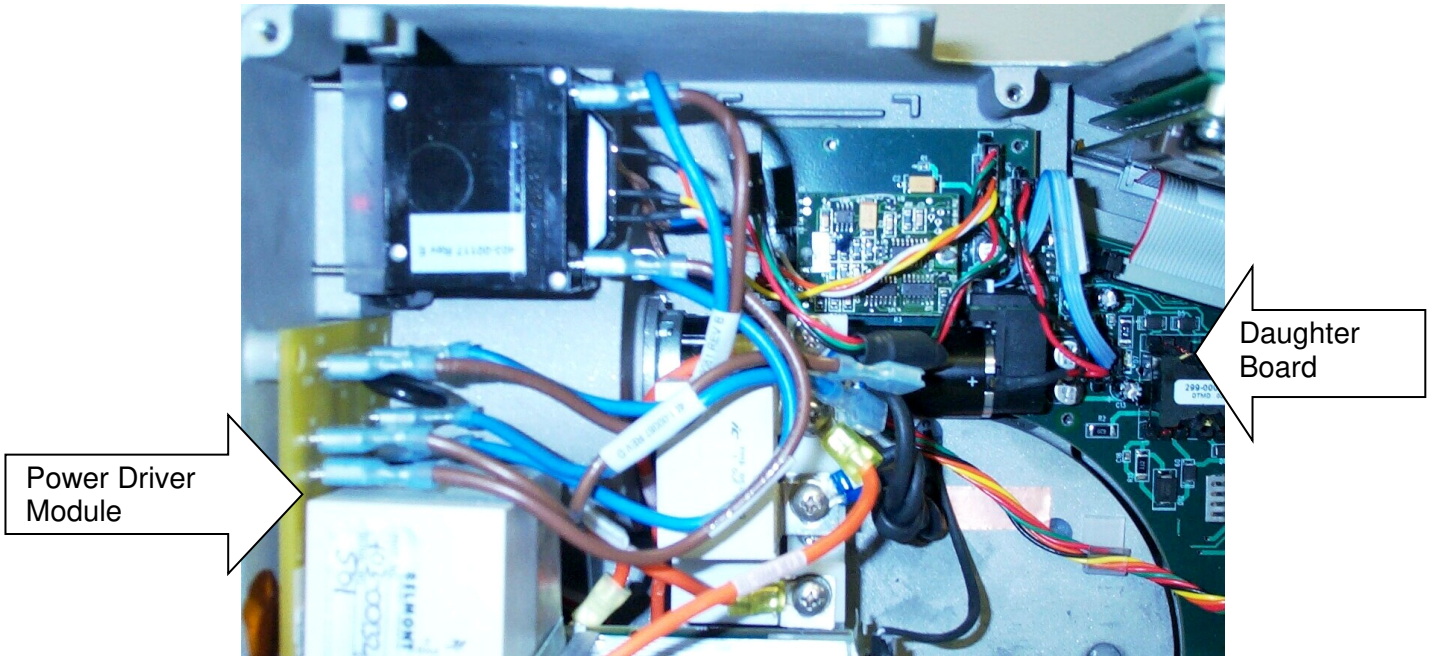


Figure 4: Attach cables and lugs as shown

J. CPU PCB & DISPLAY (**Reference Drawing:** 403-00107)

Removal

1. Ground strap must be worn.
2. Remove the instrument cover. (See Step A Removal, 1 – 7.)
3. Unplug Membrane Panel Cable from CPU PCB.
4. Unplug CPU PCB Cable from Daughter PCB.
5. Remove 2X pan head Phillips screws & 2X standoffs connecting CPU PCB to Support Housing. **Caution**; Display will come off with CPU PCB.
6. Remove 2X pan head Phillips screws, 2X standoffs & 2X nuts attaching CPU PCB to Display.
7. Gently pull CPU PCB away from Display. Caution; do not touch top of Display.
8. Store CPU PCB in a static proof bag.
9. Store Display in a static proof bag.

Installation

1. Ground strap must be worn.
2. Align connector pins on CPU PCB with mating connector on Display and gently push together. Caution; do touch the top of the Display.
3. Insert 2X pan head Phillips screws through the back holes in CPU PCB, through 2X standoffs & Display. Figure 3.
4. Secure with 2X nuts.
5. Insert 2X pan head Phillips screws through the front holes in CPU PCB, through 2X standoffs & Display. Figure 3.
6. Reinstall screws into Support Housing.
7. Reattach CPU PCB Cable to Daughter PCB.
8. Reattach Membrane Panel Cable.
9. Check parameters setting. Chapter 6.
10. Perform ‘Temperature Probe’, ‘Pressure Transducer’, and ‘Power Module and Pump’ calibrations. Chapter 6.
11. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.
12. Perform System Operational Check-Out, Chapter 7.

K. DAUGHTER PCB (**Reference Drawing:** 403-00107)

Removal

1. Ground strap must be worn.
2. Remove the instrument cover (See Step A Removal, 1 - 7)
3. Remove AC/DC PCB. (See Step B.)
4. Remove Pump Motor. (See Step X.)
5. Unplug all cables connected to Daughter PCB.
6. Remove 12X pan head Phillips screws & 2X nylon washers attaching Daughter PCB to Support Housing.
7. Remove Daughter PCB and store in a static proof bag.

Installation

1. Ground strap must be worn.
2. Apply Teflon grease to the pressure transducer 'O' ring.
3. Carefully insert Daughter PCB into Support Housing. Make certain the 4X Micro Sensors on the back of the PCB are not bent and the pressure transducer is seated correctly in its receptacle.
4. Reinstall 12X pan head Phillips screws & 2X nylon washers. Figure 5.
5. Reattach all cables connected to Daughter PCB. Figure 5.
6. Reinstall Pump Motor. (See Step X.)
7. Reinstall AC/DC PCB. (See Step B.)
8. Reinstall the instrument cover. (See Step A Installation, 1 - 5)
9. Perform "Pressure Transducer' calibration.
10. Perform a System Operational Check-Out, Chapter 7.

K. DAUGHTER PCB (continued)

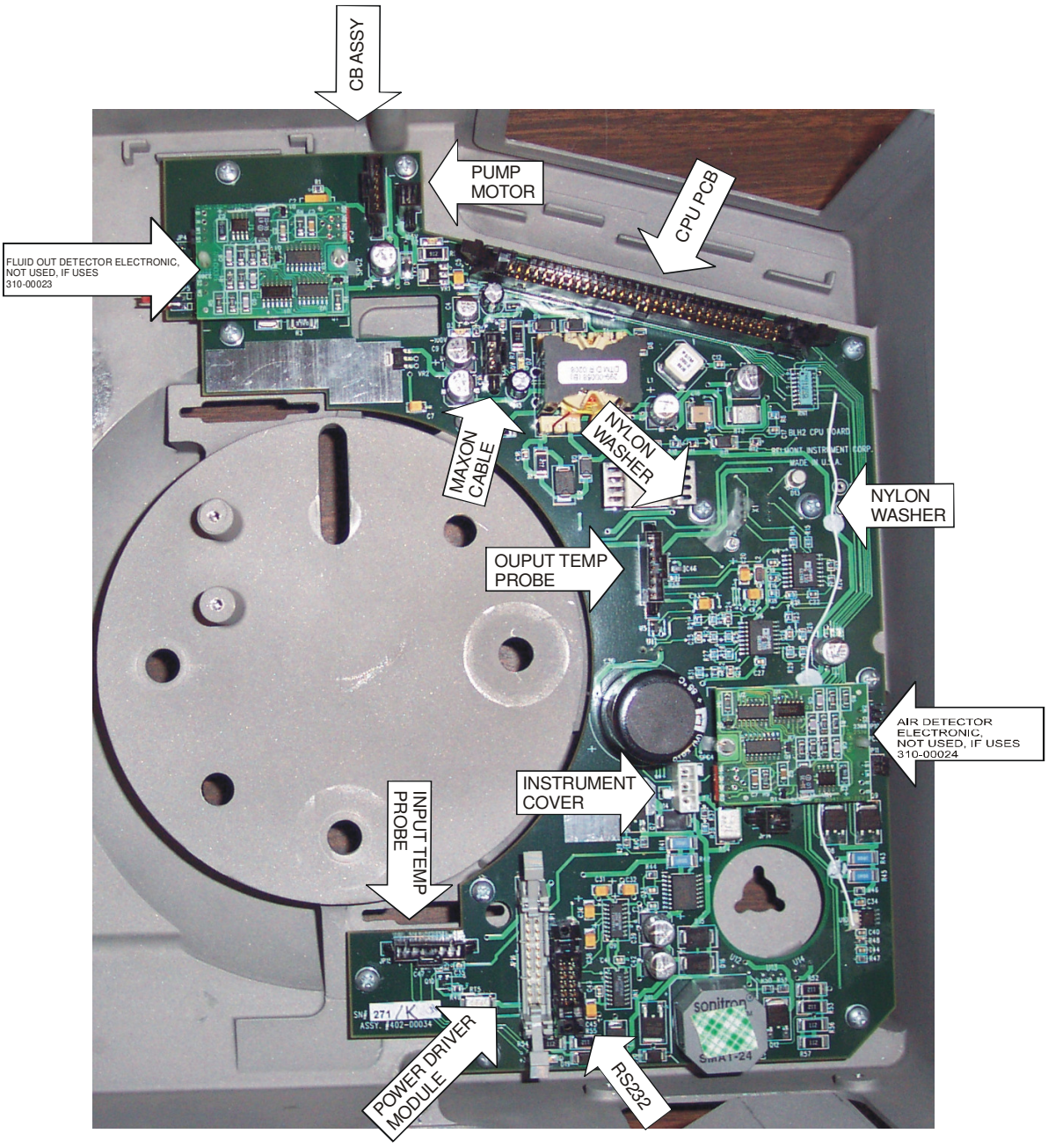


Figure 5: Daughter PCB

L. DRIVER PCB "A", DRIVER PCB "B", & HEATER CONTROL PCB

(**Reference Drawing:** 403-00132)

Removal

1. Ground strap must be worn.
2. Remove Power Driver Module. (See Step V.)
3. Remove 8X pan head Phillips screws from back of EMI Filter PCB.
4. Unplug EMI Cable from Driver PCB "B", JP4.
5. Remove 6X pan head phillps screws from each side of Driver PCBs "A" & "B".
6. Remove 4X pan head Phillips screws & Transistor Mounting Clamps.
7. Gently slide Driver PCBs "A" & "B" out of Driver Mounting Blocks.
8. Store Driver PCBs "A" & "B" in static proof bags.
9. Remove 4X pan head Phillips screws from Heater Control PCB.
10. Remove Heater Control PCB and store in a static proof bag.

Installation

1. Ground strap must be worn.
2. Slide Driver PCBs "A" & "B" into Driver Mounting Blocks.
3. Reinstall 4X pan head Phillips screws & Transistor Mounting Clamps.
4. Reinstall 6X pan head Phillips screws into each side of Driver PCBs "A" & "B".
5. Reattach EMI Cable to Driver PCB "B", JP4.
6. Reinstall 8X pan head Phillips screws into back of EMI Filter PCB.
7. Reinstall 4X pan head Phillips screws into Heater Control PCB.
8. Reinstall Power Driver Module (See Step V), perform calibration and System Operational Check-Out, Chapter 6 & 7.

L. **DRIVER PCB "A", DRIVER PCB "B", & HEATER CONTROL PCB** (continued)

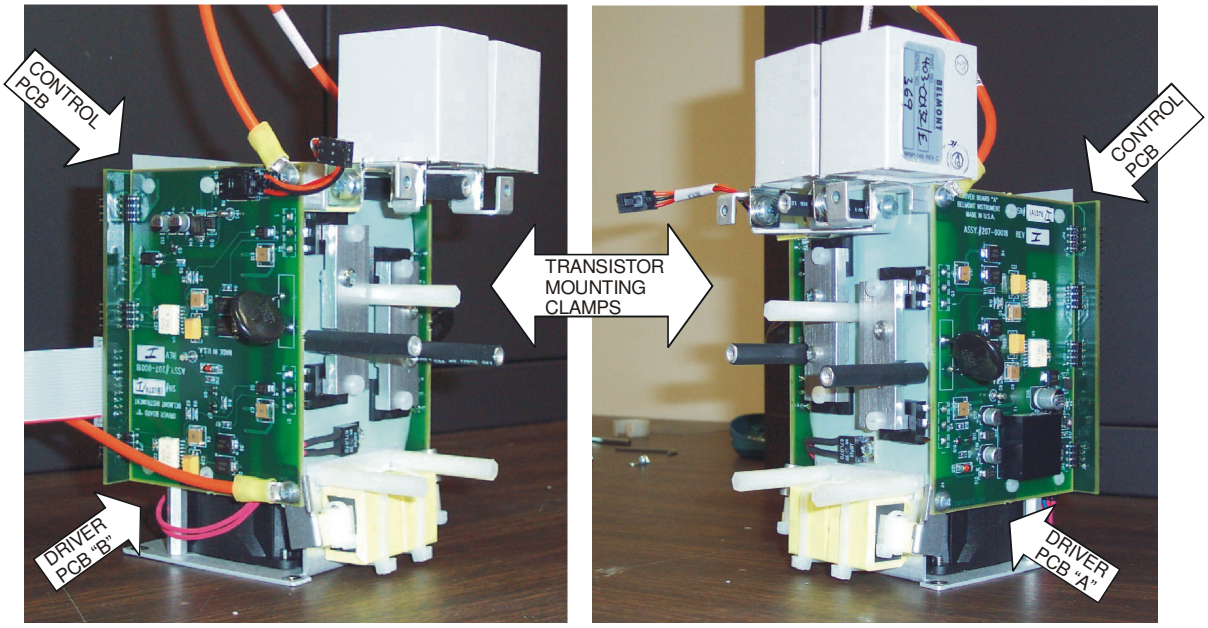


Figure 6: Driver 'A', 'B', and Heater Control PCB

M. EMI FILTER PCB (**Reference Drawing:** 403-00132)

Removal

1. Ground strap must be worn.
2. Remove Power Driver Module. (See Step V.)
3. Unplug EMI Cable from EMI Filter PCB, JP4.
4. Remove 8X pan head Phillips screws from EMI Filter PCB.
5. Remove EMI Filter PCB and store in a static proof bag.

Installation

1. Ground strap must be worn.
2. Reinstall 8X pan head Phillips screws into EMI Filter PCB.
3. Reattach EMI Cable to EMI Filter PCB, JP4.
4. Reinstall Power Driver Module. (See Step V.)
5. Perform System Operational Check-Out, Chapter 7.

N. EPROM (ICU 108 on CPU Board) REPLACEMENT

(**Reference Drawing:** 403-00107)

Removal

1. Ground strap must be worn.
2. Remove the instrument cover. (See Step A Removal, 1 – 7.)
3. Lay the unit flat on the door.
4. Unplug membrane Panel cable from CPU PCB.
5. Use the IC Removal tool, pull EPROM (ICU 108) from the socket of CPU PCB.

Installation

1. Ground strap must be worn.
2. Insert EPROM (ICU 108) in the socket, observe pin 1 and make sure all pins are in the socket. Figure 3.
3. Reattach Membrane Panel cable, using rocking motion and push in as far as in can go in.
4. Perform 'Power Module and Pump' calibration. Chapter 6.
5. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.
6. Perform System operational Check-Out, Chapter 7.

O. FAN GUARD (**Reference Drawing:** 403-00107)

Removal

1. Lay unit on its side.
2. Remove 8, 6-32 x 3/8 flat head Phillips screws attaching Fan Guards to Support Housing.
3. Remove Fan Guards.

Installation

1. Reinstall Fan Guards and screws.

P. FLUID OUT DETECTOR PCB (**Reference Drawing:** 403-00107)

(If P/N 310-00023 is used, Fluid Out detector PCB is not needed)

Removal

1. Ground strap must be worn.
2. Refer to Step B, AC/DC PCB Removal to remove the instrument cover and the board.
3. Carefully pinch the top of 2X Fluid Out Detector PCB plastic Standoffs and gently pull Fluid Out Detector PCB off the standoff.
4. If P/N 310-00023 Fluid Out Sensor is used, discard this Fluid Out detector PCB.

Installation

1. Ground strap must be worn.
2. For P/N 310-00007 Only: Place Fluid Out Detector PCB over the plastic Standoffs, aligning pins on the back of the PCB with mating connectors on Daughter PCB & press down gently until PCB snaps in place.
3. Refer to Step B, AC/DC PCB Installation to reinstall the instrument cover and the AC/DC PCB.

Q. FLUID DETECTOR SENSOR (Reference Drawing: 403-00107)

(For Fluid Out detector sensor, P/N 310-00023)

Removal

1. Refer to Step B Removal, to remove the AC/DC PCB.
2. Refer to Step I Removal, to remove the circuit breaker.
3. Disconnect the two connectors labeled JP4, JP5 from the Daughter PCB.
4. Remove the silicone from the detector with an Exacto knife.
5. Remove the two screws and the spacer.
6. Gently push the case through the front of the Support Housing

Installation

1. Feed the sensor connector through the front of the Support Housing.
2. Align the detector with its mounting holes. Install the spacer (not needed for P/N 310-00023) and fasten the two screws onto the air detector.
3. Apply RTV silicone to entire back surface and screw holes of the air detector.
4. Remove Air Detector Electronic PCB and discard, refer to step D.
5. Plug the sensor connector to JP3 on the Daughter PCB.
6. Refer to Step I Installation, to reinstall the circuit breaker.
7. Refer to Step B Installation, to reinstall the AC/DC PCB.

R. **IEC CONNECTOR (Power Entry Module)** (**Reference Drawing:** 403-00107 for 120V unit) or 403-00248 (for 230V unit)

Removal

1. Unplug AC Input Cable.
2. Remove Power Driver Module. (See Step V.)
3. Remove AC Ground Cable.
4. Remove (2) lugs, from JP2 and JP5, on the EMI board
5. Remove IEC Connector by pinching the top and bottom of connector and sliding it out of the Support Housing.

Installation

1. Attach flat washer, AC Ground Cable, flat washer, lock washer & nut to Ground Stud in that order. Figure 7.
2. Insert IEC Connector into Support Housing and snap in place.
3. Reinstall Power Driver Module. (See Step V.)
4. Reinstall 'Blue' wire to JP2 and 'Brown' wire to JP5 on the EMI board.

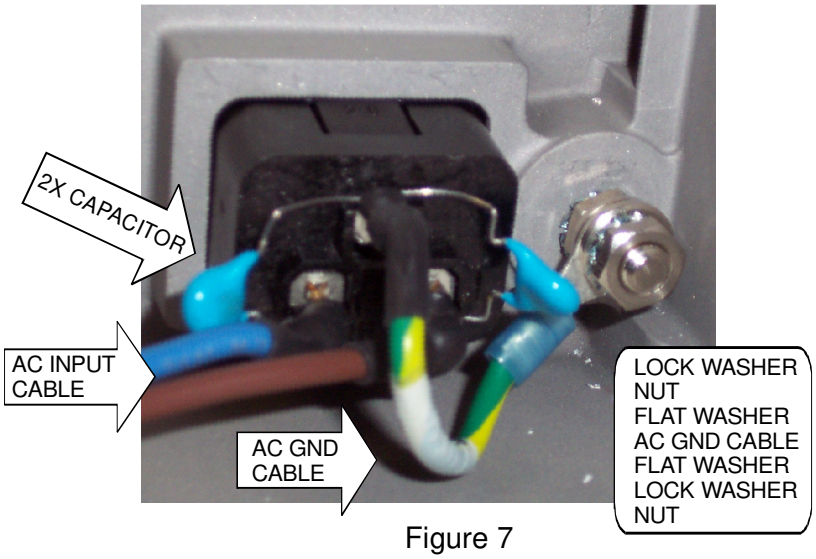


Figure 7

S. INPUT TEMPERATURE PROBE (**Reference Drawing:** 403-00107)

Removal

1. Remove the Instrument Cover. (See Step A Removal, 1 – 7.)
2. Unplug Input Temperature Probe Cable, JP15, from Daughter PCB.
3. Remove 2X pan head Phillips screws attaching Input Temperature Probe to Support Housing.
4. Cut through silicone and remove Input Temperature Probe.

Installation

1. Insert Input Temperature Probe into Support Housing with the sensor window facing the center of the Housing. Apply RTV silicone to entire back surface and screw holes.
2. Reinstall 2X pan head Phillips screws.
3. Apply a bead of silicone around the outside perimeter of Input Temperature Probe and allow silicone to dry for at least 1 hour.
4. Twist cable then reattach Input Temperature Probe Cable to Daughter PCB.
5. Reinstall the instrument cover. (See Step A Installation, 1 - 5.)
6. Perform the Input Temperature probe verification. See Chapter 7.

T. MEMBRANE PANEL (**Reference Drawing:** 403-00107)

Removal

1. Remove the instrument cover. (See Step A Removal, 1 – 7.)
2. Remove 1X pan head Phillips screw & 1X flat washer attaching Membrane Panel Ground Strap to Support Housing.
3. Remove tape from Membrane Panel Ground Strap.
4. Remove Membrane Panel Cable from CPU PCB.
5. Cut silicone from perimeter of Membrane Panel.
6. Remove Membrane Panel by pressing upward, from the inside of the Support Housing, along the sides and in the corners.

Installation

1. Remove protective backing from back surface of Membrane Panel and adhere to pocket in Support Housing. **Caution**; do not touch back surface of Membrane Panel.
2. Reattach Membrane Panel Ground Strap to Support housing with 1X flat washer and 1X pan head Phillips screw.
3. Apply tape over Membrane Panel Ground Strap to secure in place.
4. Reattach Membrane Panel Cable to CPU PCB.
5. Apply silicone around the perimeter of the Membrane Panel on the top surface and bottom surface, including around and under cable and ground strap. Allow silicone to dry for at least 1 hour.
6. Reinstall the instrument cover. (See Step A Installation, 1 – 5.)

U. OUTPUT TEMPERATURE PROBE (Reference Drawing: 403-00107)

Removal

1. Remove Pump Motor. (See Step V.)
2. Unplug Output Temperature Probe Cable, JP8, from Daughter PCB.
3. Use an Exacto knife to cut through the silicone on the front of the temperature probe.
4. Remove 2X pan head Phillips screws attaching Output Temperature Probe to Support Housing. Gently push probe out from the inside.

Installation

1. Insert Output Temperature Probe into Support Housing with the sensor window facing the center of the Housing. Apply RTV silicone to entire back surface and screw holes.
2. Reinstall 2X pan head Phillips screws.
3. Apply a bead of silicone around the outside perimeter of Output Temperature Probe and allow silicone to dry for at least 1 hour.
4. Twist cable then reattach Output Temperature Probe Cable to Daughter PCB.
5. Reinstall Pump Motor. (See Step V.)
6. Perform the Output Temperature probe verification, Chapter 7.

V. POWER DRIVER MODULE (**Reference Drawing:** 403-00132)

Removal

1. Refer to Step A Removal, 1 – 7, to remove the Instrument Cover.
2. Ground strap must be worn before removing the Power Driver Module.
3. Remove 4X flat head Phillips screws and Fan Guard attaching fan to Support Housing.
4. Remove 3, 10-32 x 1/2 pan head Phillips screws, lugs and flat washers from Capacitor Block. Figure 8.
5. Unplug Bobbin Assembly Cable, JP1, and Daughter PCB Cable, JP16, from Power Driver Module.
6. Unplug all remaining attached lugs, JP1, JP2, JP3, JP4, JP5, JP6, JP7, JP8.
7. Removed 4X pan head Phillips screws attaching Power Driver Module to Support Housing.
8. Remove Power Driver Module and store in a static proof bag.

Installation

1. Ground strap must be worn.
2. Reinsert Power Driver Module into Support Housing, making sure the EMI PCB fit into the slot on the Support Housing.
3. Reinstall 4X flat head Phillips screws and Fan Guard.
4. Reinstall 4X pan head Phillips screws attaching Power Driver Module to Support Housing.
5. Reattach Bobbin Assembly Cable and Daughter PCB Cable.
6. Reattach 3X pan head Phillips screws, lugs and flat washers to Capacitor Block. Figure 8.
7. Push locking tap, on all removed lugs, up by sliding a flat head Screwdriver between the lug plastic housing and the metal connector.
8. Reattach all lugs. Figure 8.
9. Check parameters setting. Chapter 6.
10. Perform ‘Temperature Probe’, ‘Pressure Transducer’, and ‘Power Module and Pump’ calibrations. Chapter 6.
11. Refer to Step A Installation, 1 – 5, to reinstall the Instrument Cover.
12. Perform System Operational Check-Out, Chapter 7.

V. POWER DRIVER MODULE (continued)

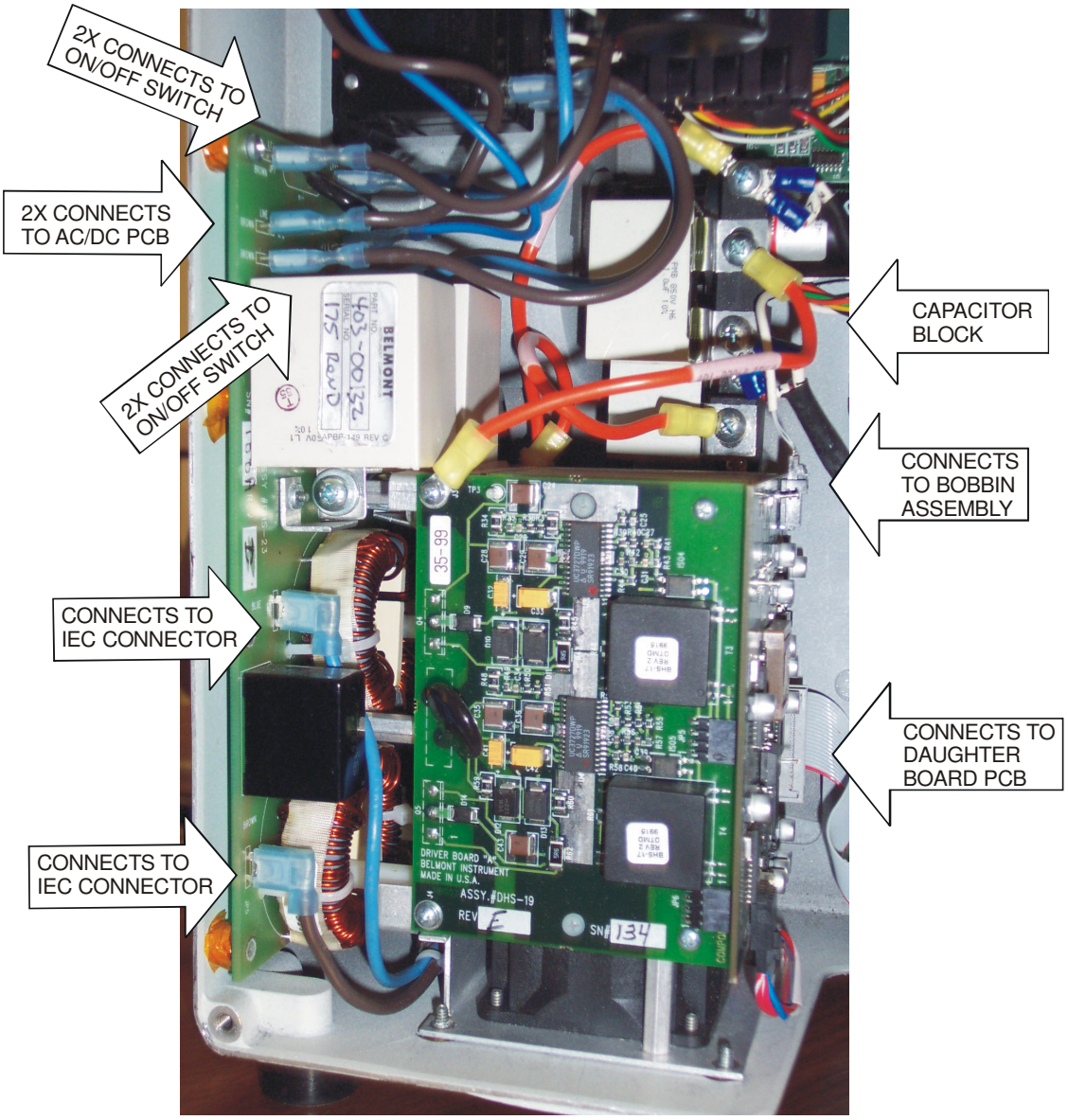


Figure 8: Power Module Assembly

W. PRESSURE TRANSDUCER (Reference Drawing: 402-00034A)

Removal

1. Ground strap must be worn.
2. Remove AC/DC PCB. (See Step B.)
3. Remove Pump Motor. (See Step X.)
4. Remove Daughter PCB. (See Step K.)
5. Cut Pressure Transducer legs off from Daughter PCB.
6. Use hot soldering iron, remove remaining legs from Daughter PCB.
7. Use a solder pull or solder wick to remove left over solder.

Installation

1. Ground strap must be worn.
2. Locate the notch on the Pressure Transducer, insert the Pressure Transducer into Daughter PCB (Solder Side), notch is at Pin 1. Solder in place.
3. Remove O-ring from Pressure Transducer.
4. Apply a thin film of Teflon Grease over O-ring.
5. Apply Kapton Tape over Pressure Transducer & reattach O-ring.
6. Reinstall Daughter PCB. (See Step K.)
7. Reinstall Pump Motor. (See Step X.)
8. Reinstall AC/DC PCB. (See Step B.)
9. Reinstall the Instrument Cover. (See Step A, 1 – 5.)
10. Perform “Pressure Transducer’ calibration.
11. Perform a System Operational Check-Out, Chapter 7.

X. PUMP MOTOR (**Reference Drawing:** 403-00107)

Removal

1. Refer to Step A Removal, 1 – 7, to remove the Instrument Cover.
2. Unplug Maxon Cables, JP 9 (Ribbon cable) and JP1 (red & black cable) from the Daughter PCB.
3. Remove 1X flat head Phillips screw from Roller Pump Assembly.
4. Remove Roller Pump Assembly by pulling outward, off the Pump Shaft Adapter.
5. Remove 4X set screws & Pump Shaft Adapter.
6. Remove 4X flat head Phillips screws attaching Pump Motor to Support Housing.
7. Remove Motor Pump Spacer & Pump Motor.

Installation

1. Slide Motor Pump Spacer over Pump Motor and attach to Support Housing with 4X flat head Phillips screws.
2. Slide Pump Shaft Adapter over Pump Motor Shaft, use a 16 AWG wire as a tool to gauge the space between the Pump Motor Shaft and Support Housing, then secure with 4X set screws.
3. Reinstall Roller Pump Assembly and secure with 1X flat head Phillips screw.
4. Reattach Maxon Cables, JP9 and JP1, to the Daughter PCB.
5. Refer to Step A Installation, 1 – 5, to reinstall the Instrument Cover.

Y. VALVE MOTOR/PINCHER (**Reference Drawing:** 403-00107)

Removal

1. Refer to Step A Removal, 1 – 7, to remove the instrument cover.
2. Unplug cable, JP14, connecting to Daughter PCB.
3. Remove 1X set screw from Valve Pincher.
4. Remove Valve Pincher.
5. Remove 3 flat head Phillips screws attaching Valve Motor to Support Housing.
6. Remove Valve Motor.

Installation

1. Reattach Valve Motor to Support Housing with 3X flat head Phillips screws.
2. Slide Valve Pincher over Valve Motor Shaft and secure with 1X set screw.
3. Reattach connector to Daughter PCB.
4. Refer to Step A Installation, 1 – 5, to reinstall the instrument cover.

Note: Older version valves have a spacer that is not needed with a new version valve.

Drawing Number	Description
402-00034A	Assembly, Daughter PCB (750 ml/min max. rate)
403-00107	Assembly, Final, 120 V unit (750 ml/min max. rate)
403-00343	Assembly, Final, 120 V unit (1000 ml/min max. rate)
403-00108	Assembly, Instrument Cover
403-00109	Assembly, Instrument Door
403-00132	Assembly, Power Driver Module
403-00248	Assembly, Final, 230 V unit (750 ml/min max. rate)
403-00344	Assembly, Final, 230 V unit (1000 ml/min max. rate)
403-00270	Assembly, Circuit Breaker 230 V unit
903-00001B	FMS Packaging, Military, 120 V Field Version

SYSTEM PARAMETERS SETUP

Listed below are System Parameters Setup and Hardware Calibration. These calibrations, pressure transducer, temperature probes, and power module, need to be calibrated only after verifying that it is operating outside accepted parameters. See Hardware Verification, Chapter 7.

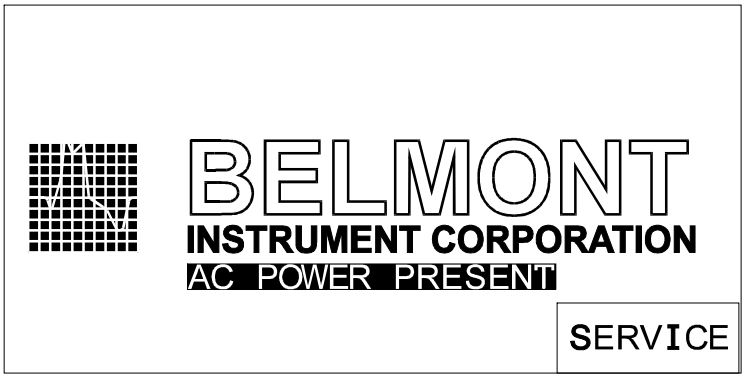
WARNING!

Do not access system parameters setup while the instrument is patient connected.

Changes in system setup can be made to:

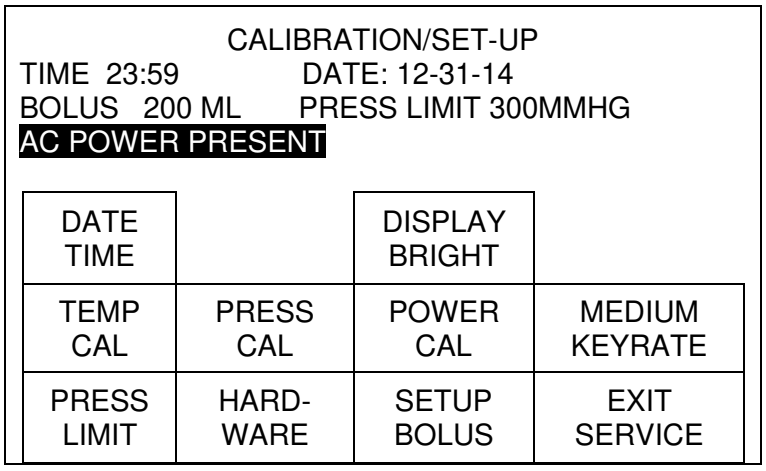
1. **Date and time**: Set the real time clock and date
2. **Display brightness**: Change the display brightness
3. **Key Rate**: Set touch key sensitivity
4. **Bolus volume**: Set the bolus delivery volume
5. **Pressure limits** for High Pressure alarm: Set the maximum allowable in-line pressure. The possible setting range from 100 - 300 mmHg.

Parameter Setup is performed in the Service mode.



SERVICE mode screen

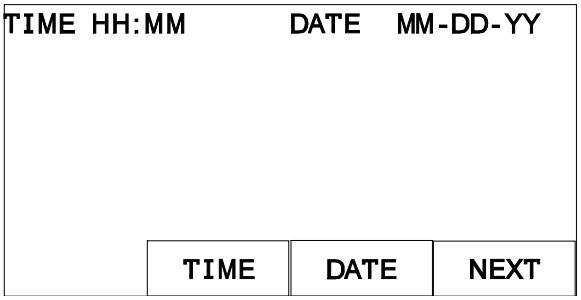
Pressing the SERVICE key accesses the Calibration/Set-up mode. This key appears on the BELMONT logo screen only at system powered-up. This screen remains active for 4.5 seconds before the system enters the Prime mode.



CALIBRATION/SET-UP screen

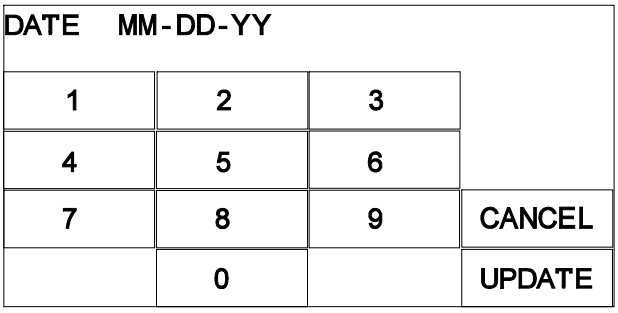
1. Date/Time

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

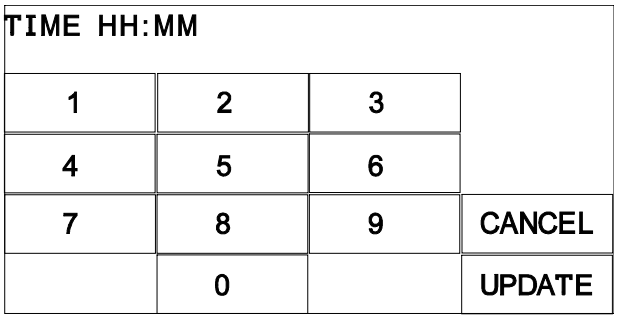


Screen after pressing DATE TIME key

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. Display Brightness

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

3. 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.

4. Bolus Volume

The bolus volume can be set from 100 to 1000 ml (**except 250ml for British Military units**) and can be changed from 100, 200, 400, 500, and 1000 ml each time SETUP BOLUS key 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 One under Main Infuse screen).

5. Pressure Limit

The user can set the maximum allowable in-line pressure. The possible setting ranges from 100 to 300 mmHg. 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 mmHg. 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 factory default value is set at 300 mmHg.**

HARDWARE CALIBRATIONS

At each startup the system automatically checks if the temperature probe, pressure sensor and the power module have lost calibration information. If any one of the hardware parameters has been corrupted, the system goes directly into the Calibration/Set-Up screen upon boot up. The TEMP CAL, PRESS CAL and/or POWER CAL key(s) will light up to indicate that calibration is needed. The system will not exit the Calibration/Set-Up mode until it is calibrated. In addition, the current time and date, bolus setup volume and the presence of AC or DC power are displayed.

Calibration of the system is done at the factory. A password is required to calibrate the system to insure that this mode is not accessed accidentally.

CAUTION
The instrument does not need regular calibration. Calibrate the instrument only after verifying that it is operating outside accepted parameters or when the calibration information has been corrupted.

Calibration must be done in the following order:

1. Pressure sensor
2. Temperature probes
3. Power module and pump

WARNING!
Do not access hardware calibration while the instrument is patient connected.

Materials needed for calibration:

- New disposable set
- Manometer or gauge (up to 300 mmHg , 2 mmHg resolution)
- Pressure source
- Thermometer with readout resolution to 0.1ºC
- Graduated cylinder (ASTM Class B accuracy)
- Timer

1. Pressure Transducer Calibration

Material Required: 3-Spike disposable set
Manometer or gauge (up to 300 mmHg, 2 mmHg resolution)
Pressure source

Setup:
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. Install the disposable set. Center the disposable's pressure chamber in the pressure chamber cavity of the FMS2000. Make certain that the pressure chamber of the disposable set is in good contact with the pressure transducer.
iii. Prepare 1 liter of 37º-43ºC water.

Procedure:

Calibration:

1.1 Power ON. Press SERVICE when it appears at the logo screen.

1.2 Press HARDWARE. Enter the password 013192.

1.3 **Warm the Disposable set**:

1.3.1 Attach water (37º-43ºC) to the disposable set and open the clamps. Make certain the water is warm. The pressure chamber of the disposable is less compliant when it is at room temperature. **Calibration must be performed with a warm disposable.**

1.3.2 Press PUMP SPEED three times to set flow rate to 500 ml/min to prime the system with warm fluid.

1.3.3 Press the LEFT VALVE to circulate warm water through the disposable set for a few minutes.

1.3.4 Press RIGHT VALVE key to set the valve to the infuse position and continue to warm up the disposable to a steady temperature close to the temperature of the fluid. Check that the pressure chamber is completely filled with fluid.

1.3.5 Press CANCEL to exit back to the Calibration/Set-Up screen when done.

Pressure Calibration:

1.4.1 Press PRESS CAL. Enter the password 013192.
1.4.2 Close the bag clamps and block the air vent on top of the reservoir chamber.
1.4.3 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.
1.4.4 Apply 100 mmHg of pressure. Press UPDATE to accept the 100 mmHg calibration point.
1.4.5 Apply 258 mmHg± of pressure. Press UPDATE to accept the calibration point. The system will return to the main Calibration/Setup screen.

1.5 **Calibration Verification:**

1.5.1 Press HARDWARE. Enter the password 013192.
1.5.2 Press RIGHT VALVE to set the valve in the right position.
1.5.3 Apply 258 mmHg into the disposable. The pressure status line should read 258 mmHg (± 25 mmHg).
1.5.4 Repeat with 100, and 300 mmHg pressure. Tolerance limit is ± 25 mmHg
1.5.5 System is now pressure calibrated and verified.

2. Temperature Probes Calibration

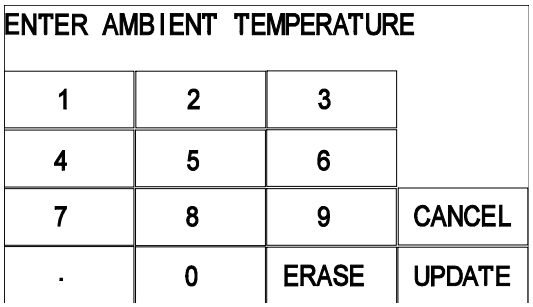
Material Required: 3.0 L Reservoir and 3-Spike disposable set
Thermometer with readout resolution to 0.1ºC

Setup:
i. Leave the FMS2000 in **STANDBY** (or unplug from the wall outlet), for at least two (2) hours, to allow the temperature probe reference to reach equilibrium. The system will not calibrate if probes are not in equilibrium.
ii. Measure ambient temperature, near the input or the output temperature probe, to the nearest 0.1ºC.
iii. Prepare 4 liters each of three (3) different temperatures water: 1º - 7ºC; 17º - 23ºC; and 37º - 43ºC.
iv. Install the 3.0 L Reservoir and the 3-Spike disposable set. Do not connect the patient line.
v. Insert the thermometer into the patient line connector as close to the heat exchanger as possible. Make sure there is no air surrounding the thermometer bulb.

Procedure:

Calibration:

2.1 Power ON. Press SERVICE when it appears at the logo screen.
2.2 Press TEMP CAL. Enter password: 013192.
2.3 Enter the measured ambient temperature. If a mistake was made entering the value, press ERASE to reenter. Press UPDATE.



Screen to enter ambient temperature in TEMP CAL.

2.4 **4 ± 3ºC Calibrate**:

2.4.1 Add 4 ± 3ºC water to the 3.0 L Reservoir

2.4.2 Press NEXT to pump water at 500 ml/min into the disposable. If the procedure has to be abandoned press EXIT and the system will return to the Calibration/Set-Up screen.

2.4.3 Keep water in the 3.0 L Reservoir at 4 ± 3ºC.

2.4.4 After a minimum of two minutes a numerical keypad will appear. Wait until the thermometer reading stabilizes then enter the actual temperature reading, minus 1ºC offset, from the thermometer, which must be between 1ºC and 7ºC. If not, add more 4 ± 3ºC water to the 3.0 L Reservoir.

2.4.5 Press UPDATE to save the value. If the temperature was still fluctuating when UPDATE was pressed, the system will not update and continue to wait until the temperature stabilizes.

2.5 **20 ± 3ºC Calibrate**:

2.5.1 Add 20 ± 3ºC water to the 3.0 L Reservoir. Continue pumping until the thermometer reading stabilizes before entering the actual temperature.

2.6 **40 ± 3ºC Calibrate**:

2.6.1 Add 40 ± 3ºC water to the 3.0 L Reservoir. Repeat.

2.7 After the last temperature water, 40 ± 3ºC is updated, the system will return to the Calibration/Set-Up screen.

Verification:

2.8 Press HARDWARE. Enter password 013192.

2.9 Add more 40 ± 3ºC water to the 3.0 L Reservoir.

2.10 Press the RIGHT VALVE key to set the valve to the infuse position.

2.11 Press the PUMP SPEED three times to set the flow rate to 500 ml/min

2.12 Wait at least 2 minutes for the temperature to stabilize. The INPUT and OUTPUT TEMPERATURE probe readings should be similar and stable (the values not in the parentheses).

2.13 Compare the displayed numbers on screen to the thermometer reading.

The accepted tolerance is 1ºC for fluid temperature between 30ºC to 40ºC.

2.14 Verify the 20 ± 3ºC and 4 ± 3ºC water. The accepted tolerance is 2ºC.

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

2.16 Press CANCEL to return to the Calibration/Set-Up screen. The system is temperature calibrated and verified.

2.17 After a temperature calibration has been completed, a power calibration should be performed. See Power Module and Pump Calibration in this chapter.

3. Power Module and Pump Calibration

CAUTION

Before the power module can be calibrated, be certain that the temperature probes are calibrated and functioning properly, verify in hardware status. Perform a temperature probe calibration before continuing with the power module calibration, if necessary.

Material Required: 3.0 L Reservoir and 3-Spike disposable set
Graduated cylinder (ASTM Class B accuracy)
Timer

Setup: i. Prepare a minimum 2 liters of cold water (cold water works best), having a temperature of app. 4ºC before starting the power module and pump calibration.

ii. Install the 3.0 L Reservoir and 3-Spike disposable set.

Procedure:

Calibration:

3.1 Power ON. Press SERVICE when it appears at the logo screen.

3.2 Press HARDWARE. Enter password 013192.

3.3 Determine the actual maximum flow rate:

3.3.1 Open bag clamps and prepare to prime the disposable.

3.3.2 Press PUMP SPEED three times to set pump speed to 500 ml/min. This will recirculate the system with fluid and prime the main fluid circuit. Check that the disposable is completely filled with fluid.

3.3.3 Press RIGHT VALVE to set the valve into the infuse position and prime and fill the patient line.

3.3.4 Measure and record the flow rate with a graduated cylinder for one minute. The flow rate should be 500 ml/min ± 10%. If the flow is not within specification check that the tubing in the pump head is well seated in between the rollers and housing. The tubing should not be kinked.

3.3.5 Press PUMP SPEED once to set the flow rate to 0 ml/min and stop the pump.

3.3.6 Press CANCEL to exit and return to the Calibration/Set-Up screen.

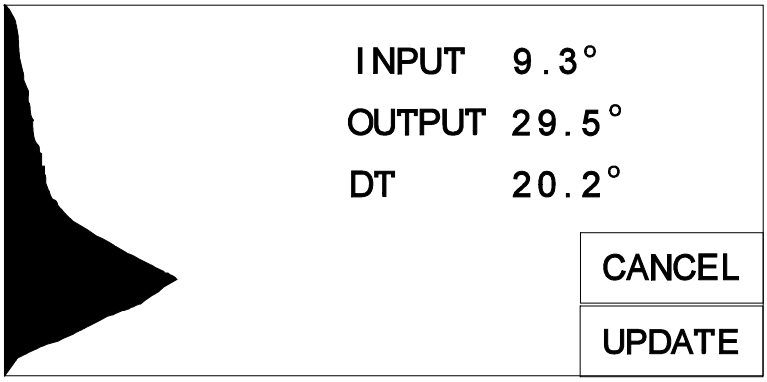
3.4 Calibrate:

3.4.1 Press POWER CAL. Enter password 013192.

3.4.2 Enter the measured flow rate. Press UPDATE to continue.

3.4.3 Prime: The system primes the disposable set automatically with 100 ml of fluid and determining the proper power module settings for the unit. To abort the procedure, press CANCEL. Two flow rates are used during calibration, 500 ml/min first followed by 10 ml/min. The entire procedure requires about eleven minutes.

3.4.4 Keep the 3.0 L Reservoir filled with cold fluid during the entire procedure.



Power calibration screen, waiting to update

3.4.5 The input and output temperature to the heat exchanger will be displayed. Wait for the DT value, the difference between input and output temperature, to stabilize. When the system has stabilized, the UPDATE key will appear.

3.4.6 Press UPDATE to complete the calibration. The display will return to the Calibration/Set-Up screen.

3.4.7 The power module and pump are now calibrated.

The 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 system operational check-out (after module changed).

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.

WARNING!

Do not perform PREVENTIVE MAINTENANCE while the system is connected to a patient.

CAUTION:

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

A. SERVICE AND PREVENTIVE MAINTENANCE SCHEDULE

For your convenience, two preventive maintenance schedules have been provided.

Schedule 1: should be performed by either the Clinical User or a Biomedical Technician (BMET).

Schedule 2: should be performed by either a BMET or other qualified service personnel.

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	Every 5000 Hrs
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		●	
7. Replace Pump Motor.			●
8. Replace Valve Motor.			●

B. 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.

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 (replacement part # 118-00096 US and part #118-00085 International).

4. Temperature Probes

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

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 (replacement part #399-00033). 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.

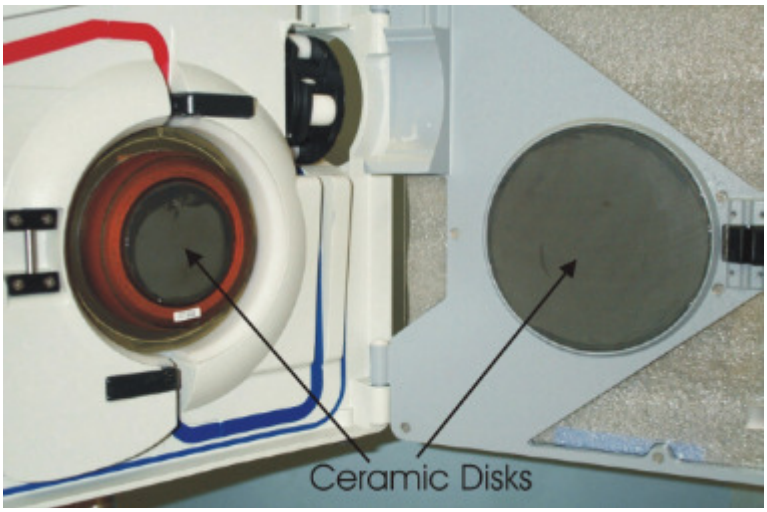
7. Instrument Door and Ceramic Disks

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. Replace or 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 (replacement #599-00314 Rubber feet & #510-00349 6-32 x 1 1/8" screw).

C. TEST / SYSTEM OPERATIONAL CHECK-OUT

The device should be serviced periodically, in accordance to schedule 1 and 2, by a qualified technician. 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, P/N 903-00006
- Bio-Tek Safety Analyzer or equivalent
- Saline or other crystalloid for testing
- 2 liters of 15º-20ºC fluid
- 1 liter of 43º-45ºC fluid
- Manometer (2 mmHg resolution)
- Pressure source
- Digital Thermometer, 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 and there are no gaps between the detectors and the Support Housing. If there are gaps, fill the gap with RTV108.
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 are 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. Remove the patient line from the luer connector. Insert the thermocouple approximately 2" into the connector previously connected to the patient line.

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

c. Close bag clamps. Hang and spike 2 liters of 15º - 20ºC 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. 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.

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

i. Press 500 ml/min. Verify the temperature, during steady state, on the screen and from the thermocouple. The output temperature should be 37.5º ± 2ºC.

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. Close bag clamps and remove this fluid bag.

k. Hang and spike 2 liters of 43º - 45ºC fluid bag.

l. Prime and infuse at 500 ml/min. Compare the numbers displayed, on screen, to the thermocouple reading. The alarm sounds when the screen reads between 42º - 42.5ºC.

m. 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 2ºC of each other.

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: Bio-Tek Safety Analyzer, Model 370 or equivalent
2 Liters of room temperature saline

Setup: Plug the FMS2000 into AC outlet on the front of Bio-Tek Safety Analyzer.

CAUTION:

Before applying voltage to Bio-Tek, make sure input line voltage is correct for the **VOLTAGE OF UNIT UNDER TEST**.

Switch found on the back of Bio-Tek: 115 or 230 V

a. Earth Leakage Currents:

i. Plug the Bio-Tek into an appropriate power source, turn Bio-Tek power ON. FMS2000 power switch To Standby.

ii. Switch selector on Bio-Tek 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. <u>Patient Leakage Current:</u>

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

ii. Attach 12 to 16 gauge stainless steel cannula to the end of patient line and attach the Bio-Tek large clamp to the cannula.

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 500 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

Properly install and prime the disposable set (see Chapter one for installation of the disposable, prime, and infuse) before beginning the Hardware Verification process.

Hardware mode verifies:

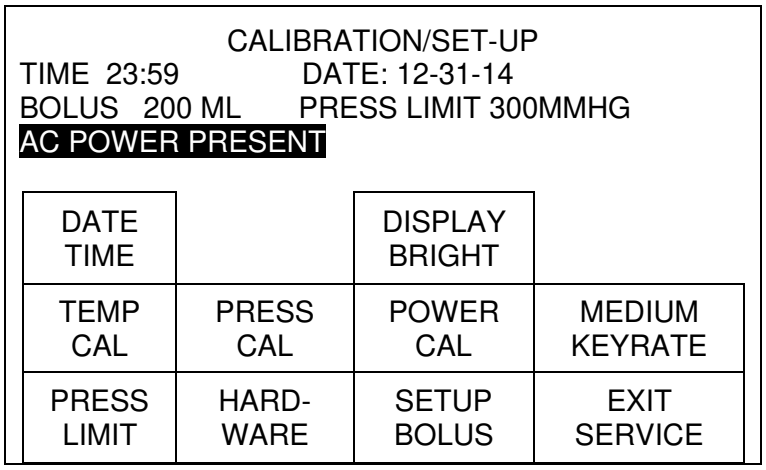
a. Valve operation
b. Fluid Out and Air Detectors
c. Battery voltage.
d. Flow Rate (Pump speed)
e. Input and Output Temperature Probes, and
f. Pressure sensor.

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

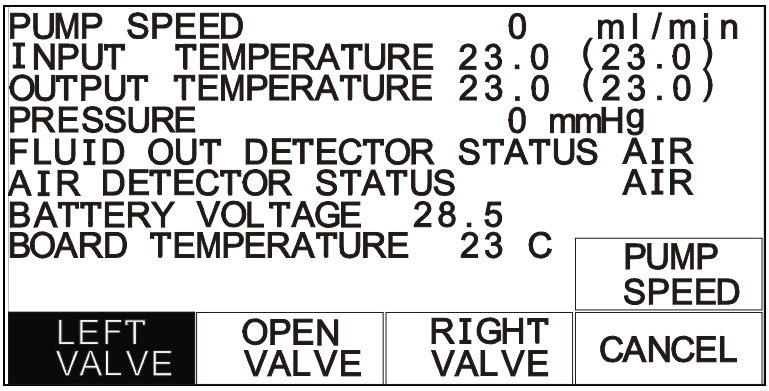
Press the SERVICE key, at power-up, to access the Calibration/Set-up screen. This screen remains active for 4.5 seconds before the system enters the Prime mode screen.

- 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 into the LEFT VALVE position before continuing to the next step.

b. Fluid Out and Air Detectors

i. Confirmed 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, 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.

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:

vi. 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%.

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

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

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

x. 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

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 to the thermocouple reading. The accepted tolerance is 1ºC for fluid temperature between 30ºC to 40ºC.

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.

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**.

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

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.**

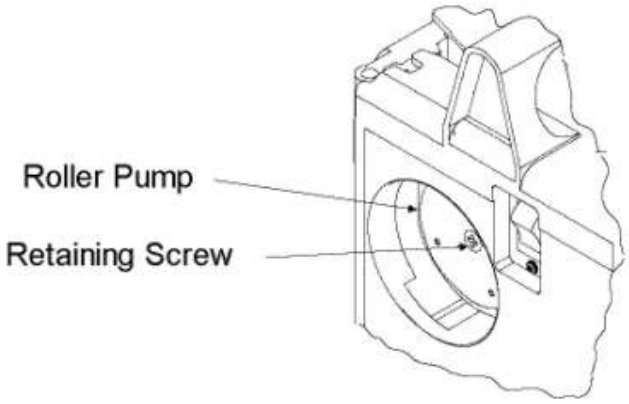
ii. Make certain the pressure chamber is properly installed and the flow path is not blocked.

iii. Make certain the fluid is warm (37º- 43ºC). 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.

iv. 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 while monitoring the amount of pressure with a manometer.

v. Verify the accuracy of the pressure transducer. Apply 300 mmHg into the disposable. The pressure status line should read 300 mmHg (± 50 mmHg). Repeat the same pressure verification for 200 and 100 mmHg. If the readings are not within the specifications, recalibrate the pressure. See Chapter 6.

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 Teflon spray (Heavy Duty Pure Silicone.)

7. Replace Pump Motor

See Chapter 5, Pump Motor Removal and Installation.

8. Replace Valve Motor

See Chapter 5, Valve Motor Removal and Installation.

D. 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		√ **if OK**
b. Back		
c. Latch/Unlatch		
2. **Operational Check-Out**		√ **if OK**
d. PRIME		√ **if OK**
e. PT. LINE PRIME		√ **if OK**
f. INFUSE ▲▼		√ **if OK**
g. AC to DC switch over		√ **if OK**
h. DC to AC switch		37.5 ± 2°C
i. Output Temp, on screen		37.5 ± 2°C
Output Temp, Thermocouple		√ **if OK**
j. FLUID OUT audible alarm		42 to 45°C
l. Temp. when "Over Temp" alarm, on screen		1 to 2°C of screen
m. Temp. when "Over Temp" alarm, Thermocouple		
3. **Battery Run Time test**		>30 min.
4. Electrical Safety Check (See attached Results Sheet)		
a. Earth Leakage Current		√ **if OK**
b. Patient Leakage Current		
5. Hardware verification:		
iii. Valve Operation		√ **if OK**
iv. Fluid Out and Air Detectors		√ **if OK**
v. Battery Voltage		**app. 24 V**
vi. Flow Rate		√ **if OK**
vii. Input and Output Temperature Probes		√ **if OK**
viii. Pressure Sensor		√ **if OK**
6. Clean Pump Head		√ **if OK**
7. Replace Pump Motor		
8. Replace Valve Motor		

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 @ 500 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 @ 500 ml/min.				
• Neutral - NORM				
• Neutral - OPEN				

E. Electromagnetic Compatibility

WARNING!

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the Electromagnetic Compatibility [EMC] information provided in the accompanying documents.

WARNING!

Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment.

WARNING!

The equipment or system should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

NOTE: The EMC tables and other guidelines that are included in the Instruction Manual provide information to the customer or user that is essential in determining the suitability of the Equipment or System for the Electromagnetic Environment of use, and in managing the Electromagnetic Environment of use to permit the Equipment or System to perform its intended use without disturbing other Equipment and Systems or non-medical electrical equipment.

Table 201 Guidance and Manufacturer's Declaration – Emissions All Equipment and Systems		
The **Belmont® Rapid Infuser, FMS2000** is intended for use in the electromagnetic environment specified below. The customer or user of the **Belmont® Rapid Infuser, FMS2000** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Enforcement – guidance**
RF Emissions CISPR 11	Group 1, Class A	The **Belmont® Rapid Infuser, FMS2000** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonics IEC 61000-3-2	Complies or Not applicable	Complies
Flicker IEC 61000-3-3	Complies or Not applicable	Complies

Table 202 Guidance and Manufacturer's Declaration—Immunity All Equipment and Systems			
The **Belmont® Rapid Infuser, FMS2000** is intended for use in the electromagnetic environment specified below. The customer or user of the **Belmont® Rapid Infuser, FMS2000** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the relative humidity should be at least 30%.
Radiated RF IEC 61000-4-3	3 V/m	3 V/m	Radiated RF frequency is negligible at any single frequency
Electrical Fast Transient/burst IEC 61000-4-4	±2kV on AC Mains	±2kV on AC Mains	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms from 150 kHz to 80 MHz	V1 = 3 Vrms	If interference occurs, it may be necessary to position the **Belmont® Rapid Infuser, FMS2000** further from sources of power frequency magnetic field.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for5 Seconds	>95% Dip for 0.5 Cycle 60% Dip for 5 Cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of the **Belmont® Rapid Infuser, FMS2000** requires continued operation during power mains interruptions, it is recommended that the **Belmont® Rapid Infuser, FMS2000** be powered from an uninterruptible power supply or battery.

INTRODUCTION

This chapter describes possible causes for alarm messages and difficulties that may be encountered with suggestions for corrective measures. When the FMS2000 recognizes a situation that is compromising effective infusing, the system not only displays alarm message, instructions for corrective measure, and sounds an audible alarm, but it also stops pumping, heating, and reverts valve into recirculate position. To silence the alarm and return to normal operation, follow instructions on the screen.

Operational alarms that may occur in the course of a procedure are:

- Air Detection
- Door Open
- Fluid Out
- High Pressure
- Low Battery
- Missing Disposable

Heating Alarms:

- Heating Fault
- Over Temperature

Hardware Alarms:

- Air Detector Fault
- Heater Fault Latch
- Heater Power Read Back Fault
- Heater Over Power Fault
- Power Module Overtemp
- Pump Fault
- Valve Fault
- Watch Dog

Other Operational Difficulties:

- Battery, no heat
- Dim display
- Flow rate is too slow or will not go to the set rate
- Key pad does not accept input, too sensitive, or not responsive
- No message, no power, power off immediately after turn on
- Pump running too loud
- System does not heat, does not prime
- Unable to calibrate temperature probes, unable to turn off

OPERATIONAL ALARMS

Operational alarms that may occur in the course of a procedure are:

Air Detection
Door Open
Fluid Out
High Pressure
Low Battery
Missing Disposable

1. AIR DETECTION

An air bubble in the Air Detection sensor located above the diversion valve will cause the pump and heating to stop. The Air Detection alarm (figure 1) and message will appear. The valve goes to the recirculate position.

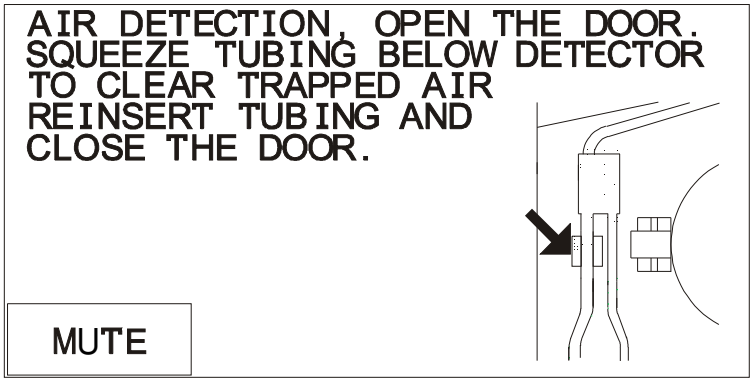


Figure 1. Air Detection alarm.

- Press MUTE to silence the alarm. Check for air in the line. Clear the air by removing the tubing from the air detector. Squeeze or tap the section of the tubing right below the air detector to clear any air bubbles trapped in the air detector back into the pressure chamber.
- Firmly reseat the tubing back into the air detector. Close the door. The screen in figure 2 will appear.

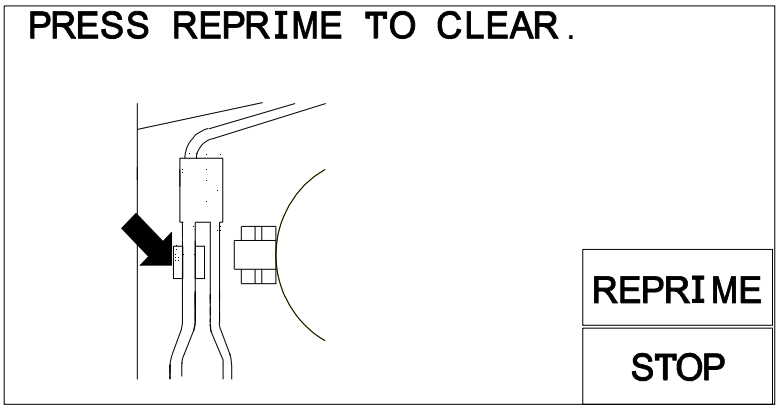


Figure 2. Air Detection alarm after checking the tubing in the air detector.

- Press REPRIME to recirculate the fluid and remove air in the main system. If the system does not complete the Reprime procedure because the hydrophobic filter on top of the reservoir chamber is clogged by blood particulates, see the previous section on how to complete the Reprime. The system will resume infusion upon completion of the Reprime.

2. DOOR OPEN

The system will not operate while the system door is open. If the door is opened while the system is pumping, the system will immediately stop heating and pumping. The valve will go to the recirculate position and an audible alarm will sound.

- Press the MUTE key to silence the alarm.
- Close the door without kinking the tubing. The error message will clear when the door is closed.

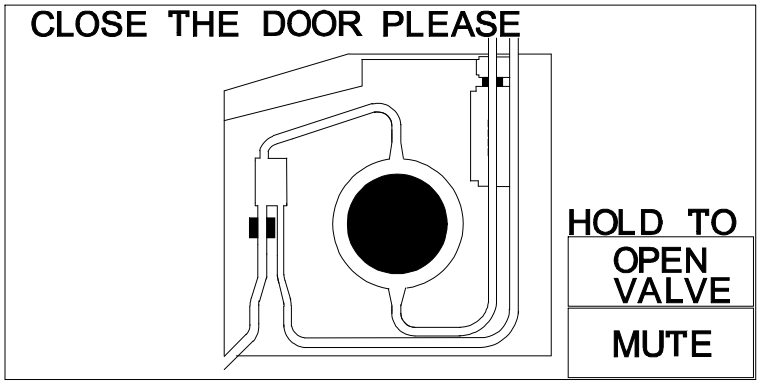


Figure 3. Door Open alarm

- If the disposable needs to be removed from the system, press and hold the OPEN VALVE to release the tubing. The valve will remain open and an audible alarm will sound while the key is pressed. Make certain the patient line is clamped shut to prevent uncontrolled fluid flow.

CAUTION:

While the open valve key is pressed, keep the patient line clamped closed to prevent uncontrolled fluid flow.

CAUTION:

Keep objects out of the valve path when releasing the open valve key to avoid injury.

3. FLUID OUT

If the blood or replacement fluid runs out while infusing or if the tubing in the fluid out detector is pulled or kinked, the pump and heating will stop. The Fluid Out message will display and an audible alarm will sound (figure 4). The valve will go to the recirculate position.

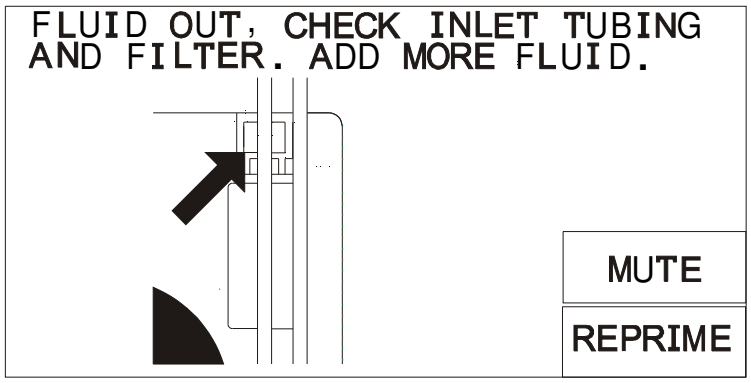


Figure 4. Fluid Out Alarm

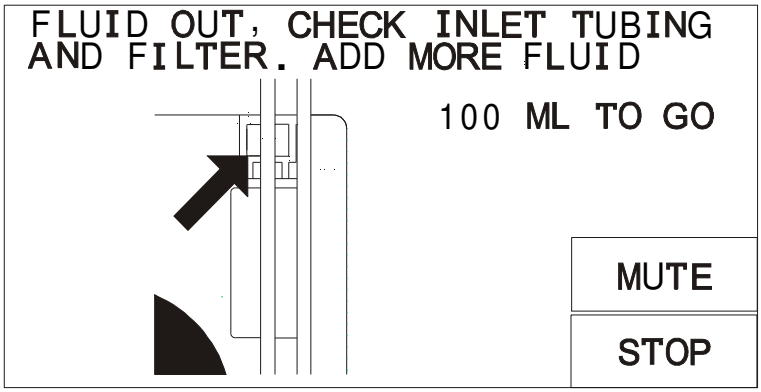


Figure 5. Fluid Out alarm after pressing REPRIME

- Press MUTE to silence the alarm
- Clamp off the empty bags and bag spikes and replace with new fluid bags. Pierce new bags and unclamp bag spikes. Open the door to let fluid into the reservoir before press REPRIME.
- The system will automatically stop and return to the Infuse screen after Reprime. Detection of air during the process will restart the 100 ml cycle.

- If the Reprime volume count does not count down from 100 to 0 ml, check and make sure that:
- The bags are fully spiked and clamps are fully opened.
- The pump tubing is filled with fluid, is not stretched and is seated firmly within the Fluid Out sensor (open the door to fill tubing with fluid, if necessary.)
- Fluid Out sensor is clean and there is nothing obstructing contact with the sensor.

REPRIMING THE MAIN SYSTEM FLUID CIRCUIT WHEN THE RESERVOIR REMAINS EMPTY AFTER EXTENSIVE OPERATION

- If the Reprime procedure cannot be completed or the reservoir chamber stays empty after a Reprime, the hydrophobic air vent filter on top of the reservoir chamber may be clogged by blood particulates. Under this condition, air in the reservoir chamber can be forced back into the fluid bag by using procedure below:
  - Pierce both bag spikes into separate fluid bags and open both clamps to allow the air in the reservoir chamber to escape into one of the fluid bags.
  - Press REPRIME to recirculate the fluid in the disposable set to remove air remaining in the disposable set.
- Inspect the disposable set and patient line to make certain that there is no air.
- If the air could not be returned into the fluid bag, either replace reservoir chamber or restart the system and replace the disposable set and proceed with the original prime.

REPRIMING THE MAIN SYSTEM FLUID CIRCUIT WHEN PERSISTENT FLUID OUT ALARM OCCURS AFTER EXTENSIVE OPERATION

- Frequent or persistent Fluid Out alarm will occur when the coarse blood filter in the reservoir chamber becomes clogged by high amounts of particulates in the blood. Either replace the reservoir chamber or restart the system and replace the disposable set and proceed with the original prime.
- Check to make sure that the disposable set is properly installed and the pump tubing is not stretched.

CAUTION:

High amounts of particulates in the blood may clog the bag filter and/or coarse blood filter inside the reservoir chamber. Replace bag filter, reservoir chamber and/or disposable set if filter(s) becomes clogged. If it becomes occluded the fluid out sensor will activate, an audible alarm will sound, a message “Fluid Out, Check inlet tubing and Filter. Add more fluid” and the pump will stop.

REPLACING THE RESERVOIR CHAMBER

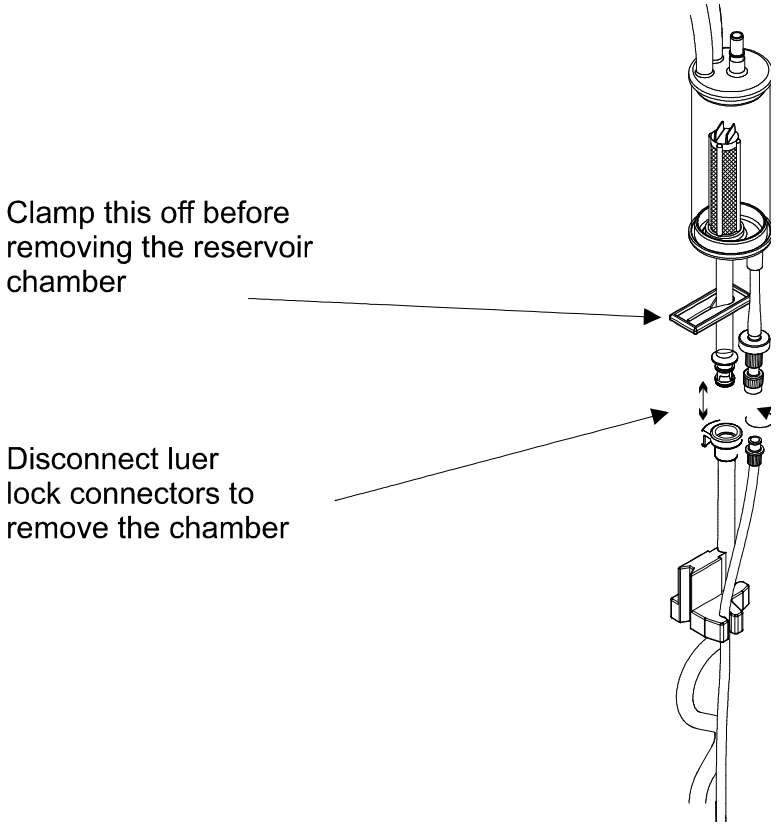


Figure 5. Replacing the Reservoir Chamber

- Clamp off the pump tubing with the large blue clamp.
- Open the luer connectors and disconnect the reservoir chamber. Using aseptic techniques, reconnect lines with a new chamber to continue.
- Take care not to kink or twist the lines. If fluid is spilled onto the Fluid Out detector, clean and dry the detector and tubing before continuing.

CAUTION:
For proper operation, keep the fluid out detector and pump tubing clean and dry.

4. HIGH PRESSURE

If the pressure in the line suddenly increases, pumping and heating will halt. An alarm will sound and the High Pressure message will appear (figure 7). The valve will go to the recirculate position.

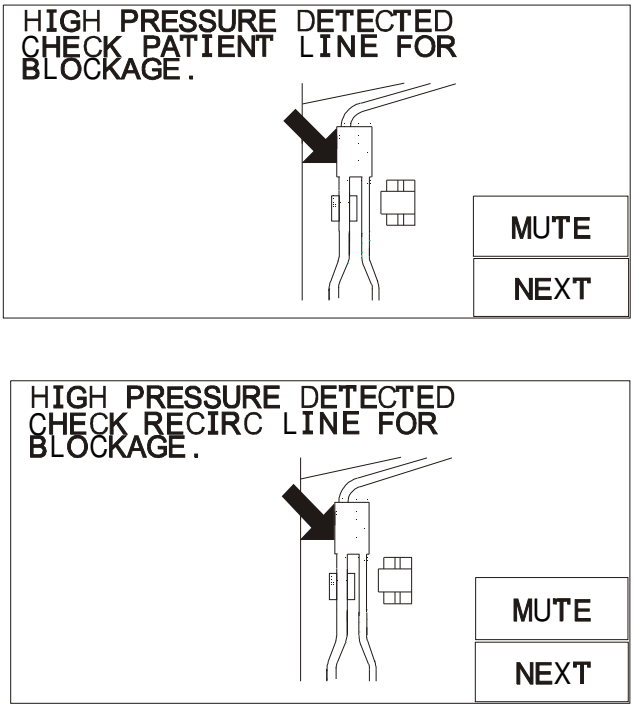


Figure 7. High Pressure alarm.

- Press MUTE to silence the alarm.
- If the patient line is indicated as the source of the alarm, check for obstructions or kinks in the patient line. Make certain that the infusion site is well placed and not blocked.
- If the recirculate line is indicated, check that the recirculation line is not obstructed.
- Use the appropriate infusion set recommended in the guide, Match the Infusion Set to Flow Rate and Fluid Type in Chapter 3.
- Check pressure limit setting (in SERVICE MODE) to make certain that it is set appropriately. Use higher pressure limit, when possible, to a maximum value of 300 mmHg. A higher pressure limit will allow for higher flow rates and fewer incidences of HIGH PRESSURE alarm.
- Press NEXT to return to the infuse screen and continue to infuse at the previous rate.

5. Low Battery

d. When the battery runs low, the system flashes 'BATT LOW' message and sounds an audible alarm. The system should be plugged into an AC outlet to continue operation and charge the battery.

e. The normal recharge time is 8 hours.

6. MISSING DISPOSABLE

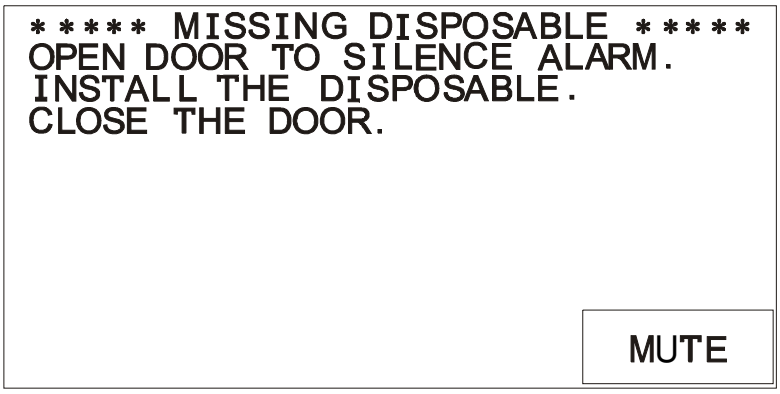


Figure 8. Missing Disposable set alarm

In AC operation, the system will check for the presence of a disposable set before the Prime screen at startup and every time the door is opened and closed. Install the disposable set and close the door to remove the alarm.

TROUBLESHOOTING ALARM MESSAGES

The following table describes alarms, messages, system responses, the possible condition that triggers the alarm, and troubleshooting actions the operator can take to rectify the situation.

A. OPERATIONAL ALARM

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
AIR DETECTION **"AIR DETECTION, OPEN THE DOOR. SQUEEZE TUBING BELOW DETECTOR TO CLEAR TRAPPED AIR. REINSERT TUBING AND CLOSE THE DOOR."**	Air in the line. Tubing inside the air detection sensor is not seated firmly in the detector. Leak in the disposable. Air detector sensor dirty. Detector electronics defective.	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Open the door to silence the alarm. Check for air bubbles and possible leaks. Squeeze the tubing directly below air detector to clear any trapped air out of the sensor. There should be no trapped air remaining within the air detector. Check the air detector and make certain that it is clean and nothing is obstructing the sensor. Reseat the tubing in the air detector and make certain that it is seated firmly in the sensor. Press REPRIME to re-prime main system fluid circuit. Check for air in the disposable set and patient line before infusing. Replace the detector electronics, on the daughter board.
DOOR OPEN **"CLOSE THE DOOR PLEASE"**	The door is open. No magnet in the door latch Magnet sensor (U11), on daughter board, defective	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Close the door to silence the alarm and resume. Check magnet in the door latch.

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
FLUID OUT **"FLUID OUT, CHECK INLET TUBING AND FILTER. ADD MORE FLUID."**	Out of fluid. Bag clamps not fully opened. Bag not fully spiked. Tubing in the Fluid out sensor is not seated firmly in the detector. Tubing in the Fluid out sensor is stretched or tubing pulls away from the sensor, due to vacuum in line. Clogged air vent filter. Clogged coarse blood filter. Reservoir or recirculate line is obstructed. Detector electronics defective	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Press MUTE to silence the alarm. If out of fluid, add additional fluid and press REPRIME. If the Re-prime volume count does not count down from 100 to 0 ml: then • Check that bags are fully spiked and clamps are fully opened. • The reservoir chamber should be seated in the holder. Check that the pump head tubing is not stretched and is seated firmly within the fluid out sensor. • Check the fluid out sensor and make certain it is clean and there is nothing obstructing contact with the sensor. If the reservoir chamber stays empty during re-prime, the air vent filter may be clogged. In this case, pierce the fluid bag(s) with bag spikes and fully open clamps to allow air in the reservoir chamber to escape into fluid bag(s) and allow fluid to fill the reservoir chamber. High amounts of particulates in the blood will clog the coarse blood filter in the reservoir chamber. Replace reservoir chamber or disposable every 4 hours of operation. Replace the detector electronics or the daughter board.

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
HIGH PRESSURE **"HIGH PRESSURE DETECTED CHECK PATIENT LINE FOR BLOCKAGE."**	Patient line is blocked. Recirculate line is kinked. Infusion site is not well placed. The catheter bore size is too small. Pressure limit setting is set too low.	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Make certain that the flow path is not blocked. Check that the recirculate line is not obstructed. Check that the infusion site is well placed and use the appropriate infusion set recommended in the guide, Match the Infusion Set to Flow Rate and Fluid Type in Chapter 3. Increase pressure limit setting. Press NEXT to silence the alarm and resume. Check functionality of the pressure transducer by gently pressing the transducer. Pressure reading on screen should change. If not, it is defective.
LOW BATTERY	Battery voltage is too low, less than 22.5 ∀ 0.3 volts.	Flash 'LOW BATTERY' message and sound periodic beep.	Plug the system into an AC outlet to continue operation and recharge the battery. Allow at least 8 hours to fully charge the battery. If LOW BATTERY displayed while plugging into the AC outlet – AC/DC board may be defective. Check LED, D18, should be ON or 30VDC output voltage at JP2 (1-3) on the AC/DC board and input voltage (120 VAC or 230 VAC) across JP4-JP5.
MISSING DISPOSABLE **"***MISSING DISPOSABLE*** OPEN DOOR TO SILENCE ALARM. INSTALL THE DISPOSABLE. CLOSE THE DOOR."**	No disposable set in the unit.	Sound alarm and display message. Valve in the load position.	Properly install disposable. Press NEXT to resume.

B. HEATING ALARMS:

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
HEATING FAULT **"CHECK TEMPERATURE PROBE WINDOWS FOR BLOCKAGE. CLEAN WINDOWS IF NECESSARY. PRESS RETRY TO CLEAR. TURN OFF POWER AND SERVICE MACHINE IF ERROR PERSISTS"**	Wet, dirty or blocked disposable set windows. Wet, dirty or blocked temperature probe (IR). Temperature probes failure. Heater fault	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Check disposable set and flow path for occlusions. Make certain the windows on the disposable set and the temperature probes are clean and dry and free from contaminates. Clean surfaces with moistened soft cloth if necessary. Dry off surfaces before continuing. Replace disposable set, if clogged. Press RETRY to continue. Power down the system and remove temperature probes (clean and dry) if error persists.
OVER TEMPERATURE **"OVER TEMPERATURE. TURN OFF POWER. DISCARD BLOOD AND DISPOSABLE. RESTART SYSTEM WITH A NEW DISPOSABLE. SERVICE MACHINE IF PROBLEM PERSISTS."**	Fluid supply is over the temperature limit, ∃ 42EC Temperature probes are wet, dirty, or blocked. Restricted flow or out of fluid.	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Check disposable set and flow path for occlusions. Make certain the windows on the disposable set and the temperature probes are clean and dry and free from contaminates. Clean surfaces with moistened soft cloth if necessary. Dry off surfaces before continuing. Make sure bag clamps are open and flow is unimpeded. Make sure that the filter is not clogged. Add more fluid, if fluid out. Clamp off the bag spikes and patient line and remove disposable. Power down and restart system with a new disposable. Power down the system and remove temperature probes (clean and dry) if error persists. **WARNING!** Do not infuse blood that is in the disposable set when over temperature condition occurs. Red cells that have been subjected to high temperature may not be safe to infuse.

C. HARDWARE ALARMS:

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
AIR DETECTOR FAULT **"AIR DETECTOR FAULT. TURN OFF POWER, SERVICE MACHINE."**	Air detector failure, did not pass hardware test when the system first powers up.	Sound alarm and display 'Air Detector Fault' message and halt all operations.	Power down and service machine: replace the air detector electronics.
HEATER FAULT LATCH **"HEATER FAULT LATCH AT LOCATION A B C D. PRESS RETRY TO CONTINUE. SERVICE MACHINE IF ERROR PERSISTS."**	Excessive AC power line noise or internal failure	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Press RETRY to try again. Power down and service machine if error persists: replace Power Driver Module.
HEATER POWER READ BACK FAULT **"HEATER POWER I/O FAULT. RESTART SYSTEM AND RETRY. SERVICE MACHINE IF ERROR PERSISTS."**	Heater power feedback sense coil open. Power feedback circuit malfunction.	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.	Restart the system, and try again. Power down and service machine if error persists: • Remove and clean input and output temperature probes • Replace Power Driver Module
HEATER OVER POWER FAULT **"HEATER OVER POWER FAULT. PRESS RETRY TO CONTINUE. SERVICE MACHINE IF ERROR PERSISTS."**	Heater hardware fault	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position. System will try to reset the error.	Push RETRY to try again. Power down and service machine if error persists: • Remove and clean input and output temperature probes • Replace Power Driver Module

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
POWER MODULE OVERTEMP **"POWER MODULE OVERTEMP FAULT. KEEP THE AIR INTAKE AT THE BOTTOM OF THE MACHINE CLEAR. PLEASE WAIT FOR SYSTEM TO CORRECT THE PROBLEM. SLOW DOWN THE FLOW RATE OR USE WARMER FLUID IF THE PROBLEM PERSISTS."**	Power driver module overheating. Temperature inside the cabinet reaches 70°C.	Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position. Power goes low and the fan will go to maximum speed to cool the system.	Make certain that the fan air vents at the bottom of the machine are not blocked. Wait for unit to correct problem. Display will return to Infuse screen when the error clears. Press MUTE to silence the alarm. Power down and service machine if error persists: • Remove door and clean around the door hinges. Push the door back, making sure it seats all the way down in the hinges. • Position system away from heat sources.
PUMP FAULT **"PUMP FAULT, CHECK PUMP FOR BLOCKAGE. RESTART SYSTEM OR PRESS RETRY. SERVICE MACHINE IF ERROR PERSISTS."**	Pump failure Pump speed feedback encoder failure. Pump runs out of control or does not move when requested.	Stop pumping and heating. Sound alarm and display message. Valve to the recirculate position.	Check that pump turns freely and head is clean. Pump tubing is seated properly on the roller pump. Press Retry to try again. Power down and service machine if error persists: • Remove door and clean around the door hinges. Push the door back, making sure it seats all the way down in the hinges, or • Replace pump motor, or • Replace roller pump.
VALVE FAULT **"VALVE FAULT, CHECK VALVE FOR BLOCKAGE. RESTART SYSTEM AND RETRY. SERVICE MACHINE IF ERROR PERSISTS."**	Valve failure Valve position sensor malfunction. Valve did not move to the desired position in 2 seconds.	Stop pumping and heating. Sound alarm and display message.	Check that the valve is not blocked. Restart the system and try again. Power down and service machine if error persists – replace valve motor, or Daughter board, or the Computer board. **CAUTION:** In a valve fault condition and fluid is in the disposable set, keep the patient line clamped closed when opening the door to prevent uncontrolled fluid flow.

ALARM MESSAGE	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
WATCH DOG (no message)	Internal computer malfunction. Hardware override circuit detects processor not operating properly.	Stop pumping and heating. Sounds a high pitch tone.	Restart the system, service machine if error persists – replace Computer board. **CAUTION:** In a Watch Dog alarm condition and fluid in the disposable set, keep the patient line clamped closed when opening the door to prevent uncontrolled fluid flow.

TROUBLESHOOTING OTHER OPERATIONAL DIFFICULTIES

There are times that problems occur that are outside the comprehensive surveillance system. These can be due to improper setup, faulty accessory equipment, or internal failure of a component. This table describes several of these potential problems, the alarm that might be generated (if any), and the corrective actions to take.

PROBLEM	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
Battery No Heating	Power cord not plugged in AC power	NA	Plug into AC receptacle; check power cord connection. Keep the system plugged in to charge the battery.
Dim display	Display brightness in Setup Routine has been turned down to the lowest brightness setting.	NA	Increase display brightness in System Setup, Chapter 6.
Flow rate is slowing down or will not go at the set rate	The system is keeping the pressure in the line under the Pressure Limit by reducing the infusion rate.	Pressure reading flashes at “Pressure Status Line” and system periodically beeps.	Check and remove kinks or obstructions in the tubing. Use the appropriate infusion set recommended in the guide, Match the Infusion Set to Flow Rate and Fluid Type in Chapter 3. Increase flow by increasing the Pressure Limit. Change the Pressure Limit in Calibration/Setup to a higher limit (maximum Pressure Limit is 300 mmHg).
Key pad does not accept input	The keypad is being continually depressed. Key pad failure	Constant beep	Release the keypad and the constant beep will cease. If the alarm persists, power down and service machine.
Keypad is too sensitive or not responsive	Keypad sensitivity in Setup Routine has been set at Fast or Slow.	NA	Reset keypad sensitivity in System Parameters Setup, Chapter 6.
No message, beep tone	Power switch not completely depressed or membrane switch failed.		Depress power switch completely. If problem persists, replace the membrane switch.

PROBLEM	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
No power or battery run time is too short	Power cord not plugged into AC power. Batteries discharged in DC operation.	Unable to turn the system to on.	Change AC power source; check power cord connections. If battery is completely discharged, turn the AC power OFF, plug the system into the AC outlet to recharge the battery. **Wait for at least 30 seconds before turning the system ON.** Recharge internal battery by connecting the power cord to the AC line. If the battery run time is less than ½ hour after a full 8 hours charge, replace the rechargeable battery.
Power off immediately after switching to ON. System turns on for 2-3 seconds, and then turns off automatically.	• IGBT's on Driver 'A' and 'B' shorted. • EPROM is not seated in the socket properly.	System turns on, then off immediately. System turns on for 2-3 seconds, and then turns off.	Service machine if problem persists. Replace Drive 'A' and 'B' boards. Reinsert the EPROM on the Computer board,
Pump is running too loud	Roller pump is hitting the door or pump tubing is not properly installed.	NA	1. Open the door and reinsert the pump tubing. 2. Check to make sure that there is no blood or debris around the door hinges caused the door to lift up resulting in the roller pump hitting the door hub.
System does not heat to physiologic temperature	Windows on the disposable or IR sensor is wet or dirty. Power module is not calibrated properly. Power module malfunction or temperature probes are out of calibration.	Incorrect temperature display. Heating fault message.	Examine the windows on the disposable set for wetness or contaminants. Clean window with soft cloth and alcohol if necessary. See procedure on power calibration in Chapter 6. Check temperature probe calibration in Chapter 6. Service machine if problem persists – replace Power Driver Module.
System does not prime	See Fluid Out in Alarm Message of this chapter	System will not count down from 100 to 0 ml in Prime.	Check the reservoir or recirculate line and make certain that it is not obstructed, the fluid bags are fully spiked and clamps are open. The pump tubing should not be stretched too taut and it must be firmly seated within the sensor. See Fluid Out in Alarm Message of this chapter

PROBLEM	POSSIBLE CAUSE	SYSTEM RESPONSE	OPERATOR ACTION
Unable to calibrate temperature probes	Temp probe malfunction Incorrect fluid temperature used for calibration.	NA	Check the temperature of fluid and make certain it is correct. If problem persists, service machine – replace temperature probe.
Unable to turn the system power to OFF	Q11 on the Daughter board shorted	Unplug from the wall outlet, not turning off. Run in the battery mode until shut down.	Service machine if problem persists – replace the Daughter board.

REPLACEMENT PARTS

This chapter provides information necessary to identify the replacement parts and assemblies of the **FMS2000**.

Some circuit boards are multilayer and use surface mount technology. Individual component replacement is not recommended on these boards. Board exchange or replacement is the most efficient method of repair. Circuit boards, returned for exchange that show evidence of improper repair and are damaged, are not considered for exchange. Damaged boards will be charged at full price.

Replacement circuit boards and assemblies are listed below. Current parts prices and exchange charges can be determined by contacting Belmont instrument LLC Sales Department.

CIRCUIT BOARDS, ASSEMBLIES, or PARTS

Module/Assembly	Ordering P/N
A. Instrument Cover with battery	403-00108
B. AC/DC PCB:	402-00032
C. Actuator Handle:	203-00232
D. Air Detector Sensor	310-00024
E. Battery:	101-00021
F. C152, on CPU PCB:	102-00401
G. Ceramic Disk and Gasket	203-00114 & 203-00276 (order as a set)
H. Circuit Breaker (120V unit):	403-00117 or
(230V unit):	403-00270
I. CPU PCB:	402-00031
Display:	106-00008
J. Daughter PCB:	402-00034 (for 903-00001 & 903-00001A)
Daughter PCB:	402-00034HP (for 903-00023 & 903-00024)
K. Driver PCB “A” or “B”:	402-00035
Heater Control PCB:	402-00036
L. EMI Filter PCB:	402-00015
M. EPROM (ICU 108):	108-00089
N. Fan Guard:	399-00033
O. Fluid Out Sensor	310-00023
P. IEC Connector:	401-00143 (for 120V unit)
(Power Entry Module)	401-00142 (for 230V unit)
Q. Input Temperature Probe:	403-00158
R. Membrane Panel:	202-00060
S. Output Temperature Probe:	403-00159
T. Power Driver Module:	403-00132
U. Pressure Transducer:	310-00017
V. Pump Motor:	403-00110 (for 903-00001 & 903-00001A)
Pump Motor:	403-00339 (for 903-00023 & 903-00024)
W. Valve Motor with Pincher:	403-00111 & 403-00116 (order as a set)

ORDERING INFORMATION

To order circuit boards or assemblies for the **FMS2000**, call or write the following:

Belmont Instrument LLC
780 Boston Road
Billerica, MA 01821, USA

(866) 663-0212, US/Canada
(978) 663-0212, Worldwide

NOTES:

Belmont Instrument LLC maintains a policy of continuous product improvement and reserves the right to change materials, specifications, and prices without notice.

System Limited Product Warranty

The FMS2000 is warranted to the original purchaser to be free from defects in material and workmanship for a period of one year from date of shipment. If the FMS2000 proves to be so defective, the purchaser may return same to Belmont Instrument, or its designated agent, for repair or replacement, or have a service representative repair the unit on site, as Belmont deems appropriate. The liability of Belmont Instrument under this limited warranty does not extend to any FMS2000, which has been abused, misused or serviced by anyone other than the authorized Belmont representative.

While the FMS2000 is within the stated warranty period, no unauthorized service repairs or modifications on this equipment other than that described in the Operations Manual should be attempted. Any unauthorized repairs will immediately void the remainder of the warranty.

No agent, employee or representative of Belmont Instrument LLC, has any authority to bind Belmont Instrument LLC, to any affirmation, representation or warranty concerning its products, and any affirmation/representation, or warranty made by any agent, employee, or representative shall not be enforceable by buyer.

THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED (INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) RESPECTING THE FMS2000 OR ANY OTHER COMPONENT, AND THE LIABILITY AND REMEDY STATED IN THIS LIMITED WARRANTY WILL BE THE SOLE LIABILITY OF BELMONT INSTRUMENT LLC AND REMEDY AVAILABLE TO PURCHASER FOR SAID PRODUCTS, WHETHER IN CONTRACT TORT OR OTHERWISE , AND BELMONT INSTRUMENT LLC WILL NOT BE LIABLE TO PURCHASER FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR INCIDENT TO THE HANDLING, USE MAINTENANCE OR SERVICING OR DISPOSITION OF SAME.