

The Belmont Fluid Management System F MS2000

Operator's Manual

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I. Introduction - System Overview

I. Introduction - System Overview
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I. Introduction - System Overview

The system must be operated by knowledgeable users. It is essential that you have read and understood this manual before operating the system.

The **BELMONT FLUID MANAGEMENT SYSTEM**, F MS2000 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). 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.

A 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.

I. Introduction - System Overview

INDICATIONS FOR USE

- Infusion of crystalloid, colloid, or blood product, including packed red blood cells, as volume replacement for patients suffering from blood loss due to trauma or surgery.
- Infusion of warmed fluid to re-warm patients after surgery or for hypothermia.
- Infusion of warmed fluid for irrigation in urology procedures.

CONTRAINDICATIONS

- The system should not be used where the desired flow rate is below 2.5 ml/min or above 750 ml/min.
- The system should not be used to warm platelets, cryo-precipitates, or granulocyte suspensions.
- This system is not intended for drug administration.
- Belmont *F MS2000* should not be used where rapid infusion is medically contraindicated.

I. Introduction - System Overview

OVERVIEW OF THE BELMONT *F MS2000*

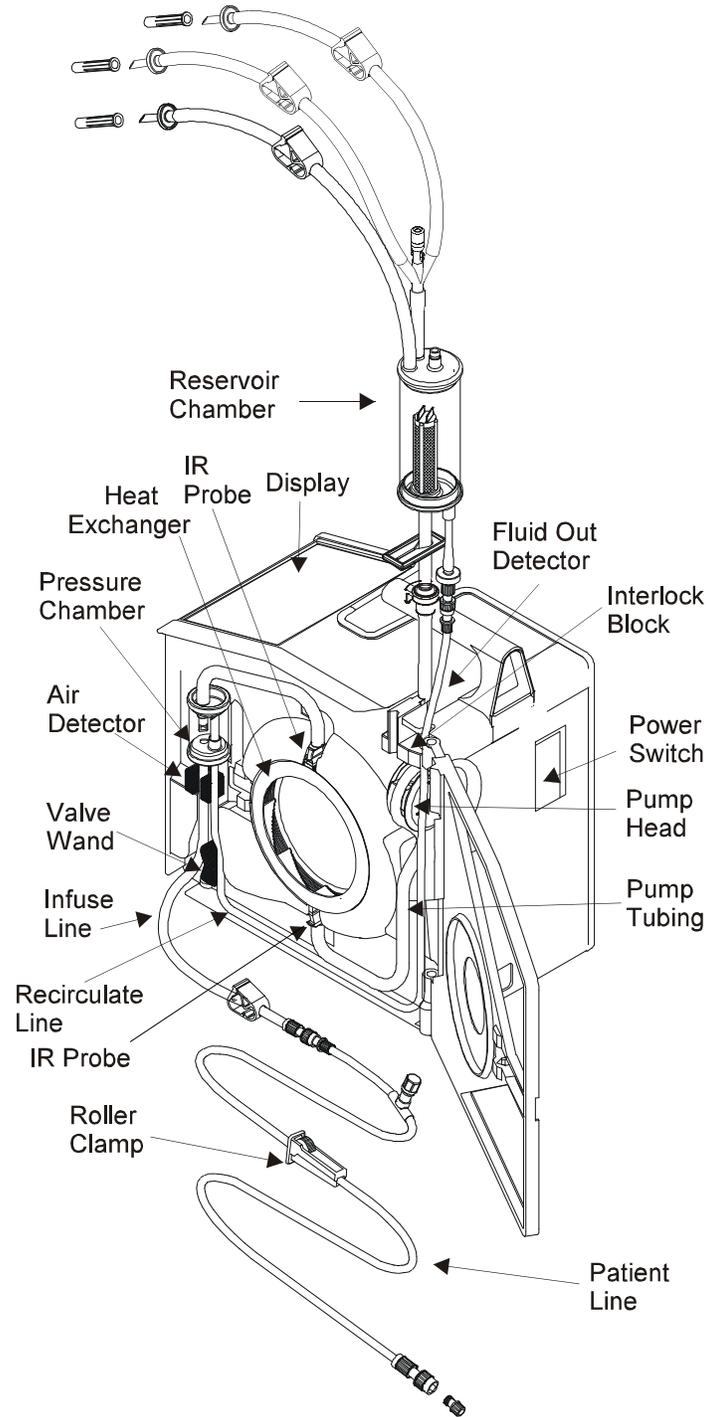
The complete system consists of the *F MS2000* **Control System**, which is mounted on an IV pole, and the *F MS2000* **System Disposable Set**.

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

- C A high speed fluid pump.
- C An efficient fluid warmer.
- C 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 *F MS2000* can be used only with the supplied disposables.**

I. Introduction - System Overview



System Diagram Showing Main Components

I. Introduction - System Overview

FLUID PUMP

The roller type peristaltic fluid pump is designed to obtain low hemolysis, consume low power, to be light weight and very reliable. 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 10°C to 37.5°C at 750 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. A guide for matching infusion set to flow rate and fluid viscosity is given in Chapter II.

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 system automatically resets the pressure limit to 300 mmHg, at power-up. 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 can not be transmitted back to the infusate bag. This high pressure sensing prevents fluid lines from "blowing out" if blocked.

I. Introduction - System Overview

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. If air is detected, the diversion 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, using a special bypass operating mode.

Out gassed air should be expected in stagnant or slow flowing warmed fluid. Patient lines external to the F MS2000 should be monitored.

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 III: Alarm Messages and Troubleshooting Procedures for complete list of alarms.

I. Introduction - System Overview

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:	C	Flow Rate in ml/min
	C	Volume Infused
	C	Infusate Temperature in °C
	C	Pressure in the Fluid Line in mm Hg
	C	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 IV for 'Key Rate' sensitivity setup.
Alarm Display:		Graphical alarm messages indicating where errors have occurred and suggested operator action.

II. Operation

II. Operation

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II. Operation

This chapter explains the procedure for setting up and initiating safe and effective operation of the **Belmont F MS2000**.

WARNING!

Do not use this product in the presence of flammable anesthetics.

WARNING!

Do not use with pressure infusers or “bag squeezers”. The system pump provides adequate pressure to infuse fluid.

WARNING!

The Belmont *F MS2000* is not for use in warming platelets, cryoprecipitates, or granulocyte suspensions.

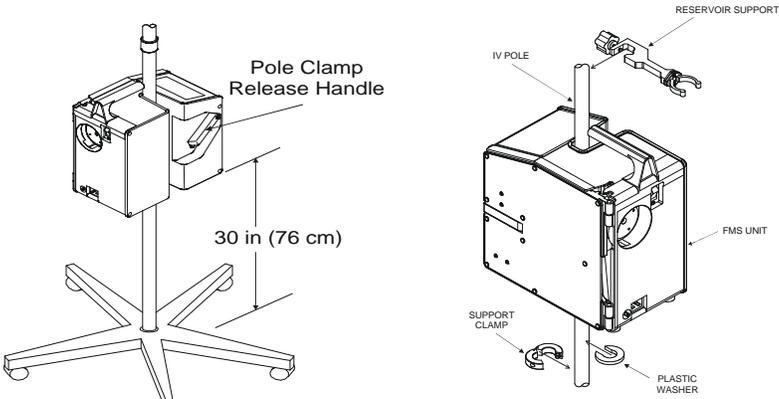
WARNING!

The F MS2000 is intended for infusion of high volume warm replacement fluid or blood component. It is not intended for drug administration.

II. Operation

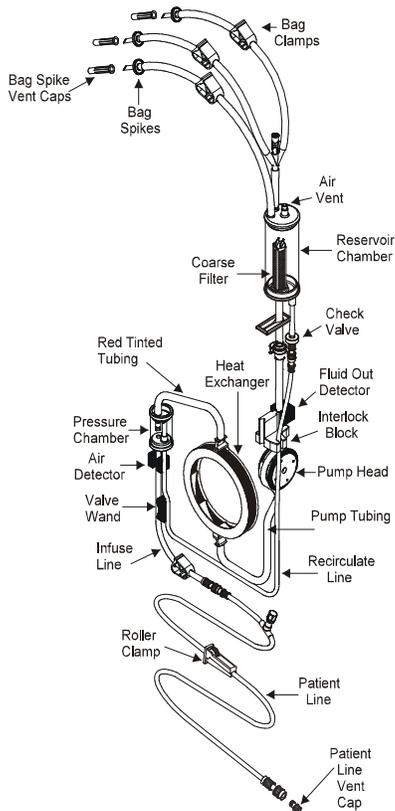
STEP-BY-STEP SUMMARY OF OPERATING PROCEDURES

The following is a step-by-step summary of the major steps; the remainder of the chapter explain each step in detail.

SET-UP	
INSPECT THE SYSTEM <ul style="list-style-type: none">• Power cord• Reservoir Support• Disposable Set• Large Reservoir and holder, if needed	Inspect the system to ensure that you have all necessary components. Use only supplied power cord.
IV POLE MOUNTING <ul style="list-style-type: none">• IV Pole: 5 wheel, maximum diameter 1 1/4"• Install the Support Assembly 30" above the IV pole base• Mount the F MS2000 on the IV Pole above the Support Assembly• Install the Reservoir Support app. 9" above the top of the system <p style="text-align: center;">CAUTION:</p> <p>Check that the system is securely clamped to an IV pole and will not tip over</p>	 <ol style="list-style-type: none">1. Install the support assembly (support clamp and washer) approximately 30" from IV pole base.<ul style="list-style-type: none">• While holding clamp closed, loosen the screw to open up the clamp. Install clamp on the IV pole, holding clamp close and tighten screw using supplied 3/16 allen wrench.• Snap the plastic washer onto the IV pole above the support clamp.2. Lift up on the "Pole Clamp Release Handle" to open. Mount the system onto the IV pole, above the support assembly, by pushing down on the pole clamp release handle. Check that the system is locked in place before proceeding.3. Clamp the reservoir support onto the IV pole approximately 9" above the F MS2000.<ul style="list-style-type: none">• Make certain that there is nothing obstructing the air vents at the bottom of the system.

II. Operation

INSTALLING DISPOSABLE SET



3-Spike Disposable set with key components

WARNING:

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

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

1. Snap reservoir chamber into the reservoir support clamp.



2. Open the door. Insert heat exchanger with red arrow pointing up (**Red tinted tubing** to red stripe on unit.)



3. Firmly position the interlock into the fluid out detector.
4. Guide the curved piece of pump tubing (**Blue tinted tubing**) over the pump head. Check that the thinner recirculate line is in the groove to the right.

Do not kink or twist the tubing



5. Place the pressure chamber into the pressure chamber well. Firmly insert the wider infuse line into the air detector and to the left of valve wand.

Do not apply excessive pressure to the pressure transducer. The pressure transducer can be damaged with excessive force. Do not use the system if the pressure transducer is damaged.

6. Place the thinner recirculate line to the right of the air detector, and to the right of the valve wand.
7. Close and latch the door. Make certain the pump tubing is not caught. Connect the patient line.

II. Operation

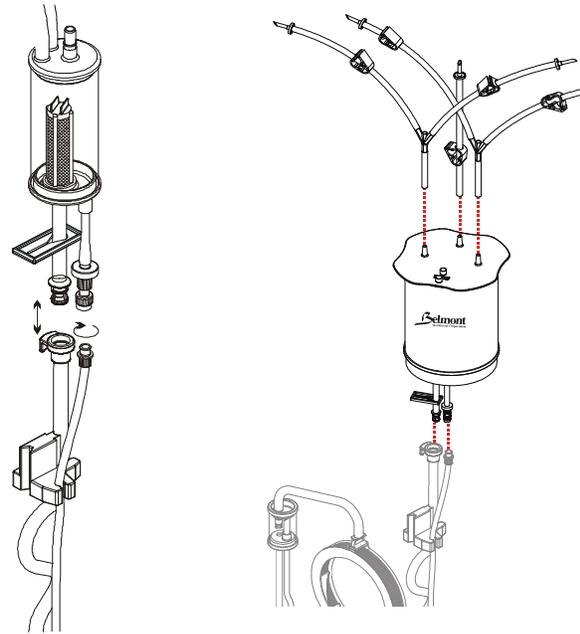
INSTALL LARGE RESERVOIR, IF NEEDED

- Install large reservoir holder
- Install large reservoir



CAUTION:

Do not pressurize or apply a vacuum to the reservoir



1. Using aseptic techniques, remove the reservoir chamber from the 3-Spike disposable set by disconnecting the luer connectors.
 - Disconnect the larger pump tubing by pressing in the luer lock tab and pulling out the connector.
 - Disconnect the thinner recirculate line by unscrewing the connector.
2. Attach the reservoir holder onto the IV pole and place the reservoir into the holder.
3. Assemble the large reservoir using aseptic techniques by attaching the three fluid supply tails onto the top of the reservoir.
4. Connect the large reservoir to the luer of the 3-Spike disposable set.
5. Adjust the reservoir holder to make sure that 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 F MS2000, as previously shown.

II. Operation

POWER ON

- Check that the detachable power cable is securely seated in the main power receptacle.
 - Plug the system power cord into a grounded, 3-prong, 20 Amp, AC receptacle. Do not use an adaptor for ungrounded outlets.
1. Turn power on by firmly pressing the circuit breaker to the ON position. The system will perform a self-check to check the integrity of system parameters.
 2. 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.
 3. PRIME screen will appear.
 4. If you turn power ON without the disposable set, MISSING DISPOSABLE message and alarm will appear.
 5. Open the door or press MUTE to silence the alarm then install the disposable set as described earlier.
 6. Press NEXT to go to the PRIME screen.

INSTALLING FLUID BAG

Install solution compatible with blood for the main system prime.

1. Hang fluid bag on the IV pole.
2. Close bag clamps, remove the bag spike cap(s). Spike fluid bag(s), pierce it fully to ensure that fluids flow freely.
3. Open bag clamps.

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.

The recirculate line must not be kinked or restricted.

II. Operation

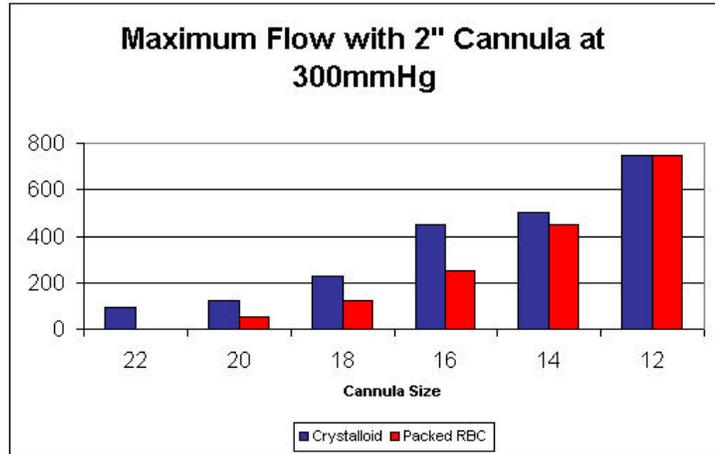
<p>PRIME THE MAIN SYSTEM</p> <p>Prime the main system with solution compatible with blood. Do not prime with blood.</p>	<ol style="list-style-type: none">1. Press PRIME to recirculate 100 ml of fluid at 500 ml/min to remove air and replace the main system with fluid.2. The prime volume, 100 ml, countdown is displayed on the screen. Stop automatically when countdown reaches 0 ml.3. If after 30 seconds and the prime volume remains at 100 ml, the system will stop, alarm and instruct the user to unclamp the lines and resume prime.4. If prime has to be stopped, press STOP. The prime volume countdown will remain on the screen. Press RESUME PRIME to continue prime.
<p>PRIME THE PATIENT LINE</p> <p>To remove air from the patient line.</p> <p>WARNING!</p> <p>Before continuing, you 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 safely continued.</p>	<ol style="list-style-type: none">1. Open the roller clamp and remove the luer cap.2. Press PT. LINE PRIME Press once, prime at 50 ml/min. Press and hold, prime at 200 ml/min.3. Press STOP after no air in patient line. Inspect to make sure that no air in the patient line. If there are air bubbles after the diversion valve, press PT. LINE PRIME to remove air.

II. Operation

CONNECT TO THE PATIENT

Match infusion set to flow rate and fluid type, see chart.

1. Select an appropriate cannula size for decided flow rate.



2. Using aseptic technique, make patient connection without entrapping air.

INITIATING INFUSION

WARNING:

Do not mix lactated Ringer's or other solution containing calcium with citrated blood products

Use only anticoagulated blood products

1. Press INFUSE to start infusing at 10 ml/min.
2. Press 500 ML/MIN key to infuse at 500 ml/min or adjust flow rate, as needed, by pressing INFUSE RATE • /INFUSE RATE — key.

There is no heat at 2.5 and 5.0 ml/min settings. Message 'LOW FLOW, NO HEAT' flashing on the screen indicates that the system is not heating at low flow rates.

II. Operation

MAINTAIN INFUSION

CAUTION:

Replace reservoir chamber or disposable set every 4 hours or less when blood products are used to limit bacterial growth and maintain proper flow.

< **Pressure Control**

Regulate the pump speed to keep line pressure under the user-set pressure limit

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

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

* American Association of Blood Banks, Technical Manual 13th Edition

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 IV, Parameters Set-Up.

< **Automatic Air Purging**

Remove air from the main system

After every 500 ml of fluid infused, the system automatically purges air from the system.

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.

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

< **Bolus**

Deliver fixed volume at a rate of 200 ml/min

The bolus volume is set at the factory to 200 ml. This can be changed in the Parameters Set-Up screen (see Chapter IV) 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 INFUSE RATE • or INFUSE RATE — or 500 ml/min RATE key.

Two sets of number are displayed within the BOLUS key space. The top number is the bolus value set and the bottom number is the volume pumped, and is counting up from 0 to the volume set on the key. 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.

II. Operation

BATTERY OPERATION

(NO HEAT)

1. Press RECIRC key to preheat fluid in the reservoir chamber.
2. Unplug the system from the wall outlet. 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.
3. Adjust the flow rate by pressing INFUSE RATE • or INFUSE RATE — or press 50 ML/MIN to immediately set the infuse rate to the maximum rate of 50 ml/min.
4. When the system is plugged back to the AC outlet, the flow rate stays at 50 ml/min if the previous flow rate was greater than 50 ml/min. The system will return to the previous flow rate if the previous rate was 50 ml/min or lower.
5. The normal running time in battery is at least 30 minutes.

END OF PROCEDURE

Before opening the door, clamp the patient line closed

1. Clamp off patient line and bag spikes.
 2. Turn circuit breaker to STANDBY.
 3. Remove disposable set and dispose in according to the hospital policy.
 4. Clean and disinfect the system, see Chapter IV.
-

SCREENS DESCRIPTION

***** MISSING DISPOSABLE *****
OPEN DOOR TO SILENCE ALARM.
INSTALL THE DISPOSABLE.
CLOSE THE DOOR.

MUTE

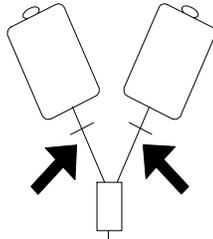
Figure 1: Missing disposable set

MISSING DISPOSABLE SET

If you turn power ON without the disposable set, this screen will appear.

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

CONNECT FLUID BAGS, UNCLAMP
LINES AND PRESS PRIME TO BEGIN.



PRIME

Figure 2: PRIME screen

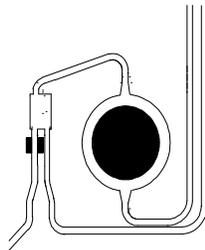
PRIME SCREEN

PRIME screen appears after the system finishes the self-check routine.

Press PRIME to prime the main system. The fluid, 100 ml, is sent through the disposable set at 500 ml/min. Priming stops automatically when the countdown reaches 0 ml.

Heating occurs during prime.

PRIMING THE DISPOSABLE
AUTOMATIC STOP 100 ml to go



STOP

Figure 3: System priming

MAIN SYSTEM PRIMING SCREEN

1. If air is detected during prime, the volume countdown will be reset to 100 ml.
2. If STOP is pressed, the prime volume countdown will remain on screen. To continue prime, press RESUME PRIME.

II. Operation

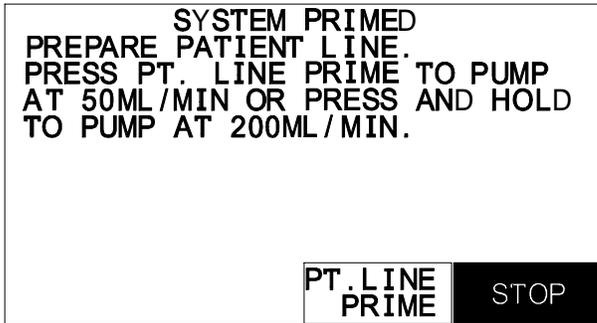


Figure 4: System primed

MAIN SYSTEM PRIMED & PATIENT LINE PRIME SCREEN

After the main system is primed, this screen appears, ready for the patient line prime.

The patient line must be primed before infusion.

1. Remove the luer cap and make sure that the roller clamp is opened.
2. Press PT. LINE PRIME once to prime at 50 ml/min. Press and hold the key to prime at 200 ml/min.

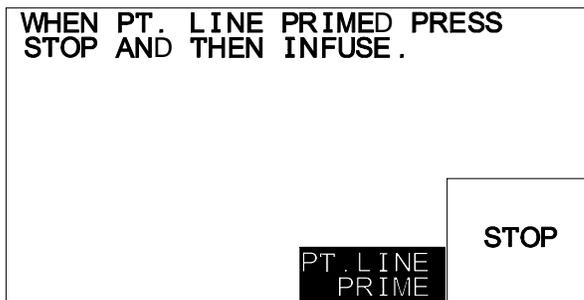


Figure 5: Patient Line Priming

PATIENT LINE PRIMED SCREEN

Press STOP when the patient line is fully primed.

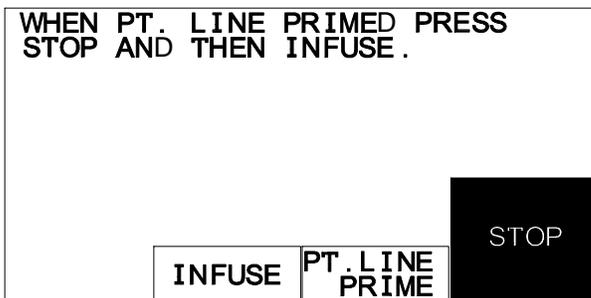


Figure 6: Patient Line Primed

PATIENT LINE PRIMED & INFUSE SCREEN

After properly priming the system, press INFUSE to go to the main operating screen and start infusion at 10 ml/min.

II. Operation

RATE= 500 $\frac{\text{ml}}{\text{min}}$		T= 37.5°C	
VOL= 1301 ml		P= 130mmHg	
INFUSE RATE ▲	500 $\frac{\text{ml}}{\text{min}}$ RATE	BOLUS 100ml	STOP
INFUSE RATE ▼		RECIRC	

Figure 7: Infuse Screen

CAUTION:

The system can infuse fluid at rates up to 750 ml per minute. A unit of blood will be emptied in less than one minute at this rate,

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.

MAIN OPERATION SCREEN

INFUSE RATE •	Press to increase the infusion rate (by 10 ml/min). Press and hold to increase the rate more rapidly. The maximum rate is 750 ml/min.
INFUSE RATE —	Press to decrease the infusion rate (by 10 ml/min). Press and hold to decrease the rate more rapidly.
500 ml/min RATE	Set the system to infuse at 500 ml/min.
BOLUS	<p>The system will infuse the volume indicated on the BOLUS key at a rate of 200 ml/min.</p> <p>Change the preset bolus volume: press and hold BOLUS key. Release the key when the desired bolus volume appears in the volume delivered position.</p> <p>Change the infusion rate by using INFUSE RATE •, INFUSE RATE — or 500ml/min RATE key.</p> <p>Two sets of number are displayed within the BOLUS key space. The top number is the bolus value set and the bottom number is the volume pumped, and is counting up from 0 to the volume set on the key.</p>
RECIRC	Recirculate fluid, warm, and remove air in the main system at a preset rate of 200 ml/min. Recirculation automatically stops and beeps after 5 minutes.
STOP	Temporarily halts pumping and heating. Status display continues to be active.

II. Operation

RATE= 0 $\frac{\text{ml}}{\text{min}}$	T= 37.5°C
VOL= 1301 ml	P= 130mmHg
PLEASE STOP THE PUMP BEFORE TURNING THE POWER OFF. TURN THE CIRCUIT BREAKER BACK ON	POWER OFF

Figure 8: Circuit breaker was turned to STANDBY while pumping

ACCIDENTAL POWER OFF

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 key.

To continue with the procedure, turn the circuit breaker back to the ON position and resume operation.

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.

END OF PROCEDURE

1. Clamp off the patient line and bag spikes.
2. Turn the system to STANDBY, using the circuit breaker.
3. Open the door and remove the disposable set from the system. Practice standard hospital policy when handling and disposing the bio-hazardous materials.
4. Follow the cleaning procedures outlined in Chapter IV to clean and disinfect the system.

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

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.

EMERGENCY MANUAL OPERATION

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.

II. Operation

RATE= 50 $\frac{\text{ml}}{\text{min}}$		BATTERY NO HEATING	
VOL= 1301 ml		P= 130mmHg	
INFUSE RATE ▲	50 $\frac{\text{ml}}{\text{min}}$ RATE	BOLUS 100ml	STOP
INFUSE RATE ▼		RECIRC	

Figure 9. Infuse screen while in battery operation

BATTERY OPERATION SCREEN

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.

Full safety monitoring remains active.

The normal running time in battery operation is at least 30 minutes.

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.

III. Alarms and Troubleshooting Guide

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III. Alarms and Troubleshooting Guide

INTRODUCTION

This chapter describes possible causes for alarm messages and difficulties that may be encountered with suggestions for corrective measures. When the F MS2000 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 revert 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:

- Alarm volume too low
- Battery, no heating
- 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 probe, unable to turn off

III. Alarms and Troubleshooting Guide

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.

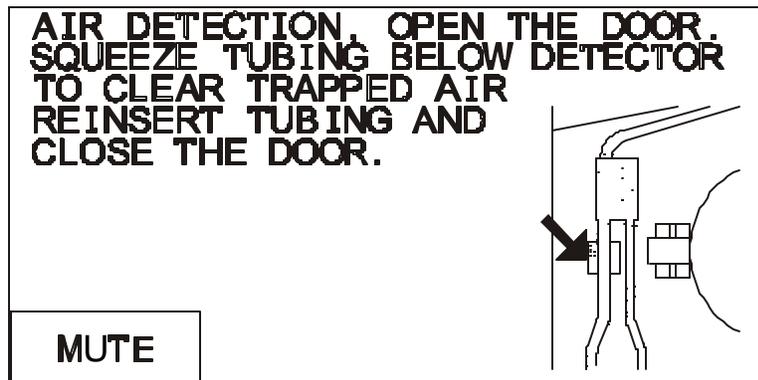


Figure 1. Air Detection alarm.

- 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.

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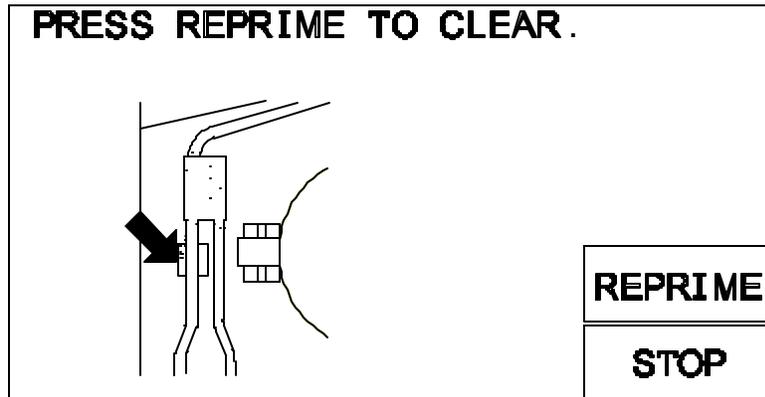


Figure 2. Air Detection alarm after checking the tubing in the air detector.

- 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.

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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.

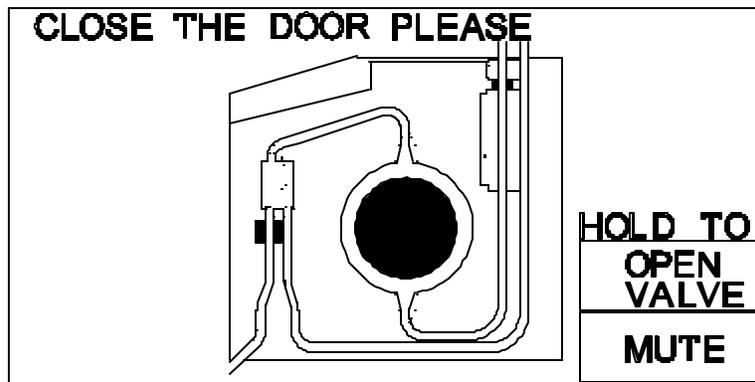


Figure 3. Door Open alarm

- 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.

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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.

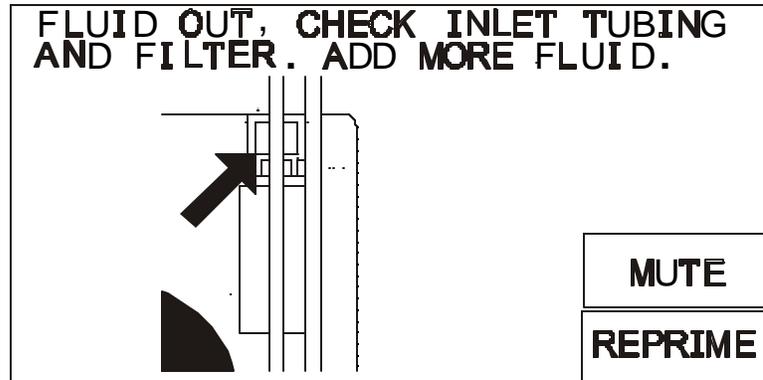


Figure 4. Fluid Out Alarm

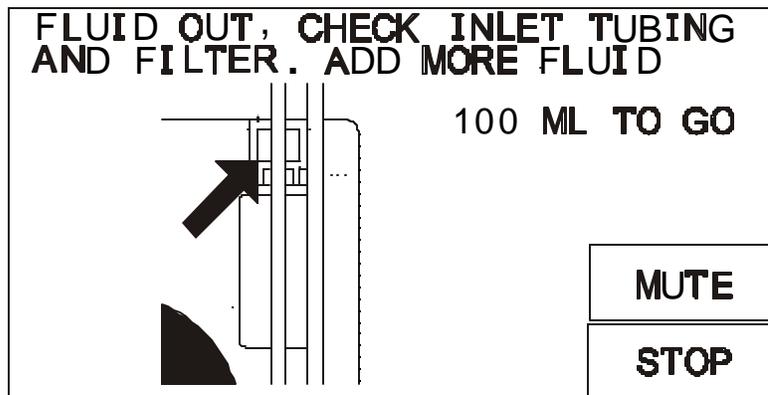


Figure 5. Fluid Out alarm after pressing REPRIME

- 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. 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.

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- If the Reprime volume count does not count down from 100 to 0 ml, check that:
 - ▶ The bags are fully spiked and clamps are fully opened.
 - ▶ The pump tubing is not stretched and is seated firmly within the Fluid Out sensor.
 - ▶ 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 can not 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 returned back into the fluid bag. This will allow the REPRIME procedure to force fluid to fill the chamber.
 - ▶ 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 main system fluid circuit.
- Inspect the main system fluid circuit 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.

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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.
- Use high quality infusate to avoid this problem.

CAUTION:

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.

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REPLACING THE RESERVOIR CHAMBER

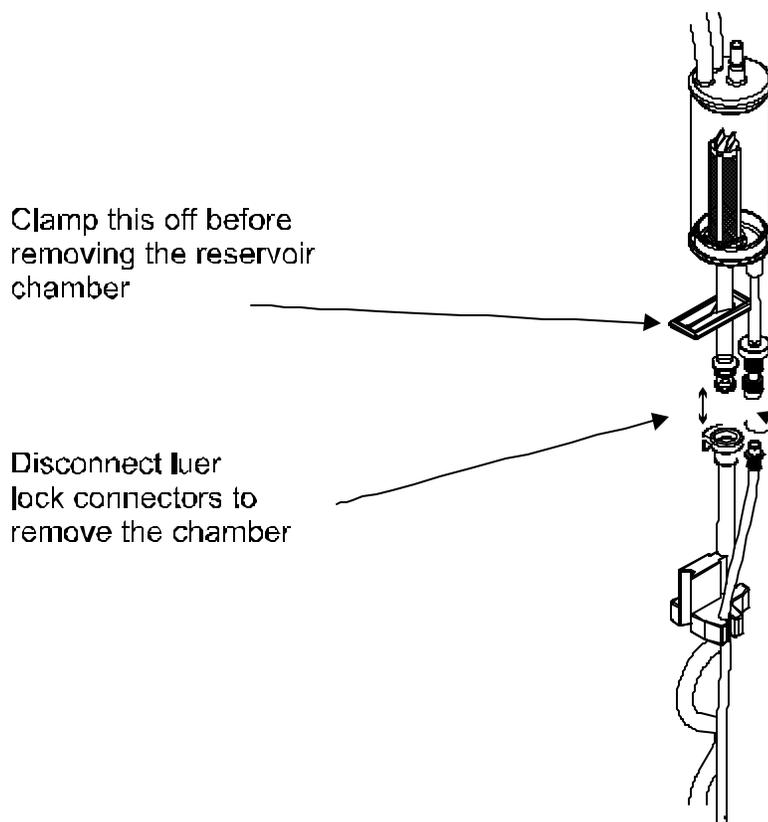


Figure 6. Replacing the Reservoir Chamber

- 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.

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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.

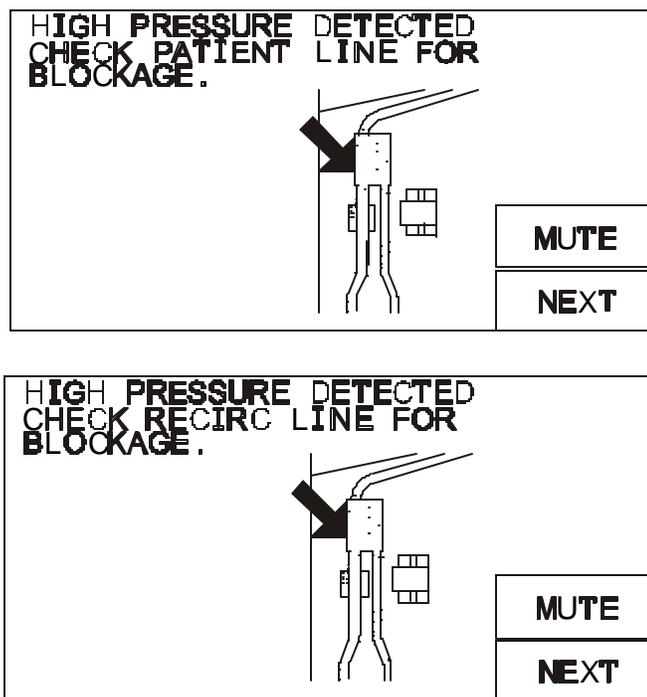


Figure 7. High Pressure alarm.

- 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 II.
- 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.

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5. Low Battery

- 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.
- The normal recharge time is 8 hours.

6. MISSING DISPOSABLE

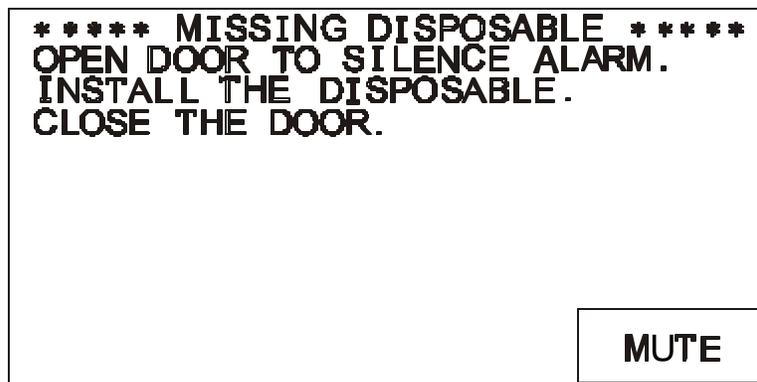


Figure 8. Missing Disposable set alarm

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.

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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 ALARMS

ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
<p>AIR DETECTION</p> <p>“AIR DETECTION, OPEN THE DOOR. SQUEEZE TUBING BELOW DETECTOR TO CLEAR TRAPPED AIR. REINSERT TUBING AND CLOSE THE DOOR.”</p>	<p>Air in the line.</p> <p>Tubing in the air detection sensor is not seated firmly in the detector.</p> <p>Leak in the disposable.</p> <p>Air detector sensor dirty.</p> <p>detector electronics defective.</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.</p>	<p>Open the door to silence the alarm.</p> <p>Check for air bubbles and possible leaks.</p> <p>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.</p> <p>Check the air detector and make certain that it is clean and nothing is obstructing the sensor.</p> <p>Reseat the tubing in the air detector and make certain that it is seated firmly in the sensor.</p> <p>Press REPRIME to reprime main system fluid circuit.</p> <p>Check for air in the disposable set and patient line before infusing.</p>
<p>DOOR OPEN</p> <p>“CLOSE THE DOOR PLEASE”</p>	<p>The door is open.</p> <p>No magnet in the door latch.</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.</p>	<p>Close the door to silence the alarm and resume.</p> <p>Check magnet in the door latch.</p>

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ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
<p>FLUID OUT</p> <p>“FLUID OUT, CHECK INLET TUBING AND FILTER. ADD MORE FLUID.”</p>	<p>Out of infusate.</p> <p>Bag clamps not fully opened.</p> <p>Bag not fully spiked.</p> <p>Tubing in the Fluid out sensor is not seated firmly in the detector.</p> <p>Tubing in the Fluid out sensor is stretched or tubing pulls away from the sensor, due to vacuum in the line.</p> <p>Clogged air vent filter.</p> <p>Clogged coarse blood filter.</p> <p>Reservoir or recirculate line is obstructed.</p> <p>Detector electronics defective.</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.</p>	<p>Press MUTE to silence the alarm.</p> <p>If out of fluid, add additional fluid and press REPRIME.</p> <p>If the Reprime volume count does not count down from 100 to 0 ml: then</p> <ul style="list-style-type: none"> • Check the 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. <p>If the reservoir chamber stays empty during reprime, the air vent filter may be clogged. In this case, pierce the fluid bag(s) with <u>bag spikes</u> and fully open <u>clamps</u> to allow the air in the reservoir chamber to escape into fluid bag(s) and allow fluid to fill the reservoir chamber.</p> <p>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.</p>

III. Alarms and Troubleshooting Guide

ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
<p>HIGH PRESSURE</p> <p>“HIGH PRESSURE DETECTED CHECK PATIENT LINE FOR BLOCKAGE.”</p>	<p>Patient line is blocked.</p> <p>Recirculate line is blocked.</p> <p>Infusion site is not well placed.</p> <p>The catheter bore size is too small.</p> <p>Pressure limit setting is set too low.</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position.</p>	<p>Make certain that the flow path is not blocked.</p> <p>Check that the recirculate line is not obstructed.</p> <p>Check that the infusion site is well placed and use the appropriate infusion set recommended in the guide, <u>Match the Infusion Set to Flow Rate and Fluid Type</u> in Chapter II.</p> <p>Increase pressure limit setting.</p> <p>Press NEXT to silence the alarm and resume.</p> <p>Check functionality of the pressure transducer by gently pressing the transducer. Pressure reading on screen should change. If not, it is defective, service machine.</p>
<p>LOW BATTERY</p>	<p>Battery voltage is too low</p>	<p>Flash LOW BATTERY message and sound periodic beep.</p>	<p>Plug the system into an AC outlet to continue operation and recharge the battery. Allow at least 8 hours to fully charge the battery.</p> <p>If LOW BATTERY displayed while plugging into the AC outlet, one of the components may be defective. Service machine.</p>
<p>MISSING DISPOSABLE</p> <p>“***MISSING DISPOSABLE*** OPEN DOOR TO SILENCE ALARM. INSTALL THE DISPOSABLE. CLOSE THE DOOR.”</p>	<p>No disposable set in the unit.</p>	<p>Sound alarm and display message. Valve in the load position.</p>	<p>Properly install disposable.</p> <p>Press NEXT to resume.</p>

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B. HEATING ALARMS:

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

III. Alarms and Troubleshooting Guide

C. HARDWARE ALARMS:

ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
AIR DETECTOR FAULT “AIR DETECTOR FAULT. TURN OFF POWER, SERVICE MACHINE.”	Air detector failure	Sound alarm and display Air Detector Fault error message and halt all operations.	Power down and service machine.
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.
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.

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ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
<p>HEATER OVER POWER FAULT</p> <p>“HEATER OVER POWER FAULT. PRESS RETRY TO CONTINUE. SERVICE MACHINE IF ERROR PERSISTS.”</p>	<p>Heater hardware fault</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve in the recirculate position. System will try to reset the error.</p>	<p>Push RETRY to try again.</p> <p>Power down and service machine if error persists.</p>
<p>POWER MODULE OVERTEMP</p> <p>“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.”</p>	<p>Power driver module overheating</p>	<p>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.</p>	<p>Make certain that the fan air vents at the bottom of the machine are not blocked.</p> <p>Wait for unit to correct problem. Display will return to Infuse screen when the error clears.</p> <p>Press MUTE to silence the alarm.</p> <p>Power down and service machine if error persists.</p>
<p>PUMP FAULT</p> <p>“PUMP FAULT, CHECK PUMP FOR BLOCKAGE. RESTART SYSTEM OR PRESS RETRY. SERVICE MACHINE IF ERROR PERSISTS.”</p>	<p>Pump tubing is installed incorrectly</p> <p>Pump failure</p> <p>Pump speed feedback encoder failure.</p> <p>Pump runs out of control or not at all.</p>	<p>Stop pumping and heating. Sound alarm and display message. Valve to the recirculate position.</p>	<p>Check that pump tubing is seated on the pump head correctly.</p> <p>Check that pump turns freely and head is clean.</p> <p>Press Retry to try again.</p> <p>Power down and service machine if error persists.</p>

III. Alarms and Troubleshooting Guide

ALARM MESSAGE	POSSIBLE CONDITION	SYSTEM RESPONSE	OPERATOR ACTION
VALVE FAULT “VALVE FAULT, CHECK VALVE FOR BLOCKAGE. RESTART SYSTEM AND RETRY. SERVICE MACHINE IF ERROR PERSISTS.”	Valve failure Valve position sensor malfunction	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. <p style="text-align: center;">CAUTION:</p> 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.
WATCH DOG (no message)	Internal computer malfunction	Stop pumping and heating. Sounds a high pitch tone.	Restart the system, service machine if error persists. <p style="text-align: center;">CAUTION:</p> 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.

III. Alarms and Troubleshooting Guide

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 CONDITION	PROBABLE ALARM OR MESSAGE	OPERATOR ACTION
Alarm volume too low	Alarm volume in Setup Routine has been turned down to the lowest volume setting.	NA	Increase volume setting in System Setup, Chapter IV.
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 IV.
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.	<p>Check and remove kinks or obstructions in the tubing.</p> <p>Use the appropriate infusion set recommended in the guide, <u>Match the Infusion Set to Flow Rate and Fluid Type</u> in Chapter II.</p> <p>Increase flow by increasing the Pressure Limit. Change the Pressure Limit in Calibration/Setup to a higher limit (maximum Pressure Limit is 300 mm Hg).</p>

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PROBLEM	POSSIBLE CONDITION	PROBABLE ALARM OR MESSAGE	OPERATOR ACTION
Key pad does not accept input	The key pad is being continually depressed. Key pad failure	Constant beep	Release the key pad and the constant beep will cease. If the alarm persists, power down and service machine.
Key pad is too sensitive or not responsive	Key pad sensitivity in Setup Routine has been set at Fast or Slow.	NA	Reset key pad sensitivity in System Setup, Chapter IV.
No message, beep tone	Power switch not completely depressed or membrane switch failed.	Constant beep	Depress power switch completely. If problem persists, replace the membrane switch.
No power or battery run time is too short	Power cord not plugged into AC power. Batteries discharged in DC operation.	NA	Change AC power source; check power cord connections. 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 hour charge, call service to replace the rechargeable battery.
Power off immediately after switch to ON. System turns on for 2-3 seconds, then turn 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, then turns off automatically.	If the problem persists, power down and service machine. 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.

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PROBLEM	POSSIBLE CONDITION	PROBABLE ALARM OR MESSAGE	OPERATOR ACTION
System does not heat to physiologic temperature	<p>Windows on the disposable or IR sensor is wet or dirty.</p> <p>Power module is not calibrated properly.</p> <p>Power module malfunction or temperature probes are out of calibration.</p>	<p>Incorrect temperature display.</p> <p>Heating fault message.</p>	<p>Examine the windows on the disposable set for wetness or contaminants.</p> <p>Clean window with soft cloth and alcohol if necessary.</p> <p>See procedure on power calibration in Chapter IV.</p> <p>Check temperature probe calibration in Chapter IV.</p> <p>Service machine if problem persists.</p>
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.	<p>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.</p> <p>See Fluid Out in Alarm Message of this chapter</p>
Unable to calibrate temperature probes	<p>Temp probe malfunction</p> <p>Incorrect fluid temperature used for calibration.</p>	NA	<p>Check the temperature of fluid and make certain it is correct.</p> <p>If problems persists, service machine.</p>
Unable to turn the system off	One of the components on Daughter Board failed.	System does not turn off, runs on battery until shut down.	Service machine.

IV. Parameters Setting and Preventive Maintenance

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IV. Parameters Setting and Preventive Maintenance

The F MS2000 requires minimal service and care. Preventive maintenance should be performed regularly to optimize performance and reduce the likelihood of down-time. Listed below are routine maintenance (as needed), periodic maintenance (at least once a year), and parameters setting. The instrument does not need regular calibration.

WARNING!

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

WARNING!

Test leakage current routinely to insure against electrical shock hazard.

CAUTION:

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

IV. Parameters Setting and Preventive Maintenance

A. SYSTEM SETUP

Changes in system setup can be made to:

- Date and time: Set the real time clock and date
- Audible alarm volume: Set the audible alarm volume level
- Display brightness: Change the display brightness
- Key Rate: Set touch key sensitivity
- Bolus volume: Set the bolus delivery volume
- Pressure limits for High Pressure alarm: Set the maximum allowable in-line pressure. The possible setting range from 100 - 300 mm Hg.

Parameter Setup changes are performed in the Service mode.



Press the SERVICE key to access 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			
TIME 23:59		DATE: 12-31-99	
BOLUS 100 ml		PRESS LIMIT 300mmHg	
AC POWER PRESENT			
DATE TIME	ALARM VOL SET	DISPLAY BRIGHT	
TEMP CAL	PRESS CAL	POWER CAL	MEDIUM KEYRATE
PRESS LIMIT	HARD- WARE	SETUP BOLUS	EXIT SERVICE

IV. Parameters Setting and Preventive Maintenance

1. Date/Time

Press DATE TIME to set the time and date. Press either the TIME or DATE key.

TIME HH:MM	DATE MM-DD-YY
TIME	DATE
NEXT	

Screen after pressing DATE TIME key

A numerical key pad 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.

DATE MM-DD-YY			
1	2	3	
4	5	6	
7	8	9	CANCEL
	0		UPDATE

Screen after pressing DATE

TIME HH:MM			
1	2	3	
4	5	6	
7	8	9	CANCEL
	0		UPDATE

Screen after pressing TIME

IV. Parameters Setting and Preventive Maintenance

2. Alarm Volume

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

3. Display Brightness

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

4. Key Rate

This key 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 when touched to be accepted as an input. The Medium setting requires more time and the Slow key requires the most time and makes the touch keys least sensitive. **The key sensitivity is set at factory to Medium.**

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

5. Bolus Volume

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

6. Pressure Limit

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

IV. Parameters Setting and Preventive Maintenance

B. PREVENTIVE MAINTENANCE SCHEDULE

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 the Rubber Feet.			●

IV. Parameters Setting and Preventive Maintenance

Schedule 2

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

Required Test/Verification	Interval	
	Every 6 Months	Every Year
1. Perform Visual Inspection.	●	
2. Perform System Operational Check-Out, including the Audible Alarm Test.	●	
3. Check the battery for rated voltage and check battery run time.	●	
4. Perform Electrical safety Test.		●
5. Hardware Verification.		●
6. Clean Pump Head.		●

IV. Parameters Setting and Preventive Maintenance

C. ROUTINE MAINTENANCE

1. Clean and/or Disinfect Exterior

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

- a. Turn the pump to standby and unplug the power cord.
- b. Wipe the surface with a cloth moistened with water or isopropyl alcohol.

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

- c. To remove dried blood and disinfect the pump, clean them with hydrogen peroxide or a mild bleach solution and dry.
- d. Also clean around the door hinges, making sure the door is pushed all the way down inside the hinges.

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 P/N 118-00096 for US and P/N 118-00085 International).

4. Temperature Probes

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

5. Fan Guards

Inspect the fan guards, on the bottom of the unit, for debris that might impede air flow. Remove guards by unscrewing the 4 retaining screws and clean, with soap and water, if necessary. Make certain the guards are not damaged (replacement P/N 399-00033). Let the fan guards dry before reinstalling.

IV. Parameters Setting and Preventive Maintenance

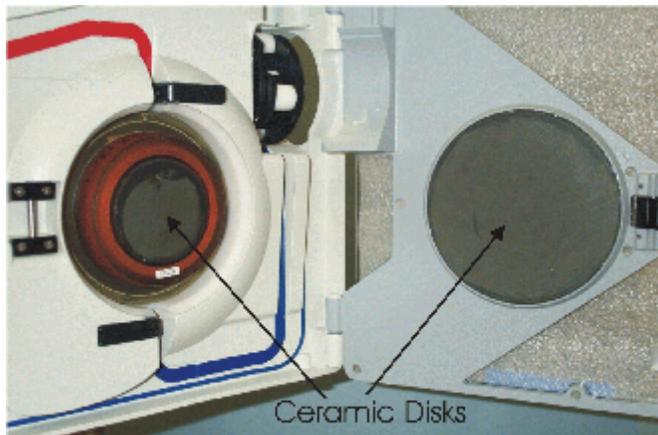
6. Seals

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 re

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, clen any dried blood from hinges area. Be sure that door is seated completely down on the hinges.
- b. Check plastic rivets and door integrity. Make sure that the door frame is not bent. Replace, if bent.
- c. Inspect the ceramic disks on the door and in the center of the unit for cracks. Return to manufacturer for replacement if they are damaged.



8. Rubber Feet

Inspect the rubber feet on the bottom of the unit for cracked or missing rubber feet. Replace if necessary (replacement #599-00314 Rubber feet & #510-00349 6-32 x 1 1/8" screw).

IV. Parameters Setting and Preventive Maintenance

D. 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 outlet for at least 8 hours to fully charge the batteries.

Material Required:

- F MS2000 Disposable
- Bio-Tek Safety Analyzer or equivalent
- Saline or other crystalloid for testing
- 2 liters of 35-42° C fluid
- Manometer (2 mm Hg resolution)
- Pressure source
- Digital Thermometer with thermocouple (0.1°C resolution)
- Graduated cylinders (ASTM Class B accuracy)
- Timer
- Tachometer (optional)

1. Visual Inspection

- a. Door Open/Right Hand Side:
 - i. Check that air and fluid out detectors are clean.
 - ii. Check that all the plastic push pins on the door are in-place.
 - iii. Check that the valve pincher set screw is tight.
 - iv. Check that there are no cracks in the ferrite on either the door or the right hand side.
 - v. Check that the pressure transducer diaphragm has no tears or rips.
 - vi. Check that each pump roller spins freely. If not, remove and clean.
 - vii. Check that the door is pushed all the way down and there is no dried blood or fluid inside or around the hinges.
- b. Back:
 - i. Check that the AC connector (IEC connector) is clean. If there is some saline residue, clean.
- c. Verify Latch/Unlatch Mechanism:
 - i. Check the rubber pads on the pole clamp assembly. If they feel smooth, clean and scrub with isopropyl alcohol.
 - ii. Mount and unmount the system on an IV pole, verify that the latch and unlatch work properly and the system will not move down the pole unexpectedly.

IV. Parameters Setting and Preventive Maintenance

2. **System Operational Check-Out**

- a. Install Disposable set.
- b. Turn power switch ON. Wait for PRIME screen to appear.
- c. Close bag clamps. Hang and spike fluid bag.
- d. Open bag clamp(s). Press PRIME to prime the system (circulate 100 ml of fluid at 500 ml/min.) Prime volume (100 ml) countdown is displayed on screen. Stop automatically when countdown reaches 0 ml.
- e. Press PT. LINE PRIME once to pump at 50 ml/min or press and hold to pump at 200 ml/min. Press STOP when line is free of air bubbles.
- f. Press INFUSE to start infusion at 10 ml/min. Press INFUSE RATE ▲▼ to change flow rate.
- g. 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. Infuse until the fluid bag is empty, verify that the system stops pumping and sounds an audible alarm with 'FLUID OUT' message displays on screen.

3. **Battery Run Time Test**

- a. Prior to performing the battery run test, plug the system into an AC wall outlet for at least 8 hours to fully charge the batteries.
- b. Follow directions in Step 2, a-g. Infuse at 50 ml/min. Start the timer.
- c. The system should run for at least 30 minutes with fully charged battery. If not, replace the batteries.

IV. Parameters Setting and Preventive Maintenance

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 F MS2000 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. F MS2000 power switch To Standby.
- ii. Switch selector on Bio-Tek to CHASSIS (μ A). Connect a single red lead to the SINGLE LEAD input jack, and attach large clamp to equipotential ground terminal on the F MS2000.
- 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 F MS2000 in ON mode (power switch ON, infuse screen displayed, not pumping or heating).

IV. Parameters Setting and Preventive Maintenance

- vii. Repeat iii & iv with the F MS2000 infusing and heating at 750 ml/min.
- viii. All measurements should be <300 μ A (for Domestic unit) and <500 μ A (for 230 V unit) .

b. Patient Leakage Current:

- i. Install the disposable set and prime with saline and proceed to the Infuse screen.
- ii. Attach 12 to 16 gauge stainless steel cannula to the end of patient line and attach the Bio-Tek large clamp to the cannula.
- iii. Prime the F MS2000 with saline. Make sure that the entire patient line including the cannula has been primed.
- iv. Repeat a.iii, and a.iv with the F MS2000 in the STANDBY, ON, and pumping at 750 ml/min modes.
- v. Maximum leakage allowable is as follows:

With NORMAL NEUTRAL

Normal Polarity - Grounded (10 μ A)

Reverse Polarity - Grounded (10 μ A)

Reverse Polarity - Not Grounded (50 μ A)

Normal Polarity - Not Grounded (50 μ A)

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

Normal Polarity - Grounded (50 μ A)

Reverse Polarity - Grounded (50 μ A)

IV. Parameters Setting and Preventive Maintenance

5. Hardware Verification

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

The 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 this screen, to insure that this mode is not accessed accidentally.

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

WARNING!

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

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

CALIBRATION/SET-UP			
TIME 23:59		DATE: 12-31-99	
BOLUS 100 ml		PRESS LIMIT 300mmHg	
AC POWER PRESENT			
DATE TIME	ALARM VOL SET	DISPLAY BRIGHT	
TEMP CAL	PRESS CAL	POWER CAL	MEDIUM KEYRATE
PRESS LIMIT	HARD- WARE	SETUP BOLUS	EXIT SERVICE

Calibration/Setup screen

IV. Parameters Setting and Preventive Maintenance

PUMP SPEED 0 ml/min INPUT TEMPERATURE 23.0 (23.0) OUTPUT TEMPERATURE 23.0 (23.0) PRESSURE 0 mmHg FLUID OUT DETECTOR STATUS AIR AIR DETECTOR STATUS AIR BATTERY VOLTAGE 28.5 BOARD TEMPERATURE 23 C			
			PUMP SPEED
LEFT VALVE	OPEN VALVE	RIGHT VALVE	CANCEL

Hardware Status Screen

Status Line	Reading
Pump Speed	0, 10, 100, 500 and 750 ml/min
Input Temperature	Temperature in °C, probe ambient reference in parentheses
Output Temperature	Temperature in °C, 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.

IV. Parameters Setting and Preventive Maintenance

Hardware Verification:

a. Valve

- i. Press the LEFT VALVE, confirm that the valve wand (valve pincher) move to the left.
- ii. Press OPEN VALVE, confirm that the valve wand move to the middle position.
- iii. Press RIGHT VALVE, confirm that the valve wand (valve pincher) move 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.

IV. Parameters Setting and Preventive Maintenance

- 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.

Measure by using a tachometer:

- i. Close the door. Set the pump speed to 10 ml/min. Use a tachometer to measure the rotational speed of the pump head. The accepted tolerance is $1.95 \text{ rpm} \pm 25\%$.
- ii. Press PUMP SPEED again to change the pump speed to 100 ml/min. The accepted tolerance is $19.65 \text{ rpm} \pm 10\%$.
- iii. Press once more to change speed to 500 ml/min, the maximum speed setting and repeat the measurement. The accepted tolerance is $97 \text{ rpm} \pm 10\%$.

e. Input and Output Temperature Probes

Prepare at least 2 liters of 37-43 °C fluid

- i. Connect the fluid supply to the disposable. Remove the patient line and insert the thermocouple into the patient line connector as close to the heat exchanger as possible.
- 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. ($2 \text{ }^{\circ}\text{C}$)
- iv. Compare the numbers displayed to the thermocouple reading. The accepted tolerance is 1°C for fluid temperature between 30°C to 40°C and 2°C outside this range.
- v. Press PUMP SPEED to set the pump speed back to 0 ml/min.
- vi. Press CANCEL to return to the Calibration/Set-Up screen.

IV. Parameters Setting and Preventive Maintenance

f. **Pressure Transducer**

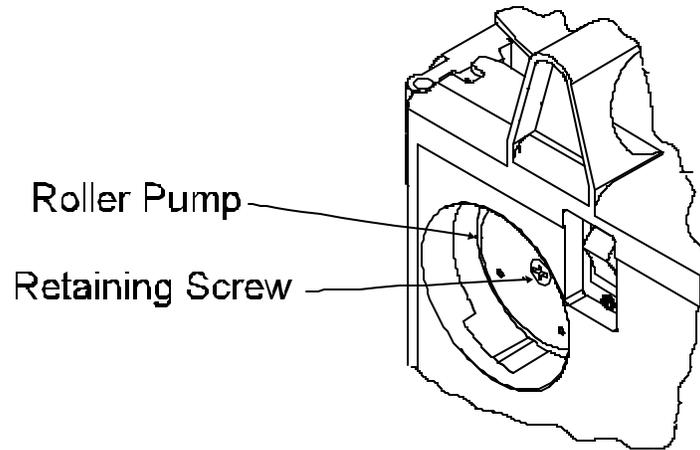
WARNING!

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

- i. **Inspect the pressure transducer for damage. Make certain the surface of the transducer is not cut or punctured. The pressure transducer must be replaced if the surface is damaged.**
- ii. Make certain the pressure chamber is properly installed (see Chapter II: Installing the Disposable) and the flow path is not blocked.
- iii. Make certain the fluid is warm (37-42° C). The pressure chamber of the disposable is less compliant when it is at room temperature. **Verification must be performed with a warm disposable.** If the fluid is not warm, go to the Main Infuse screen and warm the fluid and disposable by pressing the RECIRC key (Chapter II: Main Operating Screen: Recirculating Mode). Let the fluid recirculated for at least two minutes in AC power before returning to the Hardware mode for verification.
- iv. In the Hardware mode, close the door, the bag clamps and block the air vent on top of the reservoir chamber. Disconnect the patient line and connect the pressure source to the luer fitting at the patient line port of the disposable set and apply pressure while monitoring the amount of pressure with a manometer.
- v. Verify the accuracy of the pressure transducer. Apply 300 mm Hg into the disposable. The pressure status line should read 300 mm Hg (\pm 50 mm Hg). Repeat the same pressure verification for 200 and 100 mm Hg.

IV. Parameters Setting and Preventive Maintenance

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.
- e. Let pump head dry before replacing and make certain the pump head is securely fastened with the retaining screw.
- f. If the pump head squeaks, spray the roller with Heavy Duty Pure Silicone.

IV. Parameters Setting and Preventive Maintenance

E. CHECKLIST

F MS2000 S/N:

Tested By:

Date

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

	Results	
1. Visual Inspection a. Right Hand Side b. Back c. Latch/Unlatch		✓ if OK
2. Operational Check-Out d. PRIME e. PT. LINE PRIME f. INFUSE ▲▼ g. AC to DC Switch over h. DC to AC switch i. FLUID OUT audible alarm		✓ if OK
3. Battery Run Test		>30 min.
4. Electrical Safety Check (See attached results sheet) a. Earth Leakage Current b. Patient Leakage Current		✓ if OK
5. Hardware Verification a. Valve Operation b. Fluid Out and Air Detectors c. Battery Voltage d. Flow Rate e. Input and Output Temperature Probes f. Pressure Sensor		✓ if OK
6. Clean Pump Head		✓ if OK

IV. Parameters Setting and Preventive Maintenance

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				

IV. Parameters Setting and Preventive Maintenance

F. 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 hardware calibration. Calibrate the instrument only after verifying that it is operating outside accepted parameters or when the calibration information has been corrupted.

Calibration or testing of the hardware in this mode includes:

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 mm Hg, 2 mm Hg resolution)
- Pressure source
- Thermometer with thermocouple with readout resolution to 0.1 °C.
- Graduated cylinder (ASTM Class B accuracy)
- Timer

IV. Parameters Setting and Preventive Maintenance

1. Temperature Probes Calibration

Prepare 4 liters each of different temperature fluid at : 1 - 7 °C; 17 - 23 °C; and 37 - 43 °C before beginning the temperature calibration.

The system must left in STANDBY or unplugged at a stable ambient temperature for at least two hours before performing a temperature probe calibration. Do not leave the system ON. This allows the reference in the temperature probe to equilibrate. The system will not temperature calibrate if the probes are not in equilibrium.

- Properly install the disposable set (see Chapter two: Installing the Disposable). Turn power ON. Press the SERVICE key when it appears at the logo screen at startup.
- Press TEMP CAL to begin calibration.
- Enter password 013192.
- Enter the ambient temperature measured to the nearest 0.1°C. If a mistake was made entering the value, press ERASE to reenter. Press UPDATE to save the ambient temperature value.

ENTER AMBIENT TEMPERATURE			
1	2	3	
4	5	6	
7	8	9	CANCEL
.	0	ERASE	UPDATE

Numerical key pad to enter ambient temperature in TEMP CAL.

- Connect two (2) at least one liter bags of 4 ± 3 °C fluid to the disposable. A large reservoir of fluid will help limit the need to changing the bags often and limit temperature fluctuations during the calibration procedure. Remove the patient line and insert the thermocouple into the patient line connector as close to the heat exchanger as possible.
- Press NEXT to pump the fluid 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.
- Keep fluid filled in the disposable set by attaching more fluid filled bags while the temperature of the disposable set equilibrate.
- After a minimum of two minutes a numerical key pad will appear. Wait until the temperature reading stabilizes on the thermometer then enter the

IV. Parameters Setting and Preventive Maintenance

temperature of the disposable. Enter the actual measured value which must be between 1 °C and 7 °C (4 ± 3 °C). Do not enter the nominal 4 °C value. Press UPDATE to save the value and continue to the next temperature. If the temperature was still fluctuating when UPDATE was pressed, the system will not update and continue to wait until the temperature stabilizes.

- Continue with the same procedure for the 20 ± 3 °C and the 40 ± 3 °C fluid. In each case enter the actual value measured within the specified range. For example, the measured value at the nominal 40 °C level must be between 37 °C and 43 °C for the calibration to be valid.
- After the last temperature fluid, 40 ± 3 °C is updated, the system will return to the Calibration/Set-Up screen.
- Press HARDWARE to check on Hardware status.
- Enter password 013192.
- Add more 40 ± 3 °C fluid supply to the disposable.
- Press the RIGHT VALVE key to set the valve to the infuse position.
- Press the PUMP SPEED three times to set the flow rate to 500 ml/min
- Let the temperature to stabilize, wait at least 2 minutes. The INPUT and OUTPUT TEMPERATURE probe readings should be similar and stable (the values not between the parentheses).
- Compare the numbers displayed to the thermometer reading. The accepted tolerance is 1°C for fluid temperature between 30 °C to 40 °C and 2°C outside this range.
- Repeat with the 20 ± 3 °C and 4 ± 3 °C fluid.
- Finally press PUMP SPEED to set the pump speed back to 0 ml/min.
- Press CANCEL to return to the Calibration/Set-Up screen.
- The system is temperature calibrated and verified.
- After a temperature calibration has been completed, a power calibration should be performed. See Power Module and Pump Calibration in this chapter.

IV. Parameters Setting and Preventive Maintenance

2. Pressure Transducer Calibration

Prepare 1 liter of 37-43 °C fluid

- 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.
- Properly install the disposable set (see Chapter two: Installing the Disposable). Center the disposable's pressure chamber in the pressure chamber cavity of the machine. Make certain that the pressure chamber of the disposable set is in good contact with the pressure transducer.
- Turn power ON. Press the SERVICE button when it appears at the logo screen at system startup.
- Press HARDWARE and enter the password 013192.
- Attach fluid (37-43 °C) to the disposable set and open the clamps. Make certain the fluid 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.** Press PUMP SPEED three times to set flow rate to 500 ml/min to prime the system with warm fluid.
- Press the 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.
- Press CANCEL to exit back to the Calibration/Set-Up screen when done.
- Press PRESS CAL and enter the password 013192 from the Calibration/Set-Up screen to initiate the calibration procedure.
- 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.
- Apply 100 mm Hg of pressure. Press UPDATE to accept the 100 mm Hg calibration point.

IV. Parameters Setting and Preventive Maintenance

- Apply 258 mm Hg of pressure. Press UPDATE to accept the calibration point. The system will return to the main Calibration/Setup screen.
- Press HARDWARE and enter password to access the Hardware mode.
- Press OPEN VALVE to set the valve in the middle position.
- Verify that the system is properly calibrated. Apply 258 mm Hg into the disposable. The pressure status line should read 258 mm Hg (± 25 mm Hg).
- Repeat the same pressure verification for 100, and 300 mm Hg.
- The system is now pressure calibrated and verified.

IV. Parameters Setting and Preventive Maintenance

3. Power Module and Pump Calibration

Prepare a minimum two liters of water, having a temperature less than 10 °C before starting the power module and pump calibration.

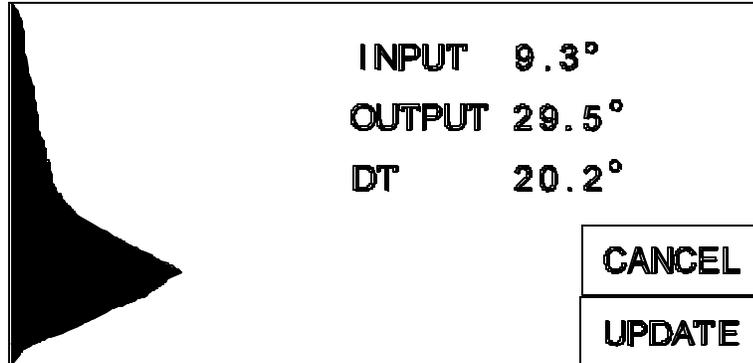
CAUTION

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.

- Properly install the disposable set (see Chapter two: Installing the Disposable). Turn power ON. Press the SERVICE key when it appears at the logo screen at startup.
- Connect two (2) one liter or larger bags of fluid to the disposable. A large reservoir of fluid will help limit the need to changing the bags often .
- **Determine the actual maximum flow rate of the disposable first:** Press HARDWARE from Calibration/Set-UP screen.
- Enter password 013192.
- Open bag clamps and prepare to prime the disposable. 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. Press RIGHT VALVE to set the valve into the infuse position and prime and fill the patient line.
- When the patient line is completely primed, measure the flow with a graduated cylinder for one minute. When completed, press PUMP SPEED key once to set the flow rate to 0 ml/min and stop the pump. Press CANCEL to exit and return to the Calibration/Set-Up screen. Record this flow rate. The flow rate should be 500 ml/min \pm 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.
- Press POWER CAL.
- Enter password 013192.
- Enter the flow rate that was previously measured. Press UPDATE to continue.

IV. Parameters Setting and Preventive Maintenance

- Prime: The system primes the disposable set with 100 ml of fluid before automatically 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.
- Keep the disposable set filled with cold fluid during the entire procedure.



Power calibration screen, waiting to update

- 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. Press UPDATE to complete the calibration. The display will return to the Calibration/Set-Up screen. The power module and pump are now calibrated.

IV. Parameters Setting and Preventive Maintenance

G. ELECTROMAGNETIC COMPATIBILITY

This equipment has been designed and tested for compliance with IEC 60601-1-2 standards for its capacity to limit electromagnetic emissions and its ability to block the effects of EMI from external source.

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause interference with other devices in the vicinity. If this equipment does cause interference with other device, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Ensure that other products used in the areas where patient monitoring and/or life-support is used comply with accepted emissions standards (EN55011).
- Try to maximize the distance between electromechanical devices
- Strictly limit exposure and access to portable radio-frequency sources, for example cellular phones and radio transmitters. Be aware that portable phones may periodically transmit even when in standby mode.
- Connect the equipment into an outlet on a circuit different from that which the other device(s) are connected. Maintain good cable management. Try not to route cables over electrical equipment. Do not intertwine cables.
- Do not use an extension power cord. Use the power cord supplied with the F MS2000.

H. FUSE

The fuse on the AC/DC supply marked F1 is rated as 1.25A, 250V, fast acting, 5x20mm.

IV. Parameters Setting and Preventive Maintenance

I. CALL FOR SERVICE

Technical support can be reached at **800-397-4547** US/Canada, **978-663-0212** Worldwide. Before calling, please have the following ready:

- Serial number of the unit. The serial number is located on the label above the power receptacle.

Please do not return any units without first obtaining a Return Goods Authorization (RGA) number.

V. Technical Specifications

V. Technical Specifications

Dimension V: 1

Power AC V: 1

Battery V: 2

Environment V: 2

Operating Parameter V: 2

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V. Technical Specifications

Technical Specifications of the Belmont *F MS2000*

DIMENSION	
Size	13.5" x 12" x 7.5" (34.29cm x 30.48cm x 19.05cm)
Weight	26 lbs (11.8 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 Current	< 300 μ A (For Domestic unit) < 500 μ A (For 230 V~ unit)
Electrical Compliance	EN 60601-1, UL 2601-1, CSA/C22.2 - No. 601.1-M90
Circuit Breaker	15Amp, 125VAC/250VAC, 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

V. Technical Specifications

Battery Type	Rechargeable lead acid
Running Time	> 30 minutes at 50ml/min. without heat
Recharge Time	8 hours

ENVIRONMENTAL	
Operating Temperature	10° C to 32° C (50° F to 90° F)
Storage Temperature	-15° C to 40° C
Relative Humidity	10% to 90%
Pressure	49-103 kPa
Shock and Vibration	Meet MIL STD.810E method 514.4 (Basic Transportation)

OPERATING PARAMETERS	
Flow Rate	10 -750 ml/min in 10 ml/min steps plus 2.5 and 5.0ml/min with fluids of viscosity 1 to 8 centipoise (Water and crystalloid fluids through packed red cells) Tolerance: ± 10% from 20 - 750 ml/min ± 25% for 2.5, 5.0,10 ml/min
Output Temperature	Set to 37.5° C for flow ≥ 60ml/min , to 39° C at 50ml/min or lower. Maximum allowable temperature: 41.9° C Tolerance: 1° C for fluid temperature between 30 °C to 40 °C and 2° C outside this range
Heating Capacity	1300 watts to fluid (35° C temperature rise at 500 ml/min)
Line Pressure	0 - 300 mm Hg, via pressure transducer

V. Technical Specifications

Operating Modes	<ul style="list-style-type: none"> 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
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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 (mm hg) Output infusate temperature (° C) 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 mm Hg/ml or exceeds 400 mm Hg, an alarm sounds, the "HIGH PRESSURE" message is displayed, the line to the patient is closed and pump comes to an immediate stop.

V. Technical Specifications

Air Detection	<p>Two ultrasonic air detectors monitor air in the fluid path. The fluid detector is mounted closest 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.</p> <p>Out of Fluid criterion: Detect 0.8ml air in input line Air detection criterion: Detect 0.1ml air in fluid line</p>
Diversion Valve	<p>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. The recirculation path is activated at all alarm conditions.</p>

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

V. Technical Specifications

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	IPX1, Drip proof
Method of Sterilization	Disposable delivered sterile, single use
Degree of Safety in Presence of Flammable Anaesthetics	Not suitable
Mode of Operation	Continuous
<p style="text-align: center;">Medical Equipment</p>  <p>1-1</p>  <p style="text-align: center;">UL260</p> <p style="text-align: center;">49WB</p>	<p>F MS2000 has been evaluated with respect to electric shock, fire and mechanical hazards only in accordance with UL2601-1, CAN/CSA C22.2 No. 601.1- M90, and EN 60601-1: 1990 + A1: 1993 + A11: 1993 + A12: 1993 + A2: 1995 + A13: 1996</p>

V. Technical Specifications

Symbols and Definitions	
Symbol	Description
	Compliance to Medical Device Directive 93/42/EEC
	Alternating current
	Equipotentiality
	Standby
	ON
	Attention, consult accompanying documents/refer to manual
	Defibrillator-proof type CF equipment
IPX1	Protected against dripping water
SN	Serial Number