

bibag® V2.0

Technician's Manual

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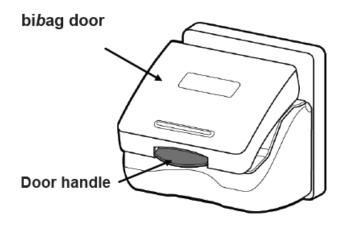
Any questions, contact Technical Support at 800-227-2572

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bibag Details

The bibag connector is a hardware option that allows the usage of a dry bicarbonate powder to generate dialysate solution for the $2008^{\mathbb{R}}$ T and the 2008K@homeTM hemodialysis machines. The bibag disposable is a bag filled with dry bicarbonate powder with special inlet and outlet ports. Underneath the bibag door, the bibag hangs on two nozzles, which allow for the entry of purified water and the exit of bicarbonate concentrate solution. A door handle locks the bibag door in place over the bibag disposable.



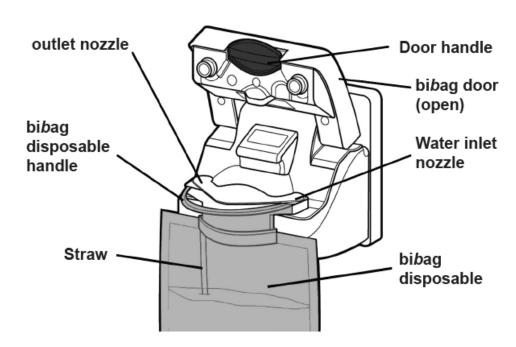


Figure 1 - bibag connector: door closed and bibag disposable inserted with door open

General Warnings



Warning: The concentrate displayed on the screen must match the labels on the acid container. Make certain there is enough concentrate in the containers to complete the treatment.

Warning: The specific concentrate, sodium, and bicarbonate settings must be prescribed by a physician.

Warning: Acid and basic bicarbonate hemodialysis concentrate must be diluted (mixed with purified water as specified in the AAMI standards for water for dialysis) immediately prior to application only.

Warning: Use aseptic technique.

Warning: Always verify the conductivity and approximate pH of the dialysate solution through independent means before initiating dialysis. Verify that the pH is normal and that the conductivity is reasonably close to the theoretical value. If it is not, do <u>not</u> initiate dialysis.



Warning: Replace a leaking bibag disposable immediately. Spills can cause damage to carpeting and other surfaces. To contain such spills, the machine should be on a spill-tolerant surface. Spills can cause slips and falls; clean up spills immediately.



Caution: Only the bags manufactured by Fresenius Medical Care may be used in the bibag connector.



Note: When the bibag connector is installed, the online pressure holding test becomes mandatory. For more information, see the Online Pressure Holding Test section of the 2008[®]T Hemodialysis Machine Operator's Manual P/N 490122 or the 2008K@homeTM Hemodialysis Machine Operator's Manual P/N 490180.

Hydraulic Flow Diagram

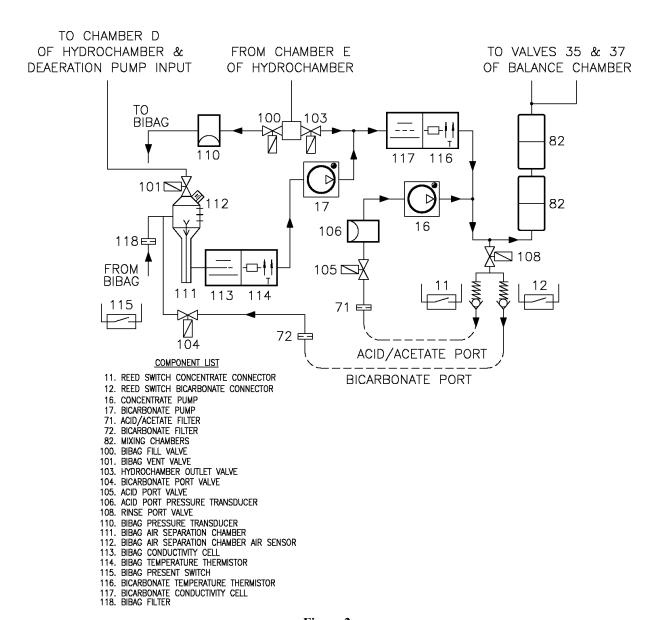


Figure 2

Hydraulic Component Descriptions

100 – bibag Fill Valve

The bibag fill valve opens as needed to add water to the bibag disposable during dialysis. When bibag is not used for bicarbonate during dialysis, this valve will remain closed. In rinse and cleaning modes, this valve will alternate with valve 103.

101 – bibag Vent Valve

The bibag vent valve opens momentarily during dialysis when air is detected in the bibag air separation chamber. When bibag is not used for bicarbonate during dialysis (jug mode), this valve will open momentarily when air is detected in the bibag air separation chamber.

103 – Hydrochamber Outlet Valve

The hydrochamber outlet valve opens in dialysis when valve 100 is closed. In rinse and cleaning modes, this valve will alternate with valve 100.

104 – Bicarbonate Port Valve

Closed for bibag dialysis. Opens to empty the bibag disposable and during bibag startup. Opens when sodium bicarbonate concentrate is supplied. When sodium bicarbonate is supplied by a pressurized supply, this valve will open and close based on pressure at pressure transducer 110.

105 – Acid Port Valve

Used to regulate the pressure to the acid pump. Will open and closed based upon pressure at pressure transducer 106.

106 - Acid Port Pressure Transducer

Senses pressure of the acid concentrate supply. Pressure detected from this sensor is used in conjunction with valve 105 to regulate the pressure to the acid concentrate pump.

108 – Rinse Port Valve

This valve is electrically in parallel with valve 104. It opens and closes at the same time as valve 104.

110 - bibag Pressure Transducer

The bibag pressure transducer is used to measure the pressure inside the bibag disposable. Also used to measure the pressure of the sodium bicarbonate concentrate source when bibag is not used.

111 – bibag Air Separation Chamber

The bibag air separation chamber separates air from the sodium bicarbonate concentrate upon leaving the bibag disposable. It also is used to separate air from the sodium bicarbonate concentrate supplied by external sources (pre-mixed concentrates).

112 – bibag Air Separation Chamber Air Sensor

The bibag air separation chamber air sensor detects air in the air separation chamber.

113 – bibag Conductivity Cell

The bibag conductivity cell is used to measure the conductivity of the sodium bicarbonate concentrate leaving the bibag disposable and the conductivity of the pre-mixed concentrates.

Hydraulic Component Descriptions (cont.)

<u>114 – bibag Temperature Thermistor</u>

The bibag temperature thermistor is used to measure the temperature of the bicarbonate concentrate leaving the bibag disposable and the pre-mixed concentrate.

115 – bibag Present Switch

The bibag present switch is built into the bibag connector. The switch is positioned so that when a bibag disposable is attached to the bibag connector the switch is pressed indicating the presence of a bibag disposable.

116 – Bicarbonate Temperature Thermistor

Used with conductivity cell 117 to measure conductivity.

117 - Bicarbonate Conductivity Cell

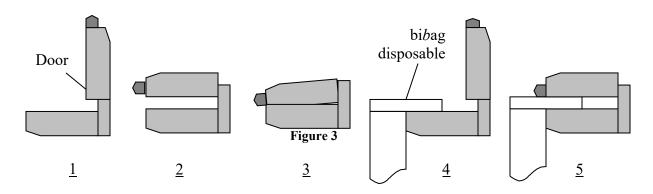
Measures conductivity of the bicarbonate concentrate from the bibag disposable after it is mixed with R.O. water.

<u>118 – bi*b*ag Filter</u>

Removes any particles that may enter through the bibag disposable.

bibag Connector

The bibag connector holds the bag with dry bicarbonate during dialysis. The bibag connector incorporates a three position door (see Figure 3). The door may be placed in the position open, operating, or bypass. In the open position (1) and (4), a bibag disposable may be installed or removed from the connector. The operating position (5) is used when a bibag disposable is installed for dialysis. The bypass position (3) is the completely closed position (not possible if a bag is hanging from the connector). The door must be in the closed position (3) for rinse, cleaning, and jug dialysis mode. Position (2) should not be used.



Hydraulic Operation

Dialysis with bibag

Heated water from chamber E of the hydrochamber flows to the junction of valves 100 and 103. Valve 100 opens and the bibag disposable will start filling when the dialysate temperature at temperature sensor 3 reaches 30 degrees C. Valve 100 will close when the pressure reaches 150mmHg as monitored by the pressure transducer 110. After this initial fill, valves 104 and 108 open, valve 103 closes, the balancing chamber valves open and any excess gas generated in the bag is flushed through the hydraulics down the drain. The flow pump runs and the machine is kept in bypass during this initial flush. Afterwards, additional water will be added to the bag to maintain pressure in the bag of about 90mmHg.

The conductivity cell (113) and temperature sensor (114) measure the conductivity and temperature of the sodium bicarbonate concentrate as it leaves the bag. The temperature compensated conductivity determines the concentration of the sodium bicarbonate concentrate and the delivery rate of the bicarbonate pump (17).

If air is sensed by the probes (112) in the air separation chamber, valve 101 is momentarily opened to vent the air.

If the pressure in the bibag disposable does not change while the bicarbonate pump is pumping, an airlock condition is detected. To remove the airlocked condition in the bicarbonate pump, valve 100 opens to pressurize the bag to 150mmHg. Next, the flow is stopped, the balance chamber valves are opened up, the flow pump runs, and the machine is kept in bypass.

Conductivity cell 117 checks the amount of sodium bicarbonate added to the dialysate and a conductivity alarm will be displayed if the solution is not within:

- $\pm 5\%$ of expected in Functional board software version less than 2.71
- $\pm 15\%$ of expected in Functional board software version 2.71 or greater.

Dialysis with Sodium Bicarbonate Concentrates

Jug bicarbonate dialysis is also supported with the bibag hydraulics. To run in this mode, the bibag connector door must be completely closed and the bicarbonate connector pulled out. Valves 104 and 108 will open and close based on pressure transducer 110 to allow bicarbonate concentrate to reach the bicarbonate pump. Conductivity and temperature of the solution is monitored.

Rinse & Mandatory Rinse

Mandatory rinse is run after a chemical disinfect. Both rinse and mandatory rinse are the same valve sequence for the valves in the bibag hydraulics. Valves 104 and 108 alternate opening every 3 seconds. Valves 100 and 103 alternate opening every 3 seconds. Valve 101 is also opened periodically when conductivity is low. Valve 105 is open.

Hydraulic Operation (cont.)

Chemical Disinfection/Rinse

The same bibag valve sequence as in rinse.

Chemical Disinfection/Dwell

The same bibag valve sequence as in rinse

Acid Clean

The bibag valve sequence is the same as chemical rinse. Both concentrate and bicarbonate connectors are plugged into acid.

Heat disinfect

The bibag valve sequence is the same as rinse.

Flow off

Valves 100 and 101 closed. Valve 103 open

bibag Empty

The bibag empty procedure removes the liquid solution from the bibag disposable to make disposal easier and cleaner. To empty the bibag disposable, valves 100, 103 and 105 are closed while the balancing chamber and valves 104 and 108 are opened up. The flow pump runs to suck solution from the bag and send it out the drain. During the emptying process, the hydraulics are kept in bypass. When the empty is complete, the operator is notified, normal balance chamber switching resumes, but the hydraulics remain in bypass until a new bag is installed and correct conductivity of the dialysate returns.

Electronic Description

bibag Interface Board

The bibag interface board 'piggybacks' onto the actuator - test board and communicates with it. The bibag hydraulic assembly and the bibag distribution box 2 connect electrically to the bibag interface board with ribbon cables.

The bibag interface board contains all of the electronics required to activate the 5 additional valves, read conductivity from the bibag and bicarbonate conductivity cells, read temperature from the bibag and bicarbonate temperature thermistor, read the status of the bibag air sensor, and read the status of the bibag door's internal switches. A microcontroller on the board controls all of these processes and communicates serially with the actuator - test board. The presence of the communications between the bibag interface board and the actuator - test board indicates to the system the presence of the bibag hydraulic components.

The bibag pressure transducer is automatically calibrated when the door is open, and the value is saved into memory on the bibag interface board.

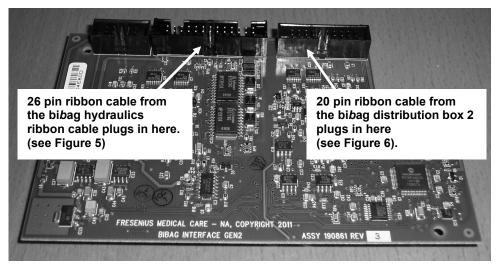


Figure 4 – bibag Interface Board

bibag Hydraulic Assembly - Distribution Board

The bibag hydraulic assembly - distribution board is a passive board that connects to the bibag interface board through a 26 pin cable. All of the individual bibag components on the bibag hydraulic assembly connect electrically to this distribution board.

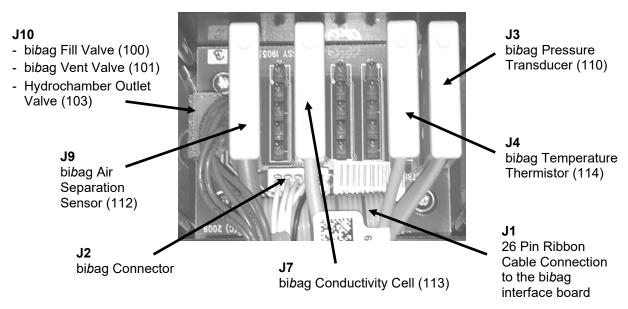


Figure 5 – bibag hydraulic Assembly – Distribution Board

bibag Distribution Box 2 – Distribution Board

The bibag distribution box 2 - distribution board is a passive board that connects to the bibag interface board through a 20 pin cable. All of the individual bibag components on the distribution box 2 connect electrically to this distribution board.

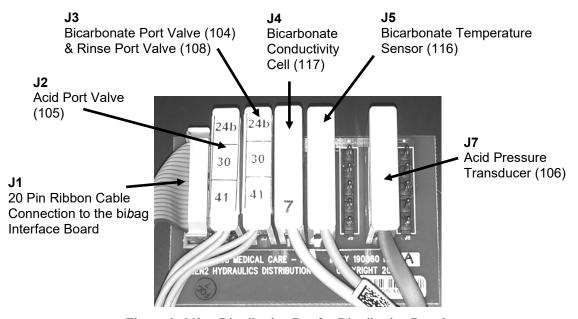


Figure 6 - bibag Distribution Box 2 - Distribution Board

Electronic Block Diagram

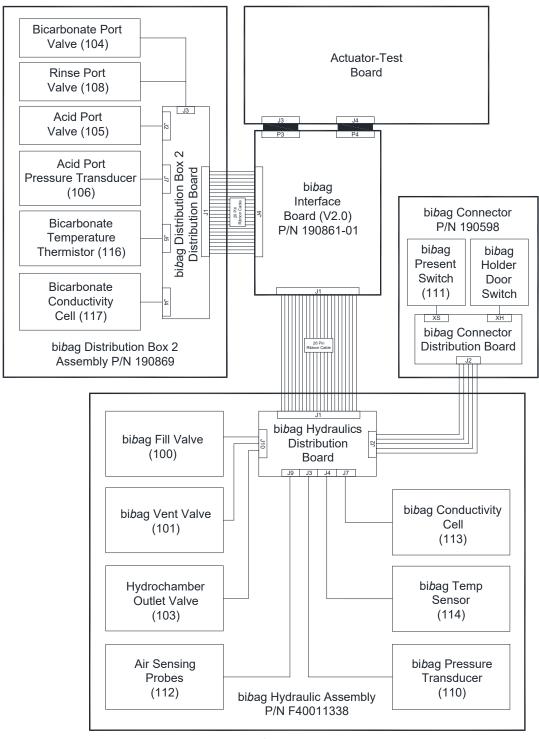


Figure 7

Calibrations

Pressure Transducers

Power the machine on and enter Service Mode.

From the Calibrate Sensors screen, select the Pressure Transducers screen button.

On the Pressure Transducers screen, select the Regulator Pressure screen button.

- 1. Pull the Acid and Bicarbonate connectors and insert them halfway back into their ports.
- 2. Press the [Confirm] key to set the 0 (zero) pressure calibration. The screen will change. When prompted, press the [Confirm] key to save the calibration. The screen will change. Press the [Confirm] key again to finish the calibration process.

Bicarbonate Conductivity Cell

Required Tools:

Mesa 90XL Dialysate Meter With Conductivity/Temperature Module	Mesa Serial Cable (P/N 368402-10)	Null Modem (P/N 190323)
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Required Supplies:

- Liquid bicarbonate
- Machine must be connected to an R.O. water source for this calibration.

Power the machine on and enter Service Mode.

From the Calibrate Sensors screen, select the Cond Cells screen button.

On the Cond Cells screen, select Bicarb Cell screen button.

1. Using the Null Modem, connect the Mesa Serial Cable between the 90XL Dialysate Meter and the RS232 port on the rear of the card cage. Refer to Figure 8 for connection assistance.

Note: A No Comm To 90XL message will occur if the internal cable for the RS232 port is not connected to P6 on the Functional board (see Figure 8).

- 2. Connect the Dialysate Lines to the 90XL Conductivity/Temperature Module.
- 3. Connect the acid connector to a container of R.O. water and the bicarbonate connector to a container of sodium bicarbonate concentrate.
- 4. Press the [Confirm] key to start the calibration.

The screen will change and the screen will display Calibration In Progress...

During the calibration process, the 90XL will communicate with the machine through the RS232 port.

When the calibration process is complete, the screen will display Bicarb Cond Cell calibration is complete.

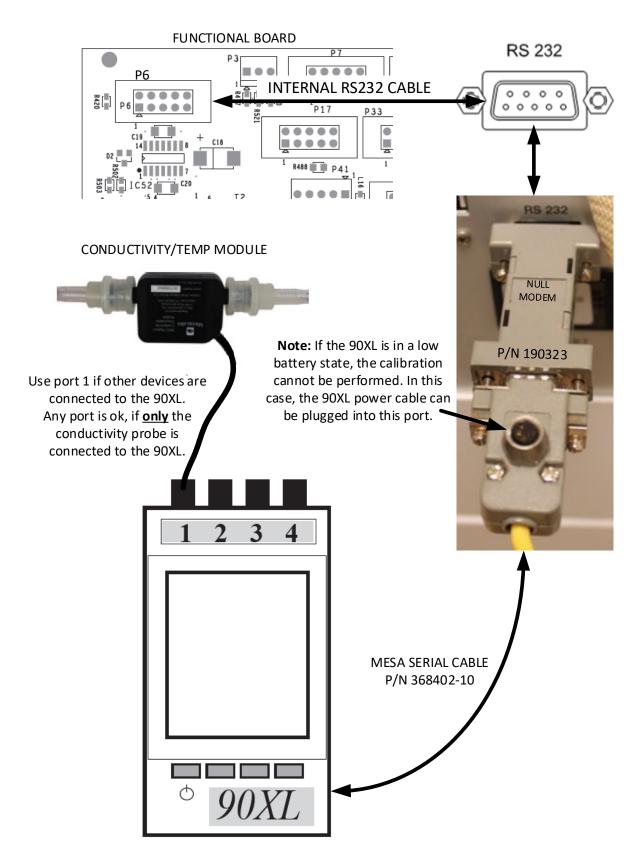


Figure 8 - Null Modem Connection to the 90XL

Annual Maintenance

bibag Annual Maintenance requirements can be found in the

2008T Preventive Maintenance Procedures P/N 508033

2008K@home™ Preventive Maintenance Procedures P/N 507655

Debug Screens

All Debug Screens with descriptions can be found in the 2008T Debug Screens P/N 490139
2008K@home[™] Debug Screens P/N 490084

Spare Parts

A list of bibag spare parts can be found in the 2008 Series Hemodialysis Spare Parts Manual P/N 490124.

Troubleshooting

All status messages are displayed on the control panel screen. These messages are generated due to conditions and events that occur in the machine during operation. These messages will reset when the condition causing the message is corrected. In some cases, the operator must reset them.

A full list of bibag related messages can be found in the

2008®T Hemodialysis Machine bibag

Operator's Manual P/N 508213.

2008K@home[™] Hemodialysis Machine bibag Operator's Manual P/N 508340.



Warning: Performing the recommended action may or may not clear the alarm, warning or advisory messages displayed. Patient treatment shall not proceed until the conditions causing these messages are corrected and the messages cleared.



Note: There are alarm messages that may be similar. Please take care that you read appropriate message to determine the "Action required" for troubleshooting.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
Acid Press Calib Err	bibag system pressure calibration error.	Advisory	Turn the machine power off and back on. If the message is not cleared, take the machine out of service.
	Acid Pressure Regulator Calibration Error		Perform Regulator Pressure Calibration
	Service Mode Advisory Message		Reseat / Replace Cable Distribution Box 2 to bibag interface Board 20pin.
Active Pressure Regulator Uncalibrated	Active Pressure calibration has not been performed and the machine is not in T&C mode	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
			Perform Regulator Pressure Calibration
bibag: +5 V Error	Electronic self-test, power supply limits exceeded.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Check for +5V yields voltage outside +5/-5% window 20 consecutive times.		Reseat / Replace Cable Distribution Box 2 to bibag interface Board 20 pin.
			Reseat / Replace Distribution Board Cable to bibag Connector.
			Reseat / Replace Distribution Board Cable to bibag Interface Board
			Reseat / Replace Actuator-Test Board
			Reseat / Replace bibag interface board

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: -5 V Error	Electronic self-test, power supply limits exceeded.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Check for -5V yields voltage outside +10/-10% window 20 consecutive times.		Reseat / Replace Cable Distribution Box 2 to bibag interface Board 20 pin
			Reseat / Replace Distribution Board Cable to bibag Connector.
			Reseat / Replace Distribution Board Cable to bibag Interface Board
			Reseat / Replace Actuator-Test Board
			Reseat / Replace bibag interface board
bibag: +12 V Error	Electronic self-test, power supply limits exceeded.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Check for +12 V yields voltage outside +5/-5% window 20 consecutive times.		Reseat / Replace Cable Distribution Box 2 to bibag interface Board 20 pin
			Reseat / Replace Distribution Board Cable to bibag Connector.
			Reseat / Replace Distribution Board Cable to bibag Interface Board
			Reseat / Replace Actuator-Test Board
			Reseat / Replace bibag interface board
bibag: Bag Leak	A leak has been detected in the bag.	Water Alarm	Open bibag door, wait 30 seconds to relieve the pressure, and remove the bag.
			Place a new bag on the connector and close the bibag door
			Check bibag assembly for leaks.
			Check / Replace V100 bibag Fill Valve
			Check / Replace bibag pressure transducer (110)

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Bag On	The bag is on the connector when user is either attempting to run a cleansing/disinfecting program or using acetate. Or The blue bicarbonate connector is out of the bicarbonate port when a bag is on the bibag connector.	Water Alarm	Remove the bag from the bibag connector if using acetate or attempting to run a cleansing/disinfecting program. Or Plug the blue bicarbonate connector back into the bicarbonate port on the machine. Check / replace bibag connector. Check / replaced cable: bibag connector to distribution board (black box).
bibag: Bic Pump Locked	The bicarbonate pump has been air locked for over two minutes.	Water Alarm	If during treatment, rinse back the patient's blood and disconnect the patient from the machine. Run a Rinse program to clear the alarm. If the alarm is not cleared, take the machine out of service. Run a rinse program. Rebuild / Replace bicarbonate pump.
bibag Board Failure	bibag Interface Board cannot boot up. bibag Fatal Alarm Messages	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service. Reseat / Replace bibag Interface Board Reseat / Replace Actuator-Test Board
bibag: Chamber Venting	The system is venting, and the machine is in bypass mode.	Advisory	Advisory only. No action is required. Note: If this message occurs repeatedly, open the bibag door, wait 30 seconds to relieve the pressure, and lift the bag off the bibag connector nozzles to vent the air. With the white bibag handle facing outward, hang the bibag disposable back on the connector nozzles. Close the bibag door, making sure it latches firmly in place. An audible click indicates the door is closed.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Cond Calib Err	Electronic self-test: bibag conductivity sensor calibration error.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Minimum calibration resistance falls outside $120.0~\Omega$ window 10 consecutive times or Maximum calibration resistance falls outside $68.0~\Omega$ window 10 consecutive times		Reseat / Replace bibag Interface Board Reseat / Replace Actuator-Test Board
bibag: Cond High	The actual or measured bibag conductivity has exceeded the high conductivity alarm limit when using the bibag disposable. The machine is in bypass mode.	Water Alarm	Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached, connect a new bag. If the alarm is still not cleared, return blood to the patient. Take the machine out of service.
	bibag Conductivity > 65 mS/cm bibag Conductivity Cell #113 Debug Debug Screen 14 - Debug Screen 15 on 2008K@Home TM		Run an Acid Clean program followed by a complete rinse cycle. Perform Temperature Control Calibration. Replace bibag Conductivity Cell (113)

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Cond Low	The actual or measured bibag conductivity is below the low conductivity alarm limit when using the bibag disposable. The machine is in bypass mode. The bibag disposable may also be nearly empty. bibag Conductivity < 50 mS/cm bibag Conductivity Cell #113 Debug Debug Screen 14 - Debug Screen 15 on 2008K@Home TM	Water Alarm	Check the bibag disposable: if there is only about one inch (2.5 cm) of bicarbonate left at the bottom of the bag, replace the bag. Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place a fresh bag back on the connector and close the door. If conductivity alarm persists: Check for a clogged filter screen in the blue bicarbonate connector handle. Clean, if necessary, with purified water. Verify that the connector and filter assembly are tightly screwed together with no air leak. If the conductivity alarm persists, take the machine out of service. Run an Acid Clean program followed by a complete rinse cycle. Perform Temperature Control Calibration. Replace bibag Conductivity Cell (113).
bibag: Cond Sensor Err	The bibag conductivity sensor is not reading the correct conductivity. The machine is in bypass mode. Conductivity cell 113 > 1.00 mS/cm for 30 consecutive seconds after at least 9 minutes of water sensed during Rinse	Advisory	Run a Rinse program until the message is cleared. If the alarm is not cleared, take the machine out of service. Replace bibag Conductivity Cell (113). Reseat / Replace Functional Board. Reseat / Replace Actuator-Test Board. Reseat / Replace bibag Interface Board. Replace Functional Board EEPROM

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Door Error	Sensor error. bibag door is in two different positions at the same time. (Mechanically impossible)	Advisory	Turn the machine power off and back on. If the alarm is not cleared, return the blood to the patient if the alarm occurs during treatment. Take the machine out of service. Check bibag Connector cable - bibag connector assembly to bibag distribution board (in black box) Check cable: bibag distribution board to bibag interface board, 26 pin. Check the bibag distribution board for signs it's been leaked on or is corroded. Replace bibag connector assembly. Replace bibag interface board.
bibag: Door Open	The bibag door is open. The machine is in bypass mode. The bibag door is open with or without bag	Water Alarm	Close the bibag door to continue. Check bibag Connector cable - bibag connector assembly to bibag distribution board (in black box) Check cable: bibag distribution board to bibag interface board, 26 pin. Check the bibag distribution board for signs it's been leaked on or is corroded. Replace bibag connector assembly. Replace bibag interface board.
bibag: Emptied	The bibag emptying program has completed. The emptied bag must be removed from the bibag connector.	Advisory	Open the $bibag$ door and remove the bag to continue.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Empty Too Long	The bag has been emptying longer than five minutes.	Water Alarm	Make sure that the blue bicarbonate connector is firmly plugged into the bicarbonate port. If the message is not cleared, remove the bag without emptying.
			Perform Regulator Pressure Calibration Reseat / Replace bibag Interface Board. Reseat / Replace Actuator-Test Board. Replace air sensor #6 Reseat / Replace Functional Board.
bibag: Emptying	The bag is being emptied by the machine.	Advisory	No action required, wait until the machine has finished emptying the bag to continue.
bibag: Filling	The bag is filling with water.	Advisory	Advisory only. No action is required.
bibag: I2C Error	I2C communication problem. I2C error determined by bibag interface board.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, return the blood to the patient if the alarm occurs during treatment. Take the machine out of service. Reseat / Replace Actuator-Test Board. Reseat / Replace bibag Interface Board.
bibag: In Bypass	User attempted to turn the "Prime Recirc" Option on while the system was in bypass mode due to a bibag process or alarm.	Advisory	
bibag: No Bag	A bag must be on the connector to continue. The machine is in bypass mode.	Water Alarm	Place a bag on the bibag connector and close the door to continue. Replace bibag connector assembly. Check bibag Connector cable. bibag distribution board to bibag interface board

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: No Comm.	The bibag interface board is not communicating with the actuator board.	Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	3 consecutive checksum faults or 1 sec of serial miscommunication		Reseat / Replace bibag Interface Board. Reseat / Replace Actuator-Test Board.
bibag: PHT Failed	The bibag Valve Leaking Test (Pressure Holding Test) has failed. The machine is in bypass mode. The bibag performs a Valve Leaking Test to prevent V100, V101, V103, and V104 from leaking, especially to prevent the bicarbonate solution leaked from V101 path to the Hydrochamber.	Water Alarm	Replace bibag disposable. Check for external leaks at bibag connector assembly. Check / Replace V100, V101, V103, and / or V104 Check / Replace bibag pressure transducer (110)
bibag: Post Rinse	The machine is rinsing the hydraulics after emptying the bag.	Advisory	Advisory only. No action is required.
bibag: Press Calib Err	bibag system pressure calibration error. bibag pressure sensor offset reading significantly off from 0 mmHg.	Advisory	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service. Perform Regulator Pressure Calibration Check / Replace bibag pressure transducer (110) Reseat / Replace bibag Interface Board. Reseat / Replace Actuator-Test Board.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Press Sensor Err	The bibag connector pressure sensor is experiencing an error. The machine is in bypass mode.	Water Alarm	Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door. If the alarm is not cleared take the machine out of service.
	bibag pressure does not change while V100 opens for 2 seconds during Initial Fill		Check for external leaks at bibag connector assembly. Check / Replace V100 Check / Replace bibag pressure transducer (110) Perform Regulator Pressure Calibration
bibag: Press Too High	The pressure inside the bibag disposable is above the set alarm limits. The machine is in bypass mode.	Water Alarm	Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door.
	bibag pressure > 250 mmHg for 3 consecutive seconds		Check / Replace V100 Check / Replace bibag pressure transducer (110) Perform Regulator Pressure Calibration
bibag: Press Too Low	The pressure inside the bibag disposable is below the set alarm limits. The machine is in bypass mode.	Water Alarm	Open the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Place the bag back on the connector and close the door.
	bibag Pressure ≤ 70 mmHg for 10 consecutive seconds once bibag starts filling or is filled		Check / Replace V100 Check / Replace bibag pressure transducer (110) Perform Regulator Pressure Calibration
bibag: Select Conc 45x	The operator has attempted to start dialysis with bibag and an acid concentrate other than 45X is selected	Advisory	Select 45x for bibag dialysis or switch to jug dialysis
	bibag dialysis is compatible only with 45X acid concentrates.		

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Temp Calib Err	Electronic self-test: temperature calibration error.	Alarm	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Calibration Temperature bibag falls		Reseat / Replace bibag Interface Board.
	outside window 10 consecutive times**		Reseat / Replace Actuator-Test Board
bibag: Temp Sensor	The bibag temperature sensor is not	Advisory	Perform a complete rinse cycle.
Err	reading the correct temperature. Temp relation between NTC 114 and NTC 3		Perform Temperature Sensor Calibration
	outside calculated range		Perform Temperature Control Calibration.
			Check / Replace Temperature Sensor #3
			Check / Replace Temperature Sensor #114
bibag: Val Comm Err	The bibag interface board was unable to communicate with the actuator board.	Water Alarm	Turn the machine power off and back on. If the alarm is not cleared take the machine out of service.
	After remaining stable for 60 ms, bibag valve status is mismatched between		Reseat / Replace bibag Interface Board. Reseat / Replace Actuator-Test Board
	actuator/test and bibag interface board.		Reseat / Replace Functional Board.
bibag: Valve 1 Err	Electronic self-test failure.	Water Alarm	Turn the machine power off and back on. If the alarm is not cleared take the machine out of service.
	V100 or V101 sends an error 10		Check / Replace V100 bibag Fill Valve
	consecutive times		Check / Replace V101 bibag Vent Valve
			Check the bibag distribution board for signs it's been leaked on or is corroded.
			Check cable: bibag distribution board to bibag interface board, 26 pin.
			Reseat / Replace bibag Interface Board.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
bibag: Valve 2 Err	Electronic self-test failure.	Water Alarm	Turn the machine power off and back on. If the alarm is not cleared, take the machine out of service.
	V103 or spare valve sends an error 10		Check / Replace V103 bibag hydrochamber outlet valve
	consecutive times		Check the bibag distribution board for signs it's been leaked on or is corroded.
			Check cable: bibag distribution board to bibag interface board, 26 pin.
			Reseat / Replace bibag Interface Board
bibag: Vent Too Long	The bibag system has been venting for longer than ten minutes. The machine is in bypass mode. Air Vent 20 times in 2 minutes or The bibag has been venting longer than ten minutes.	Water Alarm	Press the RESET key to clear the message. Pull the blue bicarbonate connector out of its port and then firmly plug it back in. If the message persists, take the machine out of service. Check for external leaks at bibag connector assembly. Check / Replace bibag Air Separation Chamber Check / Replace bibag Air Separation Chamber Air Sensor #112
Bicarb Cond 2 High	Bicarbonate conductivity cell is measuring high dialysate bicarbonate conductivity when using the bibag system. The machine is in bypass mode. If the delivered bicarbonate is 15% more than targeted amount of bicarbonate for continuous 40 strokes	Water Alarm	A single occurrence is not a problem if the machine automatically resets. If the problem lasts longer than five minutes or occurs repeatedly take the machine out of service. Perform Dialysate Composition Verification Procedure Perform Deaeration and Loading Pressure Calibration. Perform bicarb Conductivity Cell Calibration

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
Bicarb Cond 2 Low	Bicarbonate conductivity cell is measuring low dialysate bicarbonate conductivity when using the bibag system. The machine is in bypass mode. If the delivered bicarbonate is 15% less than targeted amount of bicarbonate for continuous 40 strokes	Water Alarm	A single occurrence is not a problem if the machine automatically resets. If the problem lasts longer than five minutes or occurs repeatedly take the machine out of service. Perform Dialysate Composition Verification Procedure Perform Deaeration and Loading Pressure Calibration. Perform bicarb Conductivity Cell Calibration
Bicarb Cond. Cell Uncalibrated	The Bicarbonate cell #117 calibration has not been performed and the machine is not in T&C mode,	Alarm	Perform bicarb Conductivity Cell Calibration
Bicarb: Cond High	The actual or measured sodium bicarbonate concentrate conductivity has exceeded the high conductivity alarm limit when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.	Water Alarm	Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached, make sure that the correct bicarbonate source is connected. If the alarm is still not cleared take the machine out of service. Check / Replace bicarbonate concentrate solution. Perform Dialysate Composition Verification Procedure
Bicarb: Cond Low	The actual or measured sodium bicarbonate concentrate conductivity is below the low conductivity alarm limit when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass mode.	Water Alarm	Wait five minutes for conductivity to stabilize. If the appropriate conductivity cannot be reached, make sure that the correct bicarbonate source is connected. If the alarm is still not cleared take the machine out of service. Check / Replace bicarbonate concentrate solution. Perform Dialysate Composition Verification Procedure

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
Bicarb Press Calib Err	Bicarbonate pressure calibration error. The machine is in bypass mode.	Alarm	Turn the machine power off and back on. If the alarm is not cleared take the machine out of service. (In Non-bibag Machine with Active Regulate Pressure)
Bicarb: Temp Calib Err	Bicarbonate temperature calibration error. The machine is in bypass mode.	Alarm	Turn the machine power off and back on. If alarm is not cleared take the machine out of service.
			Reseat / Replace bibag Interface Board.
Bicarb: Vent Too Long	The bibag system has been venting longer than ten minutes when using the blue bicarbonate connector for liquid bicarbonate. The machine is in bypass	Water Alarm	Press the RESET key to clear the message. If the alarm persists, turn the machine power off and back on. If alarm is not cleared take the machine out of service.
	mode.		Check for external leaks at bibag connector assembly.
			Check / Replace bibag Air Separation Chamber
			Check / Replace bibag Air Separation Chamber Air Sensor #112
Blood Sensed	The operator has selected the Empty bibag button when blood is sensed. The bag cannot be emptied using the Empty bibag button when blood is sensed.	Warning	If the treatment is not yet finished and the bag must be changed, lift up on the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Put a new bag on the connector and close the door again to continue using the bibag system for the treatment.
Conductivity Limits set to default	The operator has entered a new concentrate in Service Mode, restarted the machine, changed the default concentrate values, and restarted the machine. The last entered concentrate has been set to the default conductivity limits.	Opening Screen Message	On the "Dialysate" screen, select the prescribed concentrate, enter the prescribed Base Na+ and Bicarbonate values for the patient and press the CONFIRM key to save the new values.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
Must Calibrate To Run	Electronic self-test failure.	Alarm	Turn machine power off and back on. If alarm is not cleared, take the machine out of service.
	Calibrations have been lost or not set.		Perform necessary Calibrations.
RO Water Cond High	The Reverse Osmosis (RO) water inlet conductivity is too high.	Opening Screen Message	Press the RESET key to clear the message. Perform a complete Rinse cycle. If alarm is not cleared, take the machine out of service.
	At the end of water rinse, the conductivity measured at Bicarbonate Conductivity Cell #113 is greater than 0.3mS/cm		Check Reverse Osmosis (RO) water Run an Acid Clean program followed by a complete rinse cycle. Check / Replace Bicarbonate Conductivity Cell #113
Tx Clock On	The operator has selected the Empty bibag button when the Tx Clock is running. The bag cannot be emptied using the Empty bibag button when the Tx Clock is running.	Dialog Message	If the treatment is not yet finished and the bag must be changed, lift up on the bibag door, wait 30 seconds to relieve the pressure, and remove the bag. Put a new bag on the connector and close the door again to continue using the bibag system for the treatment.
V104 Stuck Open	Bicarbonate concentrate port valve error. The machine is in bypass mode.	Water Alarm	Turn machine power off and back on. If the alarm is not cleared, take the machine out of service.
	Valve 104 is stuck at open position		Check / Replace V104 / V108 Check cable: bibag distribution board 2 to bibag interface board, 20 pin. Reseat / Replace bibag Interface Board.

sible Solution	Type Action F		Conditions and Events	bibag Message
onate concentrate supply line. In the concentrate connector is firmly late concentrate source is a central feed line is open. It rinse, open the bibag door for at least five lached). Rerun the rinse program. In the blue bicarbonate connector larry, with purified water. Verify that the line bly are tightly screwed together with no air late late late late late late late late	Water Alarm Make sur connecte system, reseconds of the connector leak. Check for handle, connector leak. Check capin. Check / I	lief g he all be	Bicarbonate concentrate port valve error or rinse port valve error. The machine is in bypass mode. Valve 104 is stuck at close position If after 5 seconds in the pressure relief stage of the rinse program, the bibag pressure remains above 10 mmHg the alarm "V104/108 Stuck Closed" shall be generated. This alarm will be saved to the EEPROM and this alarm state setting shall persist until a rinse program successfully completes.	bibag Message V104/108 Stuck Closed
screen in the blue bicarbo ry, with purified water. Very are tightly screwed to be a surface board to bibag inter- 108 and to bibag inter- perface Board. or occurs upon power up of the control of t	Check for handle, connector leak. Check capin.	the all be	pressure remains above 10 mmHg the alarm "V104/108 Stuck Closed" shall be generated. This alarm will be saved to the EEPROM and this alarm state setting shall persist until a rinse program	

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
V105 Stuck Open	Acid concentrate port valve error. The machine is in bypass mode.	Water Alarm	Turn machine power off and back on. If alarm is not cleared, take the machine out of service.
			Check / Replace V105
	Valve 105 is stuck at open position.		Check cable: bibag distribution board 2 to bibag interface board, 20 pin.
			Reseat / Replace bibag Interface Board.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
V105 Stuck Closed	The acid concentrate supply line is not pulling in acid concentrate. The machine is in bypass mode.	Water Alarm	Check for a kinked acid concentrate supply line. Make sure that the acid concentrate connector is firmly connected. If the acid concentrate source is a central feed system, make sure that the line is open.
	Valve 105 is stuck at close position		If alarm is not cleared, turn machine power off and back on. If alarm is still not cleared take the machine out of service.
	If after 5 seconds in the pressure relief stage of the rinse program, the bibag pressure remains above 10 mmHg the alarm "V105 Stuck Closed" shall be generated.		Make sure that the acid concentrate connector is firmly connected. If the acid concentrate source is a central feed system, make sure that the line is open.
			If the error occurs during a rinse, open the bibag door for at least five seconds (with no bibag attached). Rerun the rinse program.
			Check for a clogged filter screen in the red concentrate connector handle. Clean, if necessary, with purified water. Verify that the connector and filter assembly are tightly screwed together with no air leak.
			Check / Replace V105
			Check cable: bibag distribution board to bibag interface board, 26 pin.
			Reseat / Replace bibag Interface Board.
			Note: If this error occurs upon power up or after any of the cleaning/disinfecting programs, make sure the red acid connector is firmly plugged into the acid port then run the cleaning/disinfecting program again.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
Valve 104 Err	Bicarbonate concentrate port valve error. The machine is in bypass mode.	Water Alarm	Turn the machine power off and back on. If alarm is not cleared, take the machine out of service.
	V104 or spare valve sends an error 10 consecutive times.		Check the bibag distribution board for signs it's been leaked on or is corroded.
			Check / Replace V104 / V108
			Check cable: bibag distribution board 2 to bibag interface board, 20 pin.
			Reseat / Replace bibag Interface Board.
Valve 105 Err	Acid concentrate port valve error. The machine is in bypass mode.	Water Alarm	Turn the machine power off and back on. If alarm is not cleared, take the machine out of service.
	V105 or spare valve sends an error 10 consecutive times.		Check the bibag distribution board for signs it's been leaked on or is corroded.
			Check / Replace V105
			Check cable: bibag distribution board 2 to bibag interface board, 20 pin.
			Reseat / Replace bibag Interface Board.
Bicarb Cond Cell Calibration is in Error	Service Mode Error (Bicarbonate Conductivity Cell calibration)	Error	Check for external leaks at bibag connector assembly. Run an Acid Clean program followed by a complete rinse cycle. Perform Dialysate Composition Verification Procedure
	The 2nd point of the two-point calibration is equal to or less than the first point, the slope is less than .4 or greater than 1, and the offset is less than15 mS/cm or larger than .15 mS/cm		Check / Replace bicarbonate concentrate solution. Replace / Rebuild / Calibrate Bicarbonate Pump Perform Deaeration and Loading Pressure Calibration.

bibag Message	Conditions and Events	Type	Action Required and Possible Solution
No Comm. to 90XL	Service Mode Error (Bicarbonate Conductivity Cell calibration)	Error	Confirm that the internal cable for the RS232 port is connected to P6 of the Functional Board. Confirm that the meter's Conductivity/Temperature Sensor is
	The FDS08 port is not properly connected to a 90XL meter.		Use Port 1 of the 90XL meter for Conductivity/Temperature Sensor if other devices are connected to the meter.
			The calibration cannot be performed if the meter is in a low battery state or turned off.
"No 90XL Sensor Connected Service Mode Error (Bicarbonate Conductivity Cell calibration) The 90XL meter does not have a corresponding	Confirm that the internal cable for the RS232 port is connected to P6 of the Functional Board.		
		Confirm that the meter's Conductivity/Temperature Sensor is connected to the meter.	
	The 90XL meter does not have a corresponding		Use Port 1 of the 90XL meter for Conductivity/Temperature Sensor if other devices are connected to the meter.
	Conductivity/Temperature Sensor connected.		The calibration cannot be performed if the meter is in a low battery state or turned off.
Operator Error	Service Mode Error	Error	Check for external leaks at bibag connector assembly.
	(Bicarbonate Conductivity Cell		Run an Acid Clean program followed by a complete rinse cycle.
	calibration)		Perform Dialysate Composition Verification Procedure
	While the calibration is running. if the stable conductivity reading is less than		Check / Replace bicarbonate concentrate solution.
	1.0 mS/cm or greater than 3.0 mS/cm for		Replace / Rebuild / Calibrate Bicarbonate Pump
	the first point or the stable conductivity is less than 2.5 mS/cm or greater than 4.0 mS/cm for the second point		Perform Deaeration and Loading Pressure Calibration.

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