FRESENIUS MEDICAL CARE

bi*b*ag® V2.0

Technician’s Manual

Part Number 490188 Rev. I

bi*bag*® V2.0 Technician's Manual

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

bi*b*ag V2.0 Technician's Manual
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bi*b*ag Details

The bi*b*ag connector is a hardware option that allows the usage of a dry bicarbonate powder to generate dialysate solution for the 2008®T and the 2008K@home™ hemodialysis machines. The bi*b*ag disposable is a bag filled with dry bicarbonate powder with special inlet and outlet ports. Underneath the bi*b*ag door, the bi*b*ag hangs on two nozzles, which allow for the entry of purified water and the exit of bicarbonate concentrate solution. A door handle locks the bi*b*ag door in place over the bi*b*ag disposable.

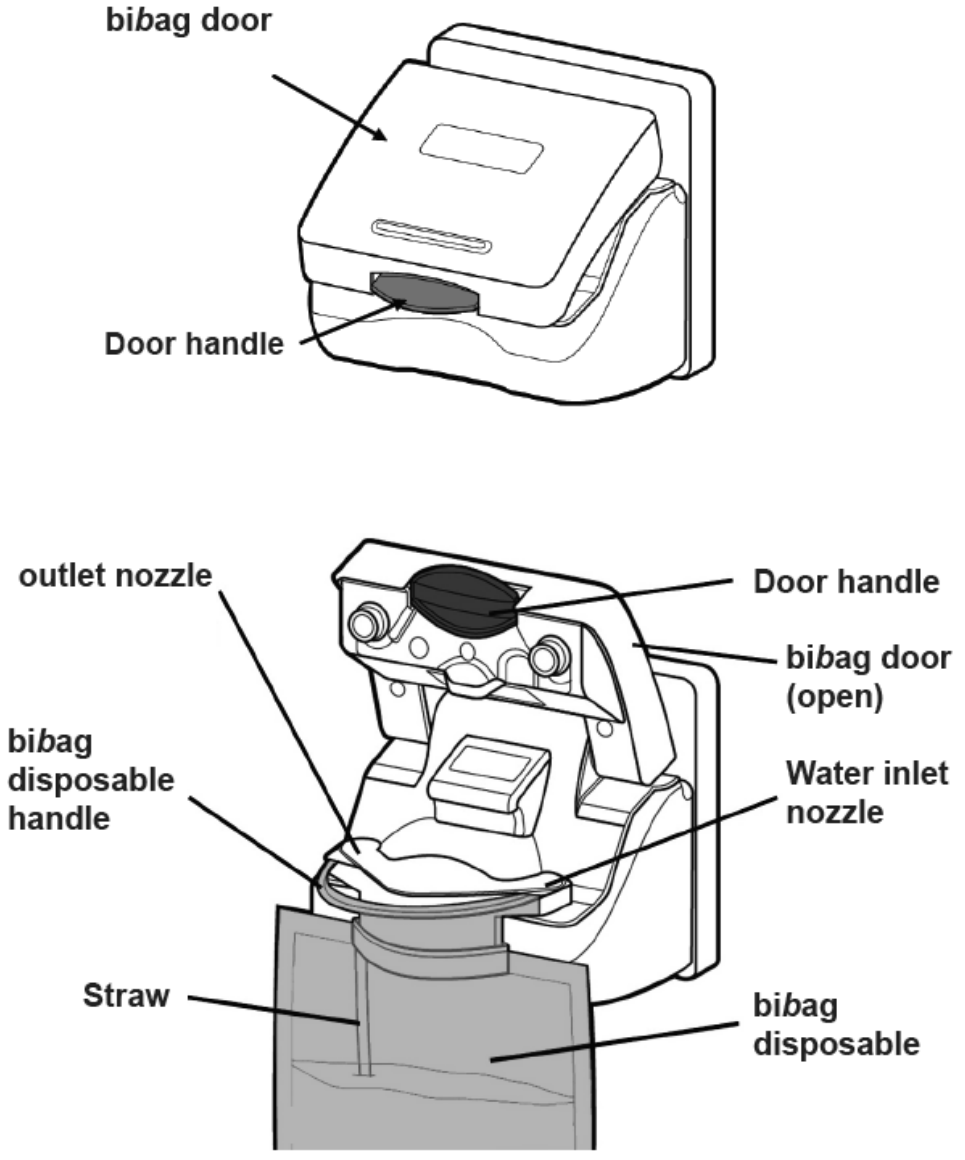


Figure 1 – bi*b*ag connector: door closed and bi*b*ag disposable inserted with door open

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.

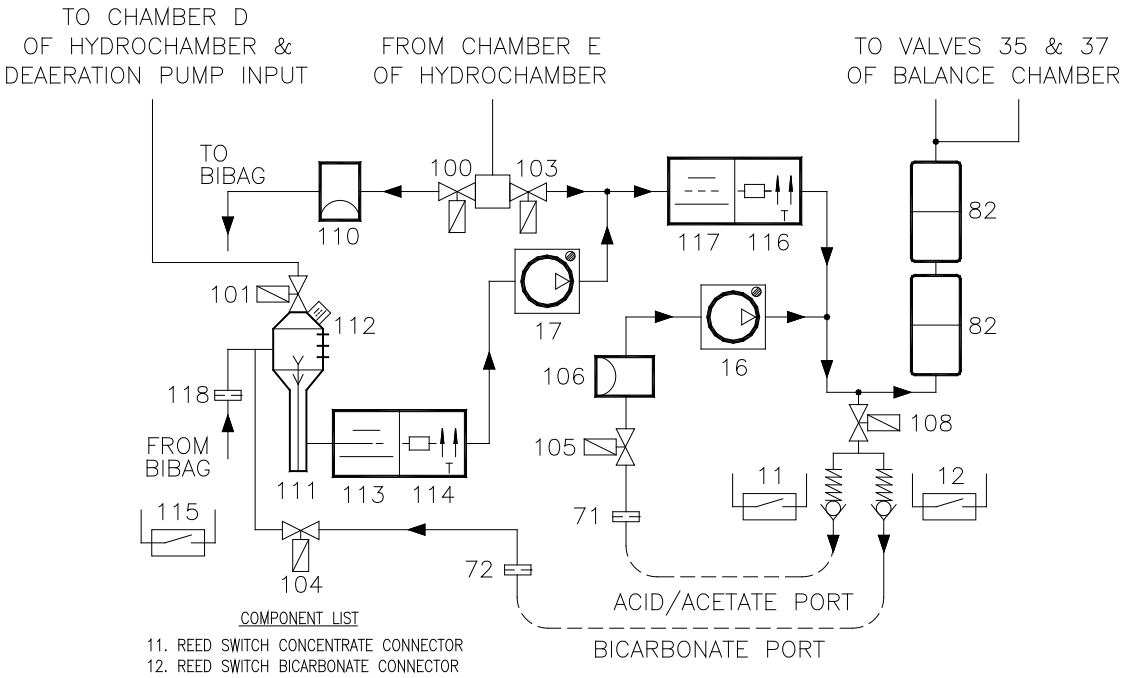
Warning: Always verify the conductivity and approximate pH of the dialysate solution through independent means before initiating dialysis. Verify that the pH is normal and that the conductivity is reasonably close to the theoretical value. If it is not, do <u>not</u> initiate dialysis.

Warning: Replace a leaking bi*b*ag 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 bi*b*ag connector.

Note: When the bi*b*ag 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@home™ Hemodialysis Machine Operator's Manual* P/N 490180.

Hydraulic Flow Diagram



COMPONENT LIST

11. REED SWITCH CONCENTRATE CONNECTOR
12. REED SWITCH BICARBONATE CONNECTOR
16. CONCENTRATE PUMP
17. BICARBONATE PUMP
71. ACID/ACETATE FILTER
72. BICARBONATE FILTER
82. MIXING CHAMBERS
100. BIBAG FILL VALVE
101. BIBAG VENT VALVE
103. HYDROCHAMBER OUTLET VALVE
104. BICARBONATE PORT VALVE
105. ACID PORT VALVE
106. ACID PORT PRESSURE TRANSDUCER
108. RINSE PORT VALVE
110. BIBAG PRESSURE TRANSDUCER
111. BIBAG AIR SEPARATION CHAMBER
112. BIBAG AIR SEPARATION CHAMBER AIR SENSOR
113. BIBAG CONDUCTIVITY CELL
114. BIBAG TEMPERATURE THERMISTOR
115. BIBAG PRESENT SWITCH
116. BICARBONATE TEMPERATURE THERMISTOR
117. BICARBONATE CONDUCTIVITY CELL
118. BIBAG FILTER

Figure 2

Hydraulic Component Descriptions

100 – bi*b*ag Fill Valve
The bi*b*ag fill valve opens as needed to add water to the bi*b*ag disposable during dialysis. When bi*b*ag 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 – bi*b*ag Vent Valve
The bi*b*ag vent valve opens momentarily during dialysis when air is detected in the bi*b*ag air separation chamber. When bi*b*ag is not used for bicarbonate during dialysis (jug mode), this valve will open momentarily when air is detected in the bi*b*ag 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 bi*b*ag dialysis. Opens to empty the bi*b*ag disposable and during bi*b*ag 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 - bi*b*ag Pressure Transducer
The bi*b*ag pressure transducer is used to measure the pressure inside the bi*b*ag disposable. Also used to measure the pressure of the sodium bicarbonate concentrate source when bi*b*ag is not used.

111 – bi*b*ag Air Separation Chamber
The bi*b*ag air separation chamber separates air from the sodium bicarbonate concentrate upon leaving the bi*b*ag disposable. It also is used to separate air from the sodium bicarbonate concentrate supplied by external sources (pre-mixed concentrates).

112 – bi*b*ag Air Separation Chamber Air Sensor
The bi*b*ag air separation chamber air sensor detects air in the air separation chamber.

113 – bi*b*ag Conductivity Cell
The bi*b*ag conductivity cell is used to measure the conductivity of the sodium bicarbonate concentrate leaving the bi*b*ag disposable and the conductivity of the pre-mixed concentrates.

Hydraulic Component Descriptions (cont.)

114 – bi*b*ag Temperature Thermistor
The bi*b*ag temperature thermistor is used to measure the temperature of the bicarbonate concentrate leaving the bi*b*ag disposable and the pre-mixed concentrate.

115 – bi*b*ag Present Switch
The bi*b*ag present switch is built into the bi*b*ag connector. The switch is positioned so that when a bi*b*ag disposable is attached to the bi*b*ag connector the switch is pressed indicating the presence of a bi*b*ag 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 bi*b*ag disposable after it is mixed with R.O. water.

118 – bi*b*ag Filter
Removes any particles that may enter through the bi*b*ag disposable.

bi*b*ag Connector

The bi*b*ag connector holds the bag with dry bicarbonate during dialysis. The bi*b*ag 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 bi*b*ag disposable may be installed or removed from the connector. The operating position (5) is used when a bi*b*ag 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.

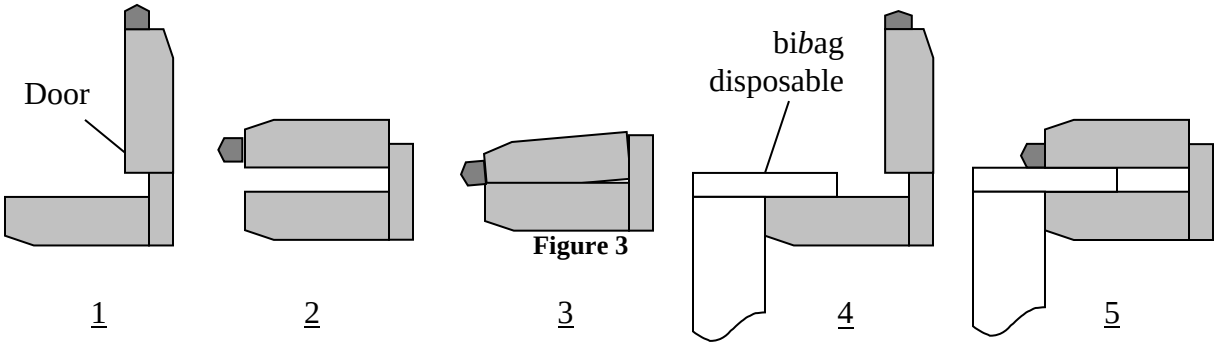


Figure 3

Hydraulic Operation

Dialysis with bi*b*ag

Heated water from chamber E of the hydrochamber flows to the junction of valves 100 and 103. Valve 100 opens and the bi*b*ag 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 bi*b*ag 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:

- ±5% of expected in Functional board software version less than 2.71
- ±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 bi*b*ag hydraulics. To run in this mode, the bi*b*ag 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 bi*b*ag 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 bi*b*ag valve sequence as in rinse.

Chemical Disinfection/Dwell

The same bi*b*ag valve sequence as in rinse

Acid Clean

The bi*b*ag valve sequence is the same as chemical rinse. Both concentrate and bicarbonate connectors are plugged into acid.

Heat disinfect

The bi*b*ag valve sequence is the same as rinse.

Flow off

Valves 100 and 101 closed. Valve 103 open

bi*b*ag Empty

The bi*b*ag empty procedure removes the liquid solution from the bi*b*ag disposable to make disposal easier and cleaner. To empty the bi*b*ag 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.

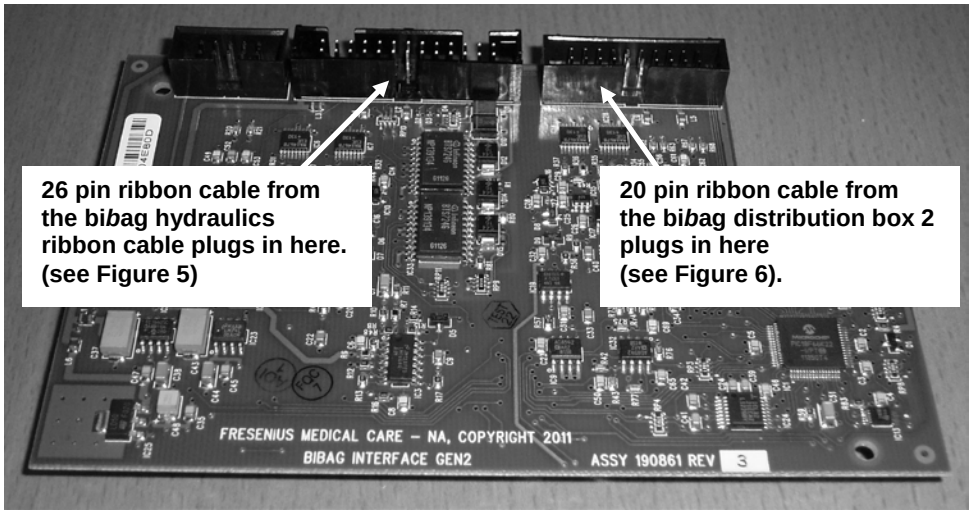


Figure 4 – bibag Interface Board

bi*b*ag Hydraulic Assembly – Distribution Board

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

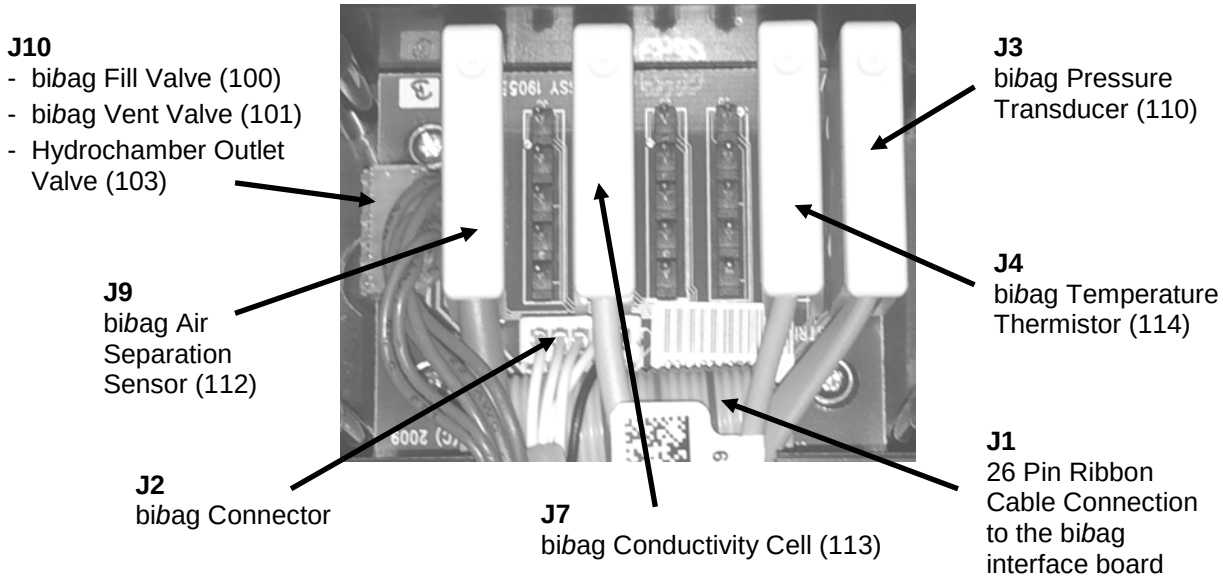


Figure 5 – bi*b*ag hydraulic Assembly – Distribution Board

bi*b*ag Distribution Box 2 – Distribution Board

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

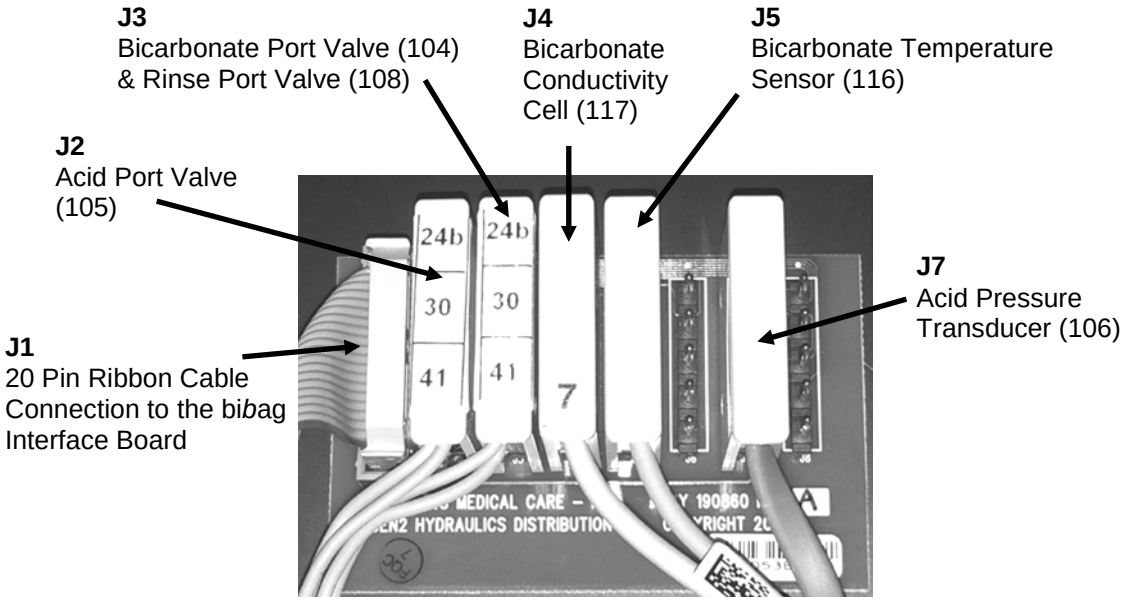


Figure 6 - bi*b*ag Distribution Box 2 – Distribution Board

Electronic Block Diagram

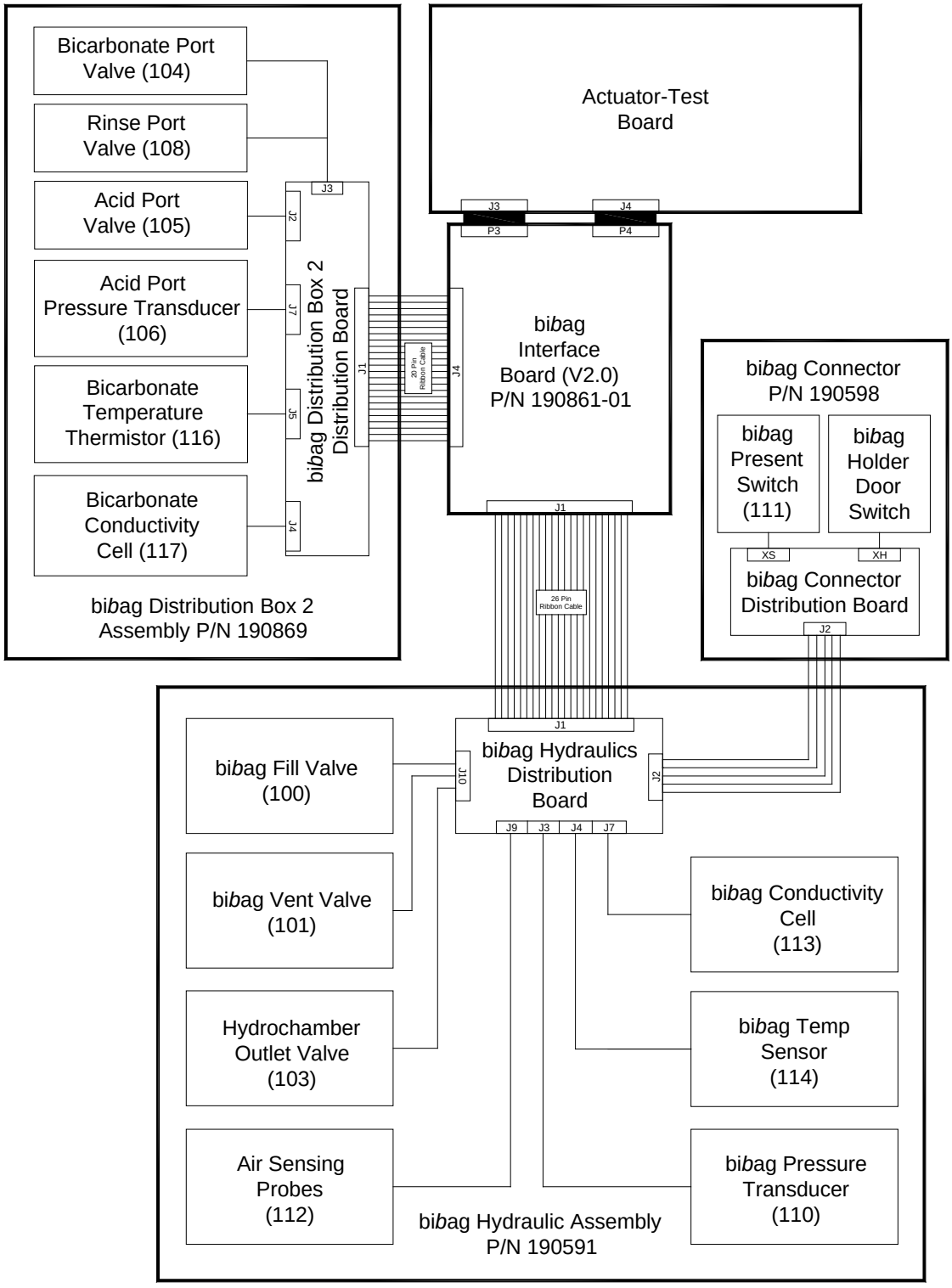


Figure 7

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)

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.

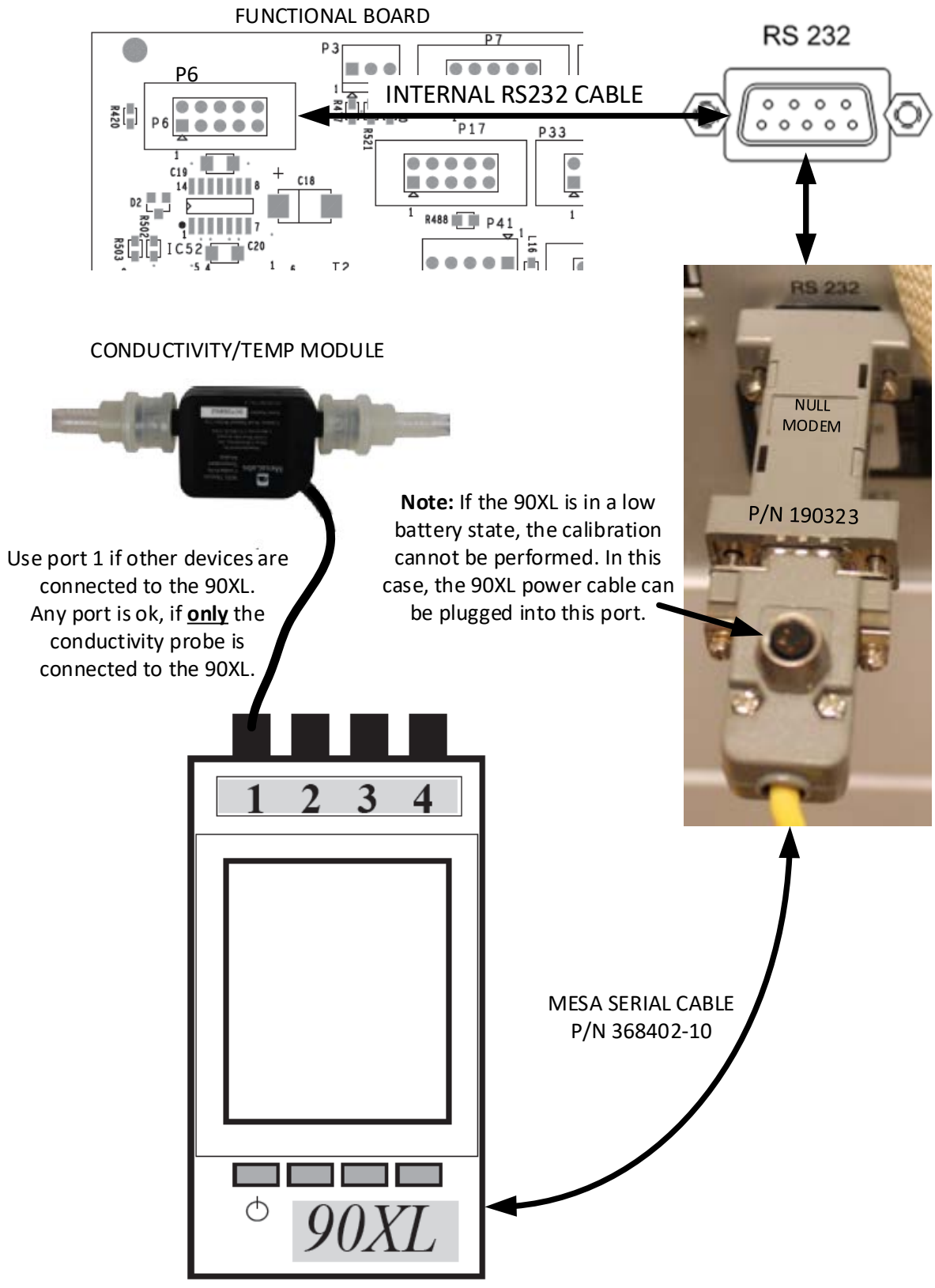


Figure 8 – Null Modem Connection to the 90XL

Annual Maintenance

Annual bi*b*ag maintenance consists of the following:

- Perform bi*b*ag Inlet Filter Replacement.
- Perform bi*b*ag Connector Maintenance.
- Perform the bi*b*ag Pressure Transducers calibration. (see page 12)

bi*b*ag Inlet Filter Replacement

Annually replace the filter (P/N M30225) in tubing assembly labeled 1 connected between the bi*b*ag connector and the bi*b*ag air separator.

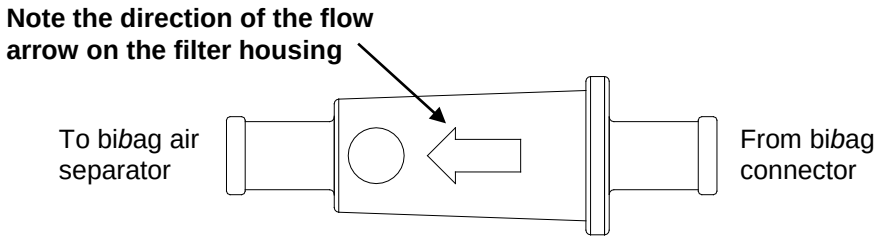


Figure 9 – bi*b*ag Inlet Filter (M30225)

bi*b*ag Connector Maintenance

Annually replace the two (2) o-rings (P/N 640919) on the bi*b*ag connector door.

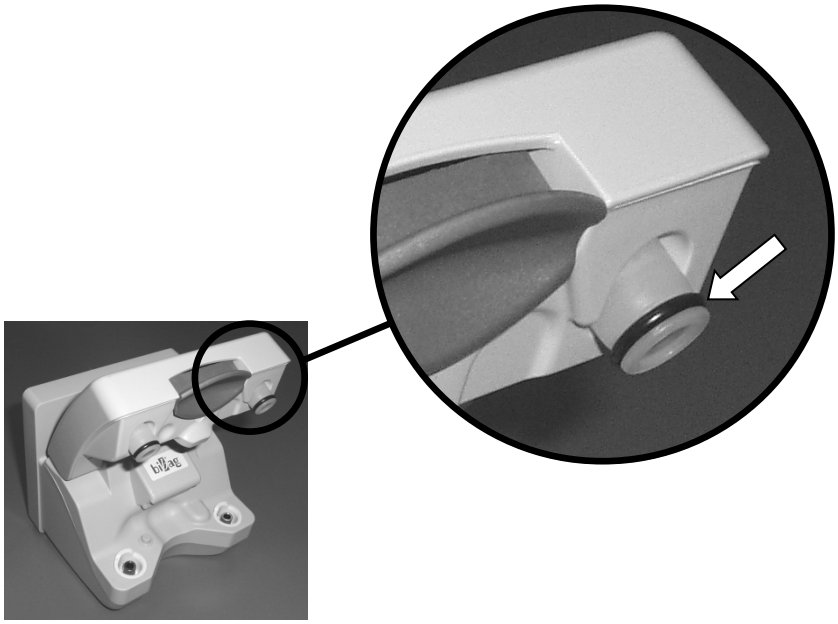


Figure 10– bi*b*ag Connector Door O-Rings (640919)

Troubleshooting

Error messages

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 list of bi*b*ag related messages can be found in the

2008®T Hemodialysis Machine bi*b*ag *Operator's Manual P/N 508213.*

2008K@home™ Hemodialysis Machine bi*b*ag *Operator's Manual P/N 508340.*

The list includes:

- The bi*b*ag related Message
- Meaning of the Message
- Action Required

A full list of machine messages may be found in the

2008®T Hemodialysis Machine Operator's Manual P/N 490122

2008K@home™ Hemodialysis Machine Operator's Manual P/N 490180

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 bi*b*ag spare parts can be found in the

2008 Series Hemodialysis Spare Parts Manual P/N 490124.

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