



***bibag*[®] V2.0**

Technician's Manual

Part Number 490188 Rev. K

bibag® V2.0 Technician's Manual

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bi*bag* V2.0 Technician's Manual

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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[®]T and the 2008K@home[™] 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.

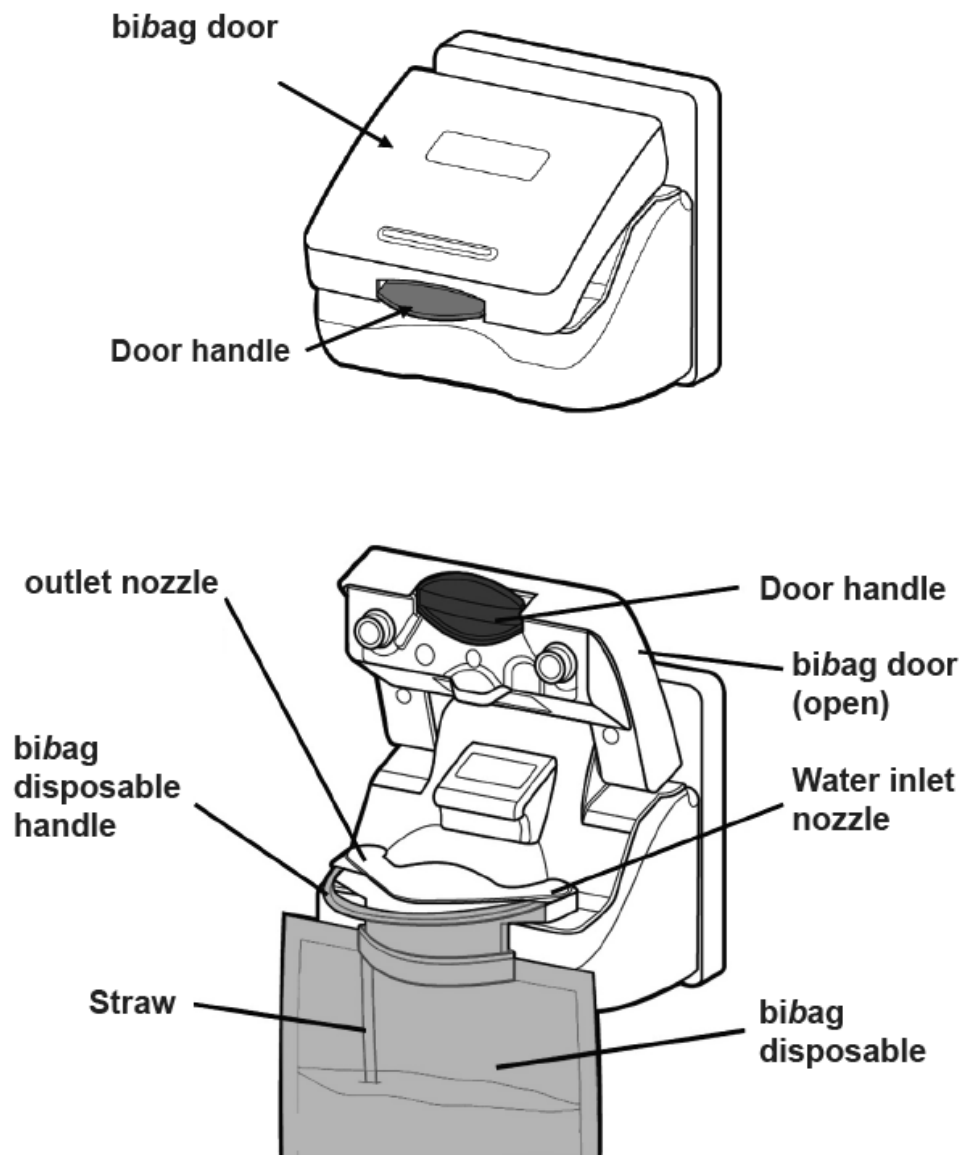


Figure 1 – *bibag* connector: door closed and *bibag* disposable inserted with door open

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 not initiate dialysis.



Warning: Replace a leaking *bi*bag 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*bag connector.



Note: When the *bi*bag 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

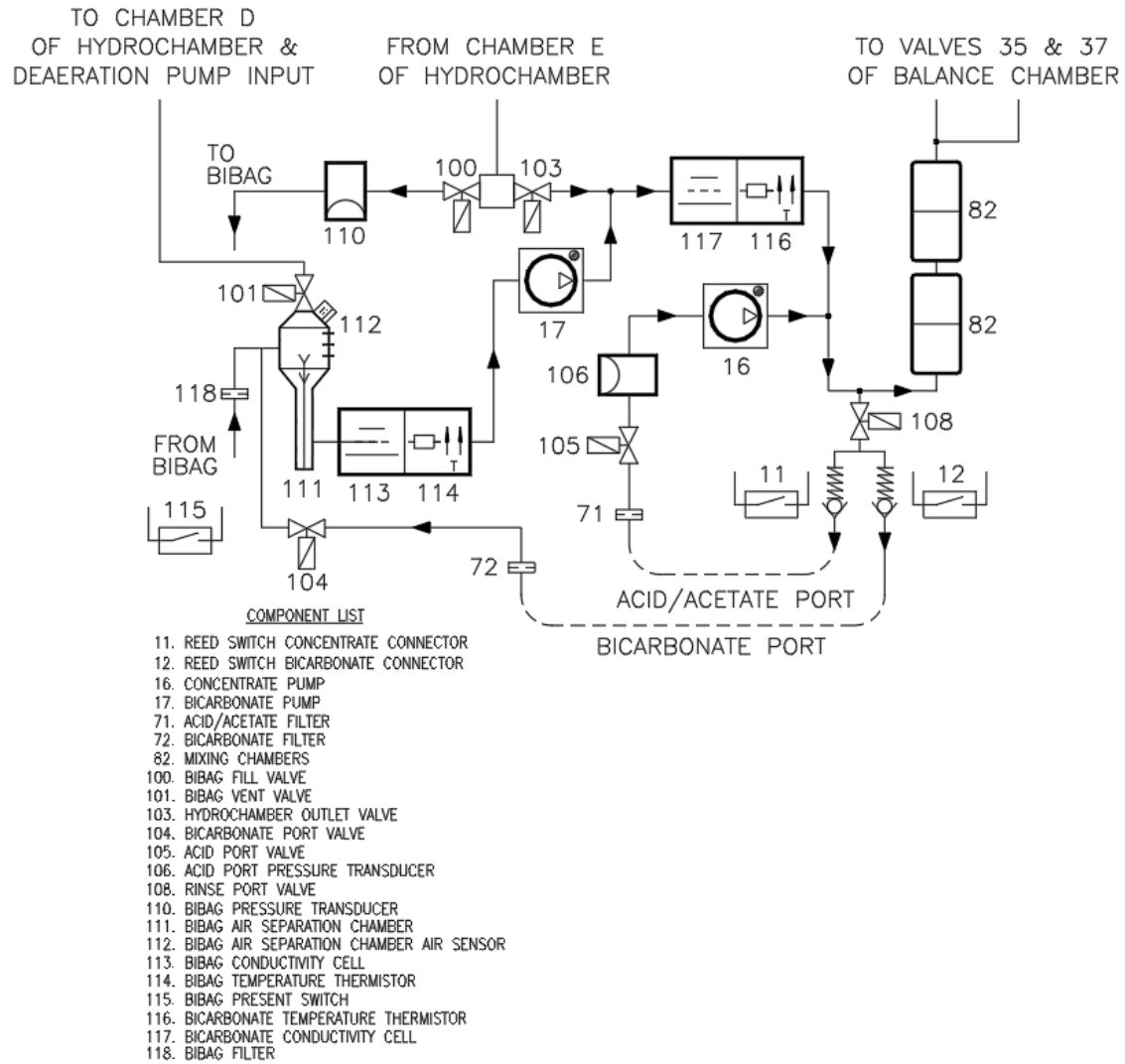


Figure 2

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.)

114 – bibag Temperature Thermistor

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

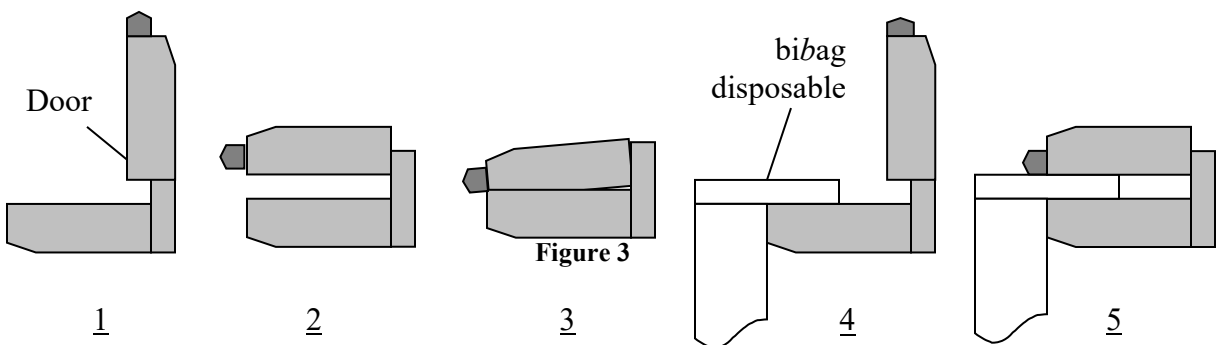
Measures conductivity of the bicarbonate concentrate from the bibag disposable after it is mixed with R.O. water.

118 – bibag Filter

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 *bi*bag

Heated water from chamber E of the hydrochamber flows to the junction of valves 100 and 103. Valve 100 opens and the *bi*bag 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*bag 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 *bi*bag hydraulics. To run in this mode, the *bi*bag 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*bag 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*bag valve sequence as in rinse.

Chemical Disinfection/Dwell

The same *bi*bag valve sequence as in rinse

Acid Clean

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

Heat disinfect

The *bi*bag valve sequence is the same as rinse.

Flow off

Valves 100 and 101 closed. Valve 103 open

bibag Empty

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

bi*bag* Interface Board

The *bi*bag interface board ‘piggybacks’ onto the actuator - test board and communicates with it. The *bi*bag hydraulic assembly and the *bi*bag distribution box 2 connect electrically to the *bi*bag interface board with ribbon cables.

The *bi*bag interface board contains all of the electronics required to activate the 5 additional valves, read conductivity from the *bi*bag and bicarbonate conductivity cells, read temperature from the *bi*bag and bicarbonate temperature thermistor, read the status of the *bi*bag air sensor, and read the status of the *bi*bag 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 *bi*bag interface board and the actuator - test board indicates to the system the presence of the *bi*bag hydraulic components.

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

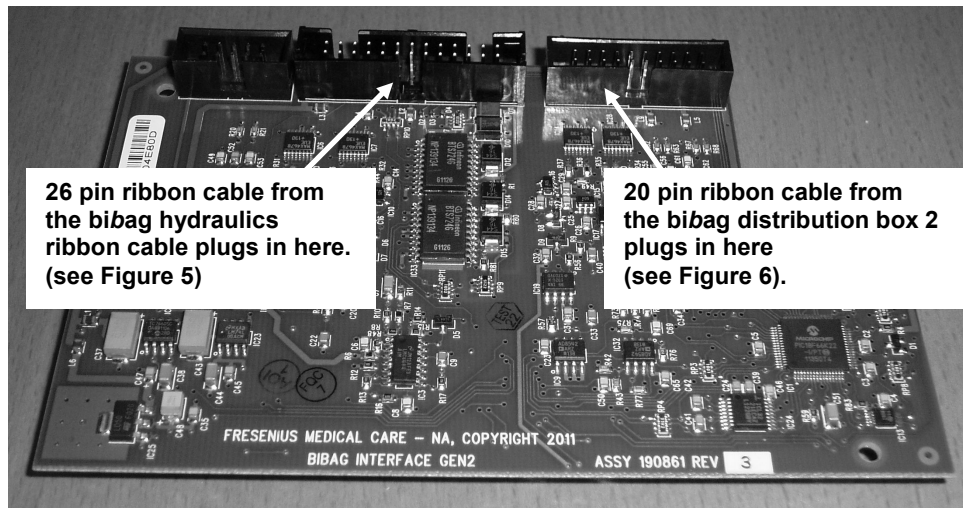


Figure 4 – *bi*bag Interface Board

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.

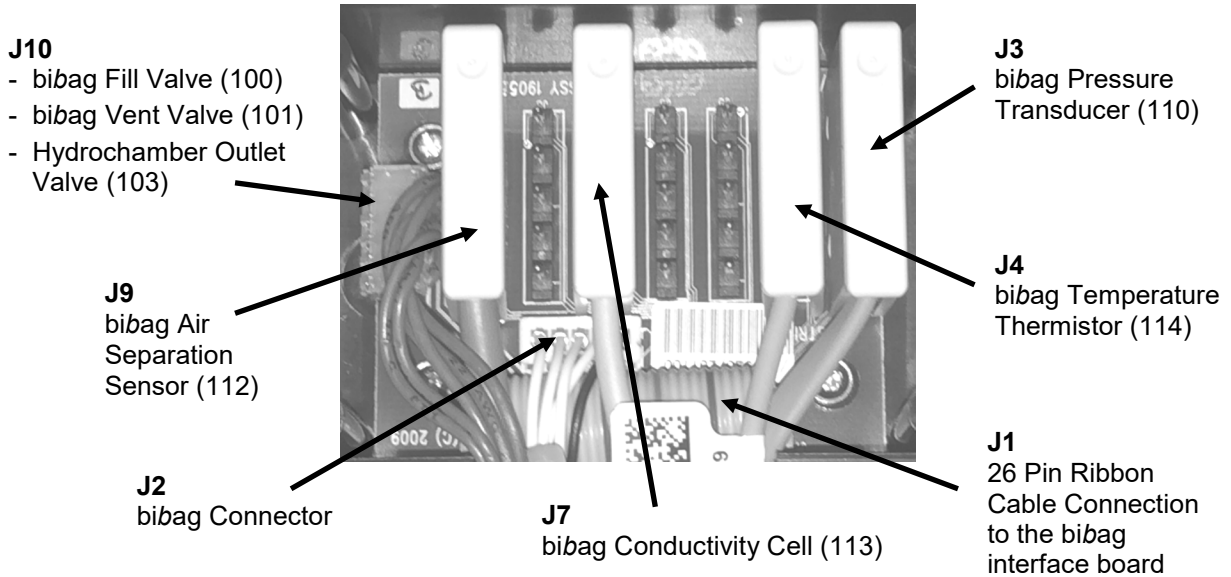


Figure 5 – bibag hydraulic Assembly – Distribution Board

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.

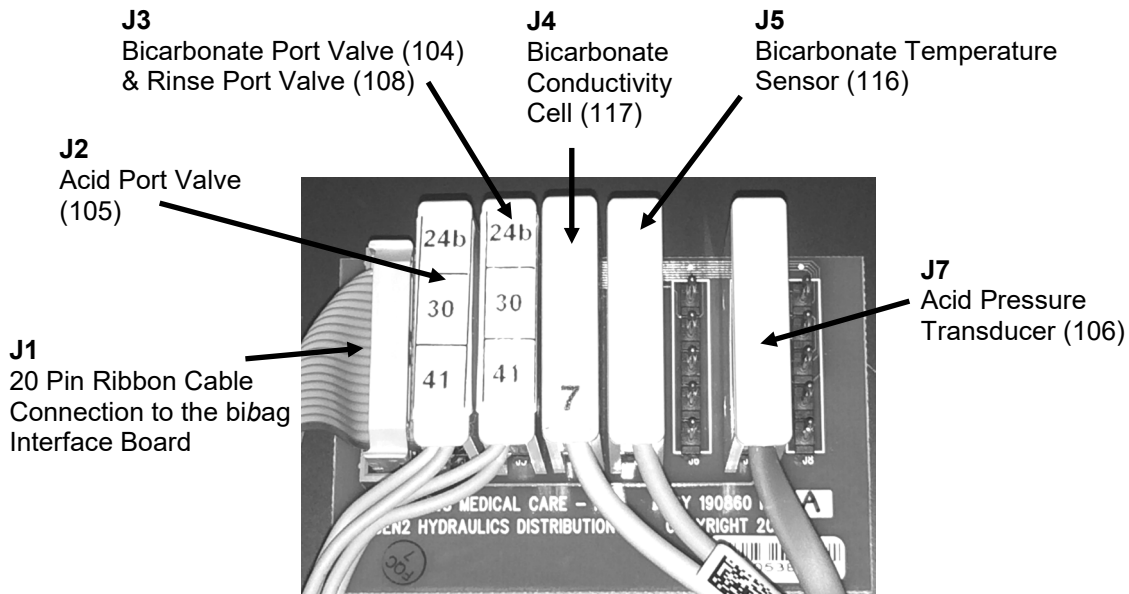


Figure 6 - bibag Distribution Box 2 – Distribution Board

Electronic Block Diagram

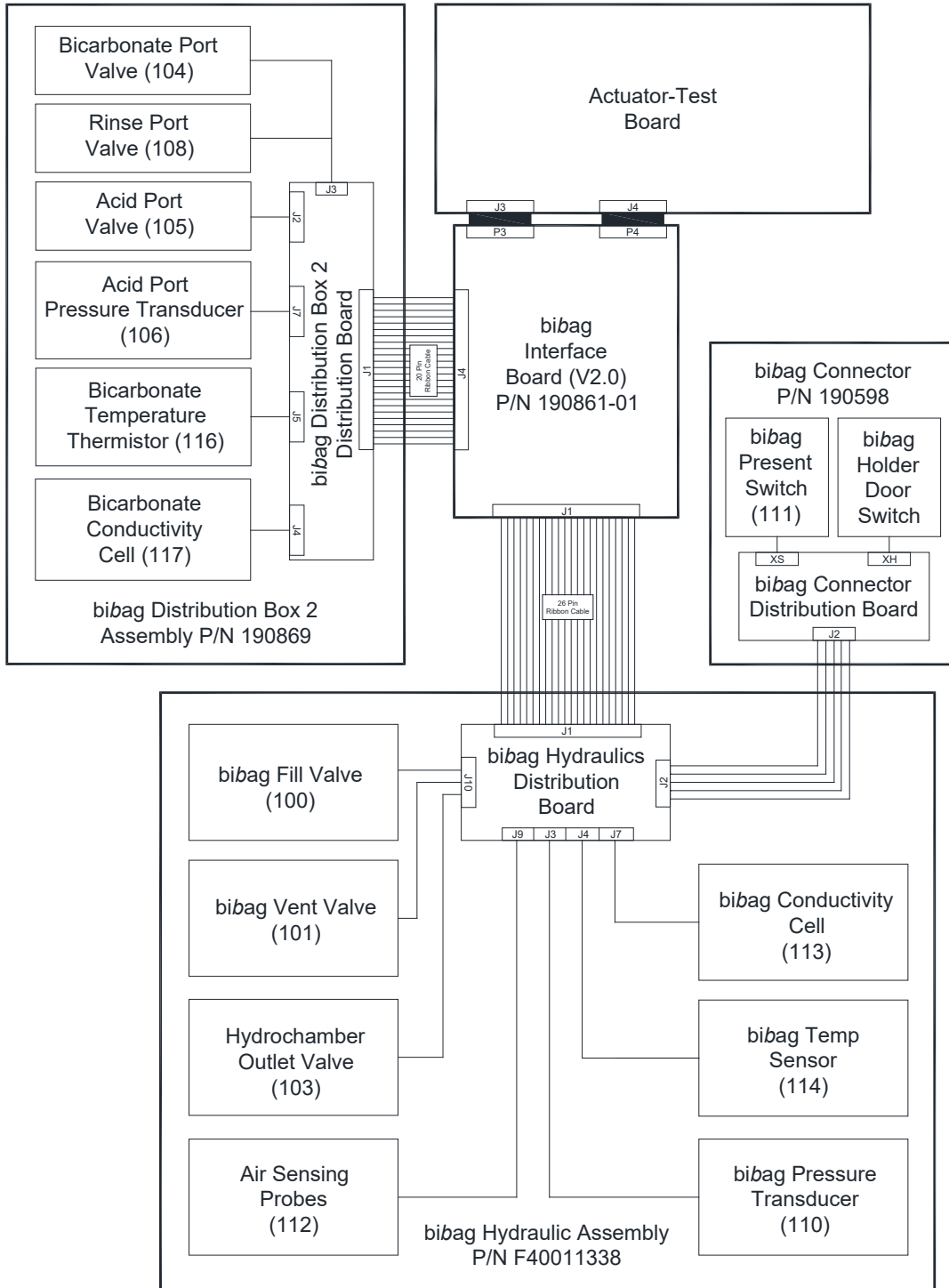


Figure 7

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.

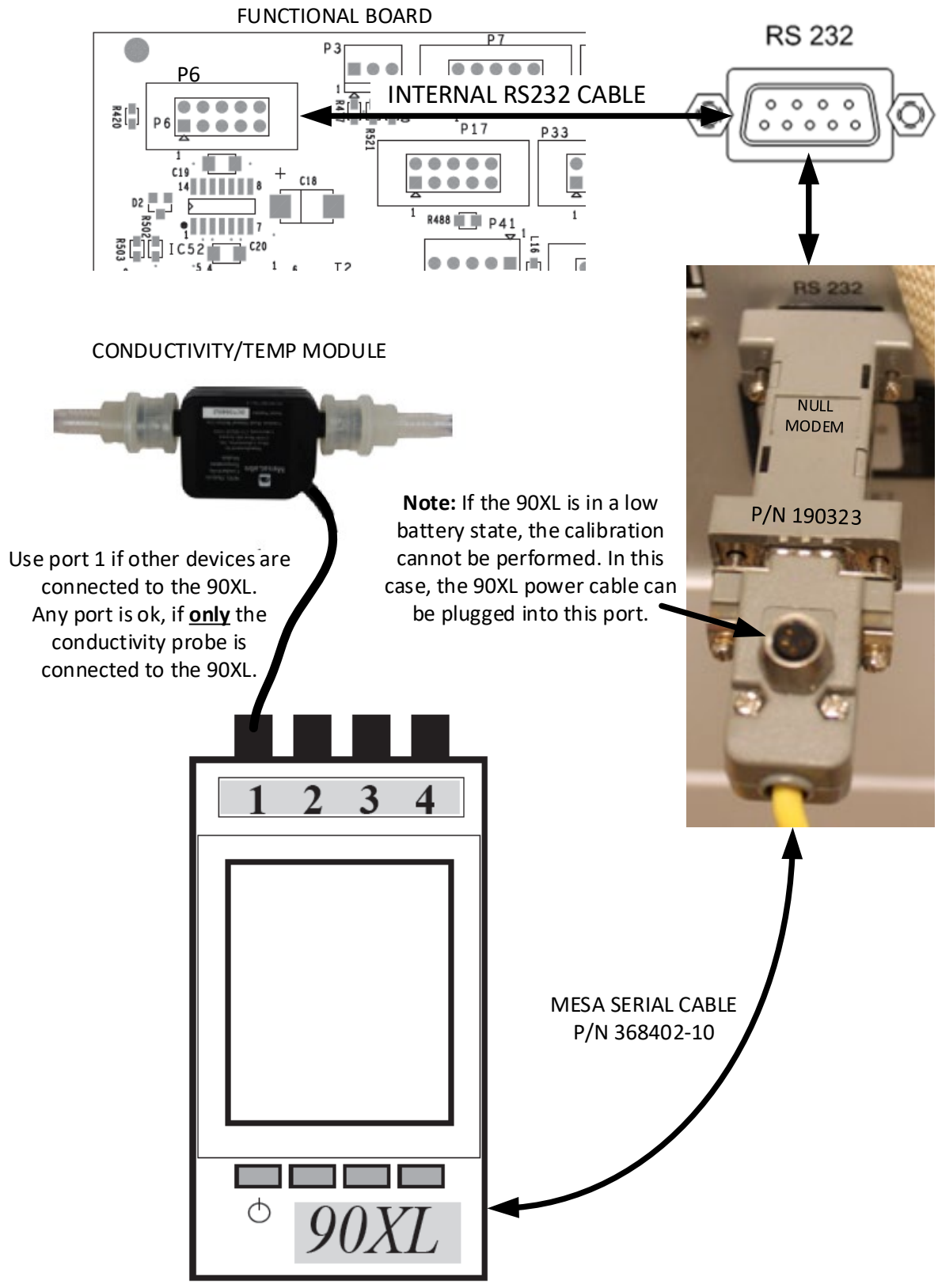


Figure 8 – Null Modem Connection to the 90XL

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

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 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.

The list includes:

- The bibag 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 bibag spare parts can be found in the

2008 Series Hemodialysis Spare Parts Manual P/N 490124.

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