

CONFIRM Concentrate

Med Primary

7:45

Unit: Connect    On: x

Med Time: 0:00

Dialysis Concentration

Conductivity Control

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# 20081

Quick Start Guide



## **Indications for Use:**

**2008T Hemodialysis Machine:** The 2008T hemodialysis machine is indicated for acute and chronic dialysis therapy.

**bibag® System (Optional):** The bibag system is used with three stream proportioning hemodialysis systems equipped with the bibag module such as the 2008T Hemodialysis Machine and is intended for use in bicarbonate hemodialysis for acute and chronic renal failure. The bibag is intended for extracorporeal bicarbonate hemodialysis according to a physician's prescription.

**Crit-Line® Clip Monitor (CLiC™) (Optional):** The Crit-Line Clip Monitor is used with the 2008T Hemodialysis Machine to non-invasively measure hematocrit, oxygen saturation and percent change in blood volume. The CLiC device measures hematocrit, percent change in blood volume and oxygen saturation in real time for application in the treatment of dialysis patients with the intended purpose of providing a more effective treatment for both the dialysis patient and the clinician. Based on the data that the monitor provides, the clinician/nurse, under physician direction, intervenes (i.e., increases or decreases the rate at which fluid is removed from the blood) in order to remove the maximum amount of fluid from the dialysis patient without the patient experiencing the common complications of dialysis which include nausea, cramping and vomiting.

This 2008T Hemodialysis Machine Quick Start Guide is intended to be a supplement to the 2008T Operator's Manual (P/N 490122) for single-use. Operators must read and understand the Operator's Manual supplied with the equipment. Attention must be given to all "Warning" and "Caution" statements in the Operator's Manual

**Caution:** Federal (US) law restricts this device to sale by or on the order of a physician.

**Note:** Read the Instructions for Use for safe and proper use of this device. For a complete description of hazards, contraindications, side effects, and precautions, see full package labeling available at [www.fmcna.com](http://www.fmcna.com).

## Notes

### **WARNING!**

**Failure to operate and maintain the machine according to the manufacturer's instructions may cause operator or patient injury or death.**

### **WARNING!**

**To maintain sterility of the blood pathway, do not allow the ends of the bloodlines to come in contact with non-sterile solutions or surfaces which may contaminate the blood pathway.**

**Note:** To confirm a changed parameter, do any of the following:

- Double-click the touchpad.
- Press the **Confirm** key.
- Press either of the **Enter** keys on the keyboard.

# Set Up Concentrate

1. Press the **Power** key on the control panel. The Select Program screen will then appear on the monitor.
2. Flip down the touchpad and/or the keyboard.
3. Plug the acid (red) concentrate connector into the acid source.
4. Select the **Dialysis** button, the Dialysate screen will appear on the monitor.
5. Confirm the concentrate. If the concentrate must be changed, select the **CONC** button, enter the concentrate type using the **Up** or **Down** Keys on the keyboard, then press **Confirm**.
6. Select the **Base Na+** and **Bicarbonate** buttons, enter the prescribed value using the data entry keys, and then press **Confirm**.
7. Select the **Home** button. The Home screen will appear on the monitor (Air Detector alarm will be displayed in the Status Box).
8. Plug the bicarbonate (blue) concentrate connector into the bicarbonate source.

**Note:** If the bibag disposable is the bicarbonate source, do not pull the blue bicarbonate connector from the machine's rinse port. Do the following to prepare the bibag disposable:

1. Remove the plastic seal from underneath the water and bicarbonate nozzles of the bibag disposable.
2. Open the bibag door on the machine by lifting up on the dark gray handle.

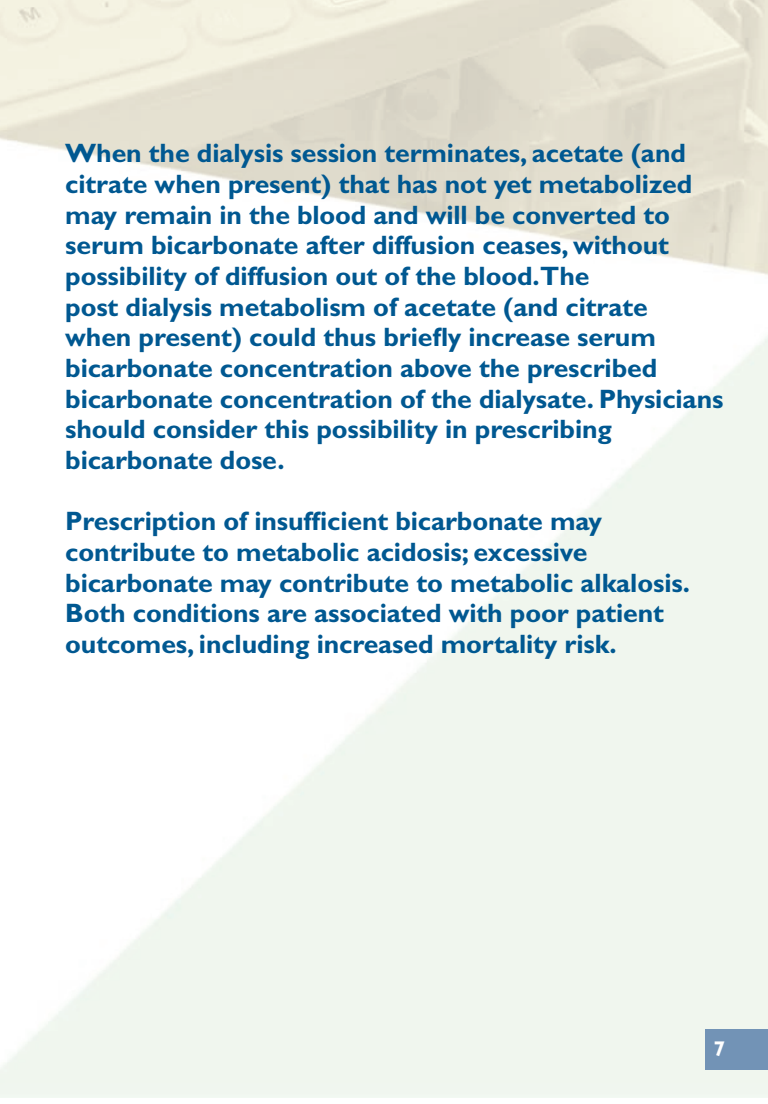
3. With the white *bibag* handle facing out (the blue labeling should be facing you), hang the bag on the *bibag* connector nozzles.
4. Close the door, making sure it latches firmly in place. You will hear an audible click indicating the door is closed.
5. When the machine is ready, (water is at the minimum temperature and no air in the hydraulics), the bag will fill with heated water to be used as a bicarbonate concentrate for dialysate production.

**Note:**

1. Dialysate flow must be on in order to fill the bag.
2. The *bibag* disposable contains a fixed amount of bicarbonate powder. Refer to the *bibag* Estimated Run Time Reference Card (P/N 101746-01 or P/N 102768-01) to verify that enough run time is available to complete a treatment.
3. Do not remove the blue bicarbonate connector from the machine's bicarbonate port while using the *bibag* system for treatment. Doing so will stop the flow to and from the *bibag* disposable.
4. The *bibag* disposable must hang freely below the *bibag* connector. Make certain that there are no jugs or other objects obstructing or touching the *bibag* disposable.

## **WARNING!**

**Acid concentrate products are used as one component in mixing dialysate bath. These acid products contain chemical compounds that, after mixing, yield acetate (and citrate in certain products) in the dialysate. (Please refer to the acid concentrate product labeling for specific acetate/citrate amounts.) After diffusion across the dialyzer membrane, acetate (and citrate when present) is metabolized by the liver to serum bicarbonate and adds to the serum bicarbonate that separately results from the diffusion of dialysate bicarbonate across the dialyzer membrane. During dialysis, the dynamic of diffusion and concentration gradients prevent serum bicarbonate concentration from exceeding the dialysate bicarbonate concentration. The bicarbonate concentration of the dialysate is the “bicarbonate” setting on the dialysis machine, and is the bicarbonate dose prescribed by the physician. On the 2008® series hemodialysis machines, the bicarbonate dose may be set in a range between 20 and 40 milliequivalents per liter, but may be set in different range in the other machines.**



**When the dialysis session terminates, acetate (and citrate when present) that has not yet metabolized may remain in the blood and will be converted to serum bicarbonate after diffusion ceases, without possibility of diffusion out of the blood. The post dialysis metabolism of acetate (and citrate when present) could thus briefly increase serum bicarbonate concentration above the prescribed bicarbonate concentration of the dialysate. Physicians should consider this possibility in prescribing bicarbonate dose.**

**Prescription of insufficient bicarbonate may contribute to metabolic acidosis; excessive bicarbonate may contribute to metabolic alkalosis. Both conditions are associated with poor patient outcomes, including increased mortality risk.**

# Setting-up Bloodlines and Priming Extracorporeal Circuit

Follow facility's policy and procedure guidelines for setting up bloodlines and priming the extracorporeal circuit.

**Note:** Policies and procedures should include the manufacturer's recommendation for use, including dialysis machine, bloodline, and blood chamber (if Crit-Line<sup>®</sup> technology is used), dialyzer and saline.



# Pressure and Alarm Tests

1. To run the tests, verify:
  - a. Dialysate lines are on the shunt interlock with the interlock door closed.
  - b. The machine is alarm-free.
  - c. Arterial and venous pressure monitor lines are clamped and disconnected so the pressure ports are open to the atmosphere.
  - d. UF and SVS are off.
2. Select the **Test & Options** button.
3. Select and confirm the **Both Tests** button to begin running the pressure and alarm tests.
4. When the message “Test Complete” is displayed in the status box, press **Reset** to clear the message.

# Recirculation

1. If applicable, based on the specific bloodline and dialyzer being used, rotate the dialyzer so the arterial (red) inlet is up.
2. Check the conductivity and the pH of the dialysate and test for residual disinfectant, if applicable, before connecting the dialysate lines to the dialyzer.

## **WARNING!**

**Always verify the conductivity and approximate pH of the dialysate solution through independent means (e.g. using a conductivity meter or pH paper or meter, as applicable) before initiating each dialysis treatment. Verify that the conductivity is reasonably close to the theoretical conductivity value (TCD) and the pH is between 6.9 and 7.6. If they are not, do not initiate dialysis.**

3. Connect the dialysate lines to the dialyzer by matching the color of the dialyzer connector to the color of the blood tube fitting (red-red and blue-blue), and then close the shunt door. Pull on the dialyzer connectors to make sure they are firmly connected to the dialyzer.
4. Connect the arterial and venous pressure monitor lines to their respective pressure ports, and then unclamp the lines.

5. When the dialysate compartment is filled, rotate the dialyzer so the arterial (red) inlet is down.
6. After priming the extracorporeal blood circuit, press **Reset** to clear all alarms. Set the blood pump per facility's policy to begin recirculating saline through the circuit.
7. Press the **Down Arrow** on the level detector module to lower the fluid level in the drip chamber. Verify that the blood pump stops and the venous clamp occludes.
8. Check blood tubing to ensure there are no kinks.
9. Replace saline bag with a fresh bag, if necessary.
10. Check for a normal dialysate flow by watching the float in the dialysate line. The float should drop four times in about 15 seconds for a 500 ml/min flow, or four times in 10 seconds for an 800 ml/min flow.
11. Open the shunt door to verify the machine goes into Bypass Mode. In Bypass Mode, the float in the flow indicator of the dialyzer supply line should drop and remain at the bottom of the indicator and an audible alarm may sound.
12. Close the shunt door again.
13. Set treatment parameters as prescribed.

**Note:** If **Prime/Recirc** option selected, wait until **Recirc** is done before entering parameters.

# Starting Dialysis

1. Complete patient assessment per unit policy and procedures.
2. Wrap blood pressure cuff around the patient's non-access arm.
3. If the CLiC™ device will be used for this treatment, clip the CLiC device on the Crit-Line blood chamber at this time. For more information, see the “2008T Hemodialysis Machine with CLiC User's Guide” (P/N 490206).
4. Verify that ultrafiltration is off (UF light is off), and that the **UF Removed** button is reset to zero. The **UF Removed** button may be reset by selecting **UF Removed** button, and then the zero key and confirm the change.
5. Verify the venous line is in the venous clamp and the optical detector door is closed.

## **WARNING!**

**Do not infuse the recirculated saline prime into the patient. Discard the recirculated saline and fill the extracorporeal circuit with fresh saline prior to connecting to the patient. The volume of fresh saline that is used to fill the extracorporeal circuit should be equal to the volume of the dialyzer and blood tubing set in use.**

6. Lower the blood pump rate to the “Facility’s Initiation of Treatment Policy and Procedures” and press the **Start/Stop** key to stop the blood pump.
7. Connect the arterial and venous bloodlines to patient’s access and initiate treatment per the unit’s protocol.

## **WARNING!**

**Check all bloodline and dialysate line connections for fluid leaks. Keep access sites uncovered and monitored. Improper bloodlines connections or needle dislodgements can result in excessive blood loss, serious injury, and death. Machine alarms may not occur in blood loss situation.**

8. Press the **Start/Stop** key to start blood pump and set QB and QD to prescribed rates.
9. Rotate the dialyzer to arterial (red) end up.
10. Select the **TX Clock** button when the status box turns yellow and press **Confirm** to start the treatment. The status box will now show “Dialysis.”
11. Check that **UF/SVS/Heparin** are on, if prescribed. Check that the Crit-Line device is attached to the Crit-Line blood chamber, if prescribed. If applicable, a blood pressure measurement is initiated.

# Completion of Dialysis

1. Press **Reset** to clear any alarms.
2. Select the **TX Clock** and press **Confirm** to stop the treatment. The status box will now show “Dialysis Paused.”
3. Press the **Start/Stop** key on the blood pump to stop the pump.
4. Replace saline bag with a fresh bag, if necessary.
5. Rinse the blood in the extracorporeal circuit back to the patient utilizing the “Facility’s Termination of Treatment Policy and Procedures.”
6. Clamp the arterial and venous bloodlines and the patient’s arterial and venous access lines and aseptically disconnect them.

**Note:** If applicable, the following procedure may be done utilizing “Facility Policies and Procedures.”

**Note:** If the bibag disposable was used for the treatment, go to the Dialysate Screen and select “Empty bibag” and confirm. Once the bibag is empty, proceed to emptying the dialyzer. The bibag disposable and the dialyzer cannot be emptied at the same time. To run the Empty bibag program, both dialysate lines must either be on the shunt or on the dialyzer.

## For Single-Use Dialyzers:

7. Open shunt interlock door.
8. Return blue dialyzer connector to shunt interlock. Pull on the dialyzer connector to make sure it is firmly connected to the shunt.
9. Reposition the dialyzer so that the red outlet port is at the bottom.

10. Close the shunt interlock door. Message “Emptying” will be displayed.
11. Drain the dialysate compartment. The dialyzer is empty as soon as there is air in the outlet line or an “Emptying stopped” message appears.
12. Open the shunt interlock door, remove red dialyzer connector from the dialyzer and place it on the shunt. Pull on the dialyzer connector to make sure it is firmly connected to the shunt. Close the shunt interlock door.
13. Discard the bloodlines, transducer protectors, and dialyzer according to facility policy.
14. Insert the concentrate wands into their proper rinse ports. The “Select Program” screen appears on the display screen.
15. Clean or disinfect the exterior of the machine according to routine cleaning and maintenance procedures described in “Disinfection and Maintenance,” on page 136.
16. ***If there is another patient:***
  - Press the new **TX** key and then **Confirm**.
  - The treatment parameters will be reset to the default settings. The sodium, bicarbonate, and concentrate type will maintain the previous TX settings.
17. ***If there is not another patient:***
  - Return acid and bicarbonate (if used) connectors to their respective ports, and then proceed with cleaning and disinfecting.

# Acid Clean & Heat Disinfection

1. To run the cleansing/disinfecting programs, verify:
  - Dialysate lines are securely on the shunt.
  - Acid and bicarbonate connectors are securely inserted into their respective ports.
2. After the last treatment of the day, select the **Acid Clean** and **Heat Disinfect** button on the Select Program screen and press **Confirm**.
3. When prompted, connect acid (red) and bicarbonate (blue) connectors to jug containing acid cleaner.
4. Press **Confirm** to start the **Acid Clean** portion of the program.
5. When completed, the message “Put Connectors in ports” will appear. Put acid and bicarbonate connectors securely into the respective machine ports.

## **WARNING!**

**During the heat disinfection cycle, it is not uncommon to see steam emitting from the vent tubing at the back of the machine. This steam may cause burns if contacted. Also, the temperature of the dialysate lines and drain line can get as hot as 69°C (156°F). Please use care.**

## **WARNING!**

**Do not open the bibag door during a heat disinfection as serious injury may occur. Keep**



**the bibag door closed when running any rinse or disinfection program.**

6. The “Heat Disinfect” screen appears next in the display. The machine will automatically run a short rinse (seven minutes standard or ten minutes with DIASAFE® Plus) or extended rinse (twenty minutes) depending how the machine was configured in Service Mode.
7. After the heat disinfection is complete, if the machine is not configured to automatically turn off at the completion of the cycle, press **Confirm** to exit when prompted.

**Note:**

- If the machine is not configured to automatically turn off at the completion of the heat cycle, press **Confirm** to exit when prompted. Press and hold the **Power** key to turn off the machine.
- If acid cleaning is not needed, select the **Heat Disinfection** button on the Select Program screen and press **Confirm** to start the **Heat Disinfection** program. When the program is complete, the machine should turn off automatically (see note above).
- If the **Auto Heat Disinfection** service option is set:
  - o After completion of the **Acid Clean**, leave the machine on the Select Program screen. The **Heat Disinfect** program will run at the scheduled time.

# Acid Clean & Chemical Rinse

1. To run the Cleaning/Disinfecting programs, verify:
  - Dialysate lines are securely on the shunt.
  - Acid and bicarbonate connectors are securely inserted into the respective machine ports.
2. After the last treatment of the day, select the **Acid Clean** button on the Select Program screen and press **Confirm**. The lines will be rinsed.
3. When prompted, connect acid (red) and bicarbonate (blue) connectors to a jug containing acid cleaner.
4. Press **Confirm** to start.
5. When the **Acid Clean** program is completed, the message “Put Connectors in Ports” will appear. Put acid and bicarbonate connectors securely into their respective ports and press **Confirm** to exit.
6. Select the **Chemical/Rinse** button on the Select Program screen and press **Confirm**. The lines will be rinsed.

**Note:** If the “**HE Leak Test**” Service Mode option is selected (software versions 2.53 and later), the machine will run a four minute pressure holding test after the 45 second pre-rinse. If the first test fails, a second test will automatically run.

If the second test fails, the machine will display a “System Leak, Can’t Run” message, meaning that the Chemical/Rinse program can no longer be run due to a leak detected in the

Heat Exchanger. However, the machine will still be able to run Heat Disinfection programs and hemodialysis treatments per unit protocol. Call a qualified service technician.

7. When prompted, connect the red acid connector to a jug containing chemical disinfectant and press **Confirm**.
8. Water pre-rinse will start. Remaining pre-rinse time meter box will count down. When the remaining pre-rinse time meter box reads **0:00**, chemical rinse will start after a delay. Remaining time meter box will count down.
9. When the remaining time meter box reads **0:00**, remove the red acid connector from the disinfectant jug and insert it into the acid rinse port when prompted. Post rinse will start, and remaining post rinse time meter box counts down.
10. Press **Confirm** to exit.

## **WARNING!**

Test for residual disinfectant prior to starting treatment following a chemical disinfection.

**Note:** The machine will automatically perform a **DIASAFE** test after the chemical rinse program completes. When the message “**DIASAFE Test Passed**” is displayed, press the **Reset** key to clear the advisory. Then, press **Confirm** to exit.



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