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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.

P/N 490148 Rev C 02/2015

A Quick Start Guide

2008K²

FRESENIUS MEDICAL CARE
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Notes

NOTE

Indication for Use: The 2008K² hemodialysis machine is indicated for acute and chronic dialysis therapy.

This 2008K² Hemodialysis Machine Quick Start Guide is intended to be a supplement to the 2008K² Hemodialysis Machine Operator's Manual (P/N 490136) using single-use dialyzers and the Prime Amount method of priming. 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.

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 path, do not allow the ends of the bloodlines to come into contact with non-sterile solutions or surfaces which may contaminate the blood path.

Setup Concentrate

Setup Concentrate:

1. Press the **POWER** key on the control panel. The "Select Program" screen will appear on the monitor.
2. Plug the acid (red) concentrate connector into acid concentrate source.
3. Use navigational arrows to highlight "Dialysis" and **CONFIRM**.
4. Use navigational arrows to highlight **Conc** button and press **CONFIRM**, use up/down arrows to choose the correct acid concentrate and press **CONFIRM**.
5. Navigate to highlight **Base Na+** and **Bicarbonate** buttons, enter value with the up/down or data entry keys and **CONFIRM**.
6. Press **Home** screen-key. The "Home" screen will appear on the monitor (Air Detector alarm will be displayed in the Status Box).
7. Plug the bicarb (blue) concentrate connector into bicarbonate concentrate source.
8. Verify the Dialysate Flow is at least 500 ml/min.

Setup Concentrate (continued)

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 ranges in 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.

Setup Bloodline

Arterial Line:

1. Close medication port clamp.
2. Snap arterial drip chamber into holder.
3. Connect monitor line to arterial pressure port with a transducer protector and verify the line is unclamped.
4. Insert blood pump segment into blood pump and close door.
5. Snap bloodline into red guides on modules.
6. Aseptically place the patient end of the arterial line into priming bucket clip. Snap the dialyzer end of the arterial line into the dialyzer holder clip.

Venous Line:

1. Close medication port clamp.
2. Roll the venous drip chamber into holder with filter below sensor heads; close and latch door.
3. Connect monitor line to pressure port with a transducer protector and verify the line is unclamped.
4. Snap bloodline into blue guides on modules (do not insert into venous clamp yet).
5. Snap dialyzer end of bloodline into dialyzer holder clip.
6. Aseptically place patient end of venous line into priming bucket clip.

Dialyzer:

1. Place dialyzer into holder, arterial end up.

Prime Extracorporeal Circuit

1. Connect dialyzer end of arterial line to the arterial port of the dialyzer. Rotate the dialyzer to the arterial end down position.
2. Connect the dialyzer end of the venous line to the venous port of the dialyzer.
3. Hang a saline bag and attach an administration line, if not already attached, to the saline port on the arterial bloodline. Aseptically spike the saline bag.
4. Gravity prime the patient end of the arterial bloodline below the saline "T" with saline. When primed, clamp off the patient end of the arterial bloodline.
5. If the heparin pump is to be used: connect heparin syringe, prime heparin line and load heparin syringe into heparin pump. If heparin pump is not used, clamp the heparin line.
6. Press the **Prime** key.
7. Press the blood pump **Start/Stop** key. Set blood speed to 150 ml/min.
8. Fill arterial drip chamber to an acceptable level using level adjust key. Clamp arterial monitor line and disconnect from machine so pressure port is open to atmosphere.
9. The blood pump will continue to run until the pre-set amount of saline has been flushed through the circuit. When blood pump stops, clamp the patient end of the venous bloodline.
10. Insert the venous line in venous line clamp and optical detector and close the optical detector door.
11. Fill venous drip chamber with **level adjust** key, clamp venous monitor line and disconnect from machine so pressure port is open to atmosphere.
12. Aseptically connect patient ends of arterial and venous bloodlines together and open arterial and venous bloodline clamps.
13. Set the blood pump rate to 350-400 ml/min. Press the blood pump **Start/Stop** key to start the pump and begin recirculation. If necessary, press **RESET** to clear any alarms.
14. Ensure that the extracorporeal circuit is free of air bubbles.

Test

1. To run the tests, verify:
   - Dialysate lines are on the shunt interlock with the interlock door closed.
   - The machine is alarm-free.
   - Arterial and venous pressure monitor lines are clamped and disconnected so the pressure ports are open to atmosphere.
   - UF and SVS are off.
2. Press the **Test & Options** screen-key and press **CONFIRM**.
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 message.

Recirculation

1. Rotate the dialyzer so the arterial end is up.
2. Check the conductivity and pH of the dialysate and test for residual disinfectant.

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 value (TCD) and the pH is between 6.9 and 7.6. If they are not, do not initiate dialysis.

3. Attach dialysate connectors to dialyzer (using counter-current flow, red to red and blue to blue) and close shunt door.
4. Connect the arterial and venous pressure monitor lines to their respective pressure ports. Unclamp the lines.
5. When the dialysate compartment is filled, rotate the dialyzer so the arterial inlet is down.
6. Press **RESET** to clear all alarms. Set the blood pump rate to 350-400 ml/min and start the blood pump to begin recirculating saline through the circuit.

Recirculation (continued)

7. Test the level detector by pressing on the level adjust **down arrow** key on the level detector to lower the fluid level in the venous drip chamber. Verify that the blood pump stops and the venous clamp closes. Use the **up arrow** key to raise the level back to an acceptable level.
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. Open the shunt door to verify the machine goes into bypass by observing the float in the dialysate line. Close the shunt door again.
11. Set treatment parameters as prescribed.

Starting Dialysis

1. Complete patient assessment per unit policy.
2. Wrap blood pressure cuff around the patient's non-access arm.
3. Verify ultrafiltration is off (UF light on control panel is off) and that the **UF Removed** button is reset to zero.
4. Verify the venous line is in the venous clamp and the optical detector. Verify that the optical detector door is closed.

WARNING
Discard the recirculated saline and fill the bloodlines with fresh, sterile saline.

5. Lower the blood pump rate to 150 ml/min and press the **Start/Stop** key to stop blood pump.
6. Connect the patient and initiate treatment per unit protocol.
7. Press the **Start/Stop** key to start blood pump and set QB & QD to prescribed rates.
8. Rotate the dialyzer to arterial end up.
9. Select the **Tx Clock** button and press **CONFIRM** to start the treatment, the Status Box will now show "Dialysis."
10. Check that UF/SVS/Heparin are on, if prescribed. If applicable, a blood pressure measurement is initiated.

Completion of Dialysis

1. Press **RESET** to clear any alarms.
2. Using navigational arrows, highlight **Tx Clock** button and then **CONFIRM**. 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 patient end of the arterial bloodline back to the patient:
   - Using a hemostat, clamp the arterial bloodline directly above the saline "T."
   - Open the saline line clamps and rinse the blood in the tubing below the saline "T" back to the patient. When the blood in the line has been rinsed back to the patient, close the saline line clamps.
6. Rinse the remaining blood in the bloodline back to the patient:
   - Clamp the arterial bloodline directly under the saline "T."
   - Remove the clamp on the bloodline above the saline "T" and open the saline line clamps.
   - Start the blood pump and set a rate of 150-200 ml/min.
   - When the blood has been returned to the patient, turn the blood pump off and close the saline line clamps.
7. Clamp the arterial and venous bloodlines and the patient's arterial and venous access lines and aseptically disconnect them.
8. Empty the dialyzer:
   - Open the shunt interlock door and return the blue dialysate line to the shunt interlock. Place a dialyzer cap on the open dialyzer port.
   - Rotate the dialyzer so the red connector is down then close the shunt door. The Status Box will display "Emptying."
   - When "Emptying stopped" is displayed, open the shunt door, return the red dialysate line to the shunt interlock and close the shunt door. Place a dialyzer cap on the open dialyzer port.
9. Discard the bloodlines, transducer protectors, and dialyzer according to unit policy.
10. Clean or disinfect the machine exterior according to unit policy.
11. ***If there is another patient:***
    Press the **New Tx** key and then **CONFIRM**. The treatment parameters will be reset.

    If there is not another patient:
    Return acid and bicarb connectors to their respective ports securely and proceed with cleaning and disinfecting.

Acid Clean & Heat Disinfect

1. To run the cleansing/disinfecting program, verify:
   - Dialysate lines are securely on the shunt.
   - Acid and bicarb connectors are securely inserted into machine ports.
2. After the last treatment of the day, highlight the **Acid Clean** button and then press **CONFIRM**. The lines will be rinsed.
3. When prompted, connect acid (red) and bicarb (blue) connectors to jug containing acid cleaner.
4. Press **CONFIRM** to start the Acid Clean program.
5. When completed, the message "Put Connectors in ports" will appear. Put acid and bicarb connectors securely into respective machine ports and press **CONFIRM** to exit.
6. ***If the "Auto Heat Disinfect" service mode option is set:***
   Leave the machine on the "Select Program" screen. The heat disinfect program will run at the scheduled time.

   If the "Auto Heat Disinfect" service mode option is not set:
   Highlight the **Heat Disinfect** button on the "Select Program" screen and press **CONFIRM** to start the Heat Disinfect program. The lines will be rinsed with hot water. After the heat disinfect is complete, press **CONFIRM** to exit. Press and hold the **POWER** key to turn off the machine.

Acid Clean & Chemical Rinse (Bleach)

1. To run the cleansing/disinfecting programs, verify:
   - Dialysate lines are securely on the shunt.
   - Acid and bicarb connectors are securely inserted into machine ports.
2. After the last treatment of the day, highlight **Acid Clean** button and then press **CONFIRM**. The lines will be rinsed.
3. When prompted, connect acid (red) and bicarb (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 bicarb connectors securely into respective machine ports and press **CONFIRM** to exit.
6. Highlight the **Chemical/Rinse** button on the "Select Program" screen and press **CONFIRM**. The lines will be rinsed.
7. When prompted, connect the red acid connector to a jug containing chemical disinfectant and press **CONFIRM**.
8. When completed, the message "Put Connectors in Ports" will appear. Return red acid connector securely to machine port and machine will initiate a mandatory post-rinse.
9. If applicable, the machine will then run an automatic DIASAFE® filter test. When the message "Diasafe Test Passed" is displayed, press **CONFIRM** to exit.
10. Test for residual disinfectant prior to starting treatment following a chemical disinfection. When the residual disinfectant test results are negative, press and hold the **POWER** key to turn off the machine.