HEMODIALYSIS BLOOD TUBING SET WITH ATTACHED PRIMING SET, TRANSDUCER PROTECTORS AND INTEGRATED CRIT-LINE TECHNOLOGY

CATALOG NUMBER: 03-2722-9C and 03-2742-9C

INSTRUCTIONS FOR USE

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Operating Environment 20° C - 25° C

INDICATIONS FOR USE

- The Blood Tubing Set is a sterile, single use, disposable indicated for use with a prescribed hemodialyzer. The suitability of a particular bloodline/hemodialyzer configuration is the responsibility of the physician.
- The Blood Tubing Set is intended for acute and chronic hemodialysis therapy.
- The Blood Tubing Set is intended to be used with Fresenius Medical Care 2008® Series K, K^2 and T Hemodialysis Machines equipped with Crit-Line hardware.
- The Crit-Line Blood Chamber is an optical cuvette designed for use with the Crit-Line monitor's sensor clip during acute and chronic hemodialysis therapy to non-invasively measure hematocrit, percent change in blood volume, and oxygen saturation.

CONTRAINDICATIONS

- None Known

WARNINGS

- Single-use only; Do not reuse or alter this set.
- Product sterilized by ethylene oxide gas (EtO). STERILE EO
- Store in cool dry place. Protect from moisture, freezing, and excessive heat.
- Read, understand and follow all warnings, precautions and instructions contained in this document before attempting treatment. Failure to do so may result in patient injury or death.
- Do not use Blood Tubing Set if protective caps are missing, as blood pathway is no longer sterile and non-pyrogenic.
- Remove all paper tape as necessary before use.
- Do not use Blood Tubing Set if damaged or if protective caps are missing as the blood pathway is no longer sterile and non-pyrogenic.
- Always use aseptic technique when making or breaking any fluid path connection.
- Disinfect Blood Tubing Set access sites using 70% alcohol or 10% Povidone-Iodine solution. Other disinfectants intended to be used with this set must be determined as compatible prior to clinical use.
- Do not expose Blood Tubing Set connections to a lubricant. Exposure could cause connections to separate resulting in patient injury or death.
- Ensure all connections are secure before use and monitor for leaks regularly during patient use. Blood leaks can result if connections are not secure.
- Do not over-tighten arterial and venous Transducer Protectors (TP) to machine monitor ports. Twist connectors into the threaded machine monitor ports until secure and finger tight. Over-tightening may cause the connector to crack, resulting in inaccurate pressure readings and a leak.
- Do not perform a treatment without the use of a properly calibrated venous level detector. Always monitor the venous chamber with a level detector. Lack of detection may allow air to enter the Blood Tubing Set resulting in patient injury or death.
- Do not infuse recirculated saline into patient. Discard recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to patient.
- Ensure visibility of bloodline connection to fistula needles or catheter at all times during the treatment. Do not cover the access or bloodlines with a blanket or clothing prior to or during the treatment.
- Do not perform Air rinse-back at termination of dialysis.
- Do not exceed 600 mL/min blood flow rate.
- Do not exceed arterial or venous pressures of -300 mmHg or +500 mmHg, respectively.
- Hemolysis may occur at elevated negative or positive pressures. Excessive negative pressure may cause partial collapse of the pump segment resulting in an actual blood flow substantially less than indicated on the hemodialysis machine.
- Arterial pressures must always be monitored. Check bloodline and patient access when excessive arterial pressures are noted. Deficiencies in access flow or improper position of the fistula needles, bloodline, or catheter may cause reduced blood flow that can result in increased negative pressures.
- Potential consequences of not detecting inadequate pressure include hemolysis and vascular access complications.
- Clotting may result from inadequate heparinization, inappropriate fluid removal and stagnant blood flows.
- **Ensure there are no kinks in the bloodline tubing during set-up and patient use. Significant hemolysis of red blood cells can occur in kinked blood tubing, especially in the post pump arterial tubing segment.**
- All Blood Tubing Set clamps must be used either completely open or completely closed. These clamps are not intended to regulate the flow of fluids.
- Use of catheters, AVF needle sets or other devices not compatible with this set may result in blood/air leakage or accidental disconnection, air embolus, significant blood loss, patient injury or death. Multiple patient treatments with temporary or permanent catheters may deform such catheter's luer connectors from compliance with ISO 80369-7 at the time of treatment, which would make them incompatible with this set. Use of incompatible connectors with this set may result in blood loss, patient injury or death.
- Adhere to the facility's procedure for securing the blood tubing/access device connections to the patient. Taping should be secure despite potential changes in the patient's position or stress on the set tubing or blood access device.
- Do not use this Blood Tubing Set for therapies longer than 12 hours.
- If patient shows any sign of hypersensitivity reaction, immediately discontinue treatment and initiate appropriate medical intervention. A history of allergies is an indication for careful monitoring of hypersensitivity reactions.
- This set must be used only by qualified medical personnel fully trained in its use, qualified under state and federal regulations and under the direct supervision of a licensed physician.
- Do not open shipping carton with any sharp instrument. Sharp instruments may cut set within carton, causing blood/air leakage which may result in patient injury or death.

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FEATURES

- Compatible with 2008® Series K, K² and T Hemodialysis Machines equipped with an external CLM IV Monitor or internal CLiC software utilizing USB CLiC Sensor (CL10041001).
- Priming volume: **94 mL arterial, 62 mL venous.**
- Blood path length: **152" (385 cm) arterial, 116" (295 cm) venous.**
- Bloodline path tubing (arterial and venous): **0.180" (4.57 mm) I.D., 0.265" (6.73 mm) O.D.**
- Bloodline pump segments: **0.317" (8.0 mm) I.D., 0.474" (12.0 mm) O.D., and 13.5" (34.3 cm) length.**
- Bloodline provided with color coded components: **Red** on the arterial side and **Blue** on the venous side.
- Attached priming set with Y-injection site.
- Arterial and Venous Split Septum Injection Sites
- Arterial and Venous chamber "pigtail" access site (needleless)
- Arterial and Venous Transducer Protectors (TP)
- Heparin Line (if applicable)

The bloodline is part of the extracorporeal circuit by which blood is transported from the patient through a hemodialyzer (for cleansing), and back to the patient. The pump segment in the bloodline interfaces to the blood pump rotor mechanism on the hemodialysis machine that drives the flow of blood through the circuit. The bloodline contains interfaces to the hemodialysis machine safety mechanism to ensure proper operation. These include monitor lines for the monitoring of the arterial and venous pressures, as well as a venous chamber for the detection of air in the blood path.

Ancillary equipment required but not provided are the following:

- Arterial/Venous (AV) Fistulas Needles (not required for catheter patients)
- Sterile Normal Saline
- Hemodialyzer

KEY COMPONENT LOCATIONS

Key bloodline and priming set components and their related locations are shown in Figure 1. Illustration is not to scale.

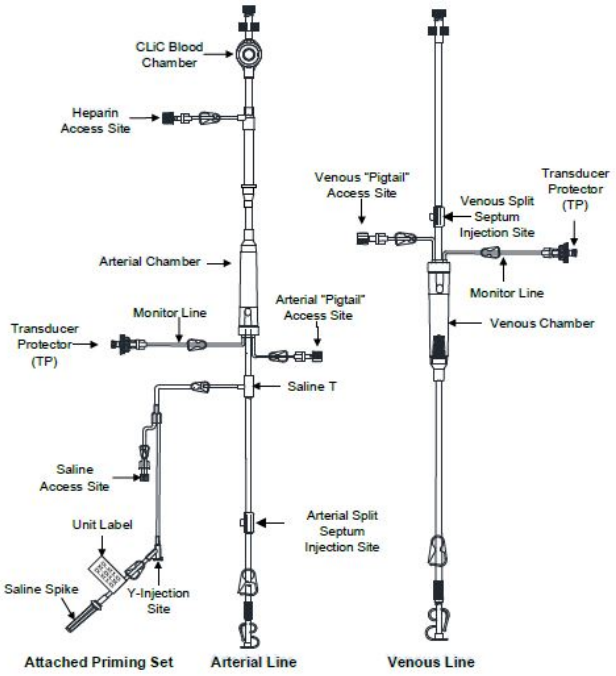

Figure 1: Bloodline Components and Locations

PRECAUTIONS

Refer to dialyzer manufacturer and 2008® Series K, K² and T Hemodialysis Machine Operator's Instructions for bloodline setup, detailed priming, heparinization, dialysis and rinsing procedures. The following precautions are emphasized to ensure patient safety:

Blood Pump Calibration Precautions:

1. Ensure blood pump is calibrated for 8mm pump segments according to 2008® Series K, K² and T Hemodialysis Machine Operator's Instructions. If the pump is not recalibrated for the pump segment used, significant under-dialysis or overdialysis may result.
2. Actual blood flow rate may differ from the blood flow rate indicated by the machine and may change with time. The machine blood pump setting displayed may not represent actual blood flow. Actual blood flow is affected by arterial and venous pressures, hematocrit, AV fistula needle size and other factors.

Table 1 represents how the blood flow rate (i.e. pump segment performance) at a Qb setting of 450 mL/min can change over a treatment period of 4 hours.

	Dialysis Time				
Arterial Pressure mmHg	0 hr	1 hr	2 hr	3 hr	4 hr
-100	0.0%	-0.10%	-0.41%	-0.51%	-0.51%
-200	0.0%	-0.44%	-0.98%	-0.98%	-1.51%
-250	0.0%	-0.82%	-2.07%	-2.52%	-3.18%
*Blood Pump Speed of 450 mL/min shown					

Table 1: Typical Bloodline Flow Accuracy vs Dialysis Time

Setup Precautions:

1. Follow the 2008® Series K, K2 and T Hemodialysis Machine Operator's Instructions for installation of the pump segment.
2. Ensure that the pump segment is not kinked, stretched or twisted. Failure to properly install the pump segment may kink the tubing which may result in hemolysis undetected by machine pressure monitors or can rupture the tubing resulting in blood loss.
3. Typical bloodline routing configuration is shown in Figure 3.
4. Ensure the machine's venous occlusion clamp is functioning properly and will effectively occlude the tubing.
5. Ensure the connection of the transducer protector to the bloodline monitor line is tight before connecting to the machine pressure port. Twist the female luer clockwise while twisting the transducer protector in the opposite direction. See figure 2a.

Figure 2a.

6. Attach the arterial and venous transducer protectors to the machine pressure ports by inserting the transducer protector into the port and twisting the female luer clockwise to tighten. Ensure both the transducer protector and female luer connections are finger tight to maintain a closed system. See figure 2b.

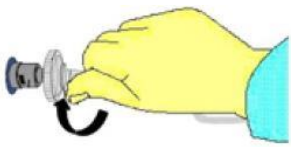

Figure 2b.

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7. Use a luer lock syringe on all heparin infusion, access site and monitor lines.

8. To spike saline bag, remove the spike protector without touching the spike and insert the spike through the port on the saline bag.

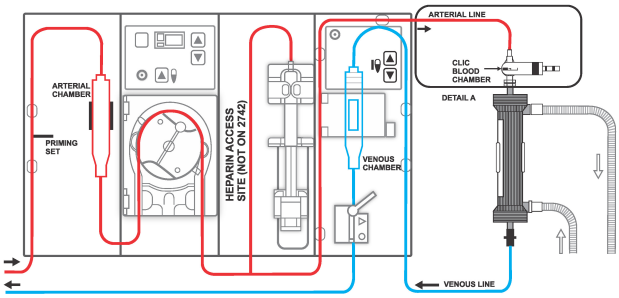

Figure 3: Bloodline Routing Configuration

Priming Precautions:

1. During pump priming, leave the recirculation connector caps closed to reduce the potential of blood path contamination.

   NOTE: 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.

2. Prime the dialyzer according to manufacturer's instructions.

3. If instructions require clamping bloodlines, unclamp pressure-monitoring lines before occluding tubing to prevent excessive dialyzer pressures.

4. Prime arterial chamber approximately 90% full and venous chamber to approximately 70% full. See figure 4.

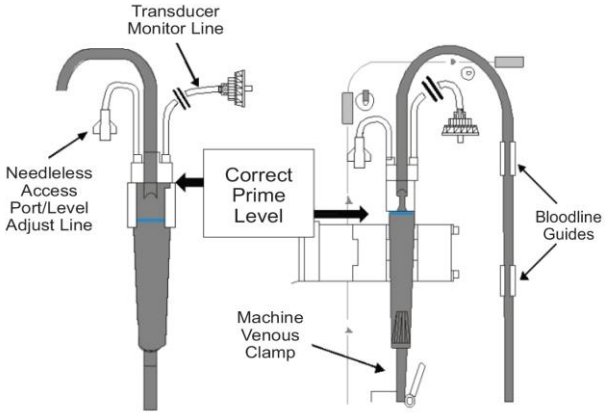

Figure 4: Arterial and Venous Chamber Levels

NOTE: If there will be a significant waiting period prior to the start of dialysis, the following steps should be taken:

a. Ensure that the extracorporeal circuit contains fresh saline immediately prior to initiation of treatment in accordance with facility protocol.

b. To use the recirculation technique with saline, connect the arterial patient end connector to the recirculation connector off the venous patient end of the bloodline.

c. Verify the connector is securely attached to each bloodline by twisting securely.

d. Open the priming set clamps and set blood pump speed according to facility protocol.

Dialysis Treatment Precautions:

1. Before initiation verify:
   a. The air detector clamp is engaged.
   b. The venous drip chamber is positioned and secured correctly in the venous level detector according to the 2008® Series K, K² and T Hemodialysis Machine Operator's Instructions.
   c. The absence of any air bubbles in the extracorporeal circuit.
   d. Monitor lines and Blood Tubing Set clamps are open.
   e. All connections are secure. For proper connection between fistula needle/catheter and bloodline:
      1. Firmly insert the male luer of the bloodline into the female luer of the fistula needle. See figure 5a.

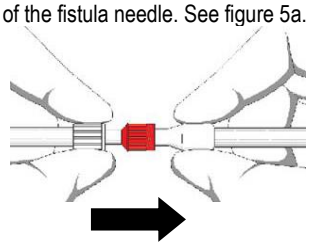

Figure 5a: Fistula Needle Connection: Insertion Technique.

      2. Twist the colored collar of the bloodline in the direction shown while holding the female luer of the fistula needle or catheter to secure the connection. See figure 5b.

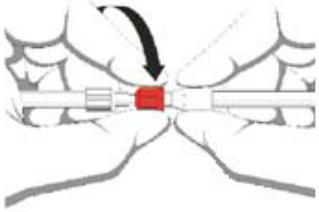

Figure 5b: Fistula Needle Connection: Securing Technique.

NOTE: Always use aseptic techniques when making or breaking any fluid path connection. It is recommended to use a large gauge fistula needle (i.e. 15 gauge or larger) for prescribed blood flow rates > 350 mL/min.

2. During Treatment:
   a. Periodically check the extracorporeal circuit for any evidence of possible separation or leaks.
   b. Do not allow the access or bloodline connections to be covered with a blanket or clothing during the treatment.
   c. Maintain fluid level in arterial chamber at approximately 90% full and venous chamber at approximately 70% full. Levels may rise or drop during the treatment due to changes in pressure or flow rate. Readjust levels as needed. Air leaks will also cause the chamber levels to fluctuate.
   d. Monitor arterial and venous pressures. Pressure readings which are clinically inappropriate for treatment (i.e.: 0 mmHg) must be addressed immediately and may indicate a clamped, loose, kinked or disconnected monitor line or wet Transducer Protector (TP). If blood samples are required, they can be drawn from the Arterial and Venous Split Septum Injection Sites.
   e. Periodically monitor rate of heparin delivery to ensure proper dosage.
3. During Completion of the Treatment:
   a. Maintain a proper fluid level in chambers to ensure that no air is returned to the patient.
   b. To complete termination procedure, refer to machine, dialyzer and manufacturer instructions, physician prescription, and/or facility protocol.

   NOTE: Air rinse-back at termination of dialysis is not recommended.

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4. Properly dispose of the extracorporeal circuit after termination of dialysis.

   NOTE: Discard the extracorporeal circuit in an appropriate biohazard waste receptacle.

   References: 29 CFR 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state or local codes.

Y-INJECTION SITE

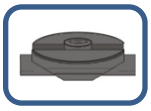
Purpose – Used for the administration of medication.

Y-Injection Site Precautions:

1. Use a 21 gauge or smaller conventional metal needle.
2. To disinfect injection site use 70% alcohol or 10% Povidone-Iodine solution.

   NOTE: Ensure administered medication is flushed with adequate volume of saline to transport through the priming set to the bloodline.

SPLIT SEPTUM INJECTION SITE



Purpose - are used for intermittent sampling of blood or administering medication.

Split Septum Injection Site Precautions:

1. Use a 21 gauge or smaller conventional metal needle or an approved plastic anti-stick needle (i.e.: Medisystems MEDIC®) for intermittent sampling of blood or administering medication. See Figure 6a.
2. Disinfect injection site immediately prior to use with 70% isopropyl alcohol or 10% povidone-Iodine solution.

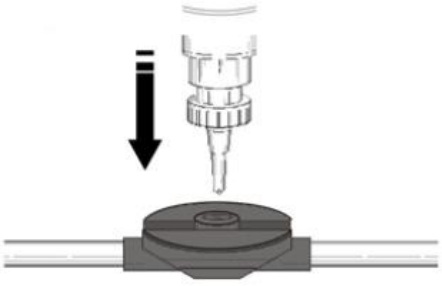


Figure 6a: Split Septum Injection Site

3. Insert appropriate needle or plastic needle into the center of the injection site at 90 – degree angle as shown on Figure 6b.

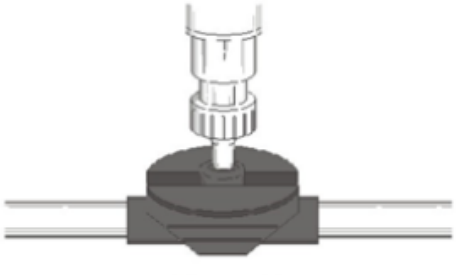
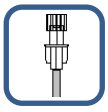


Figure 6b: Split Septum Injection Site insertion technique

NEEDLELESS ACCESS SITES



Purpose – Venous and Arterial "Pigtail": Used for intermittent administering of medication; Saline Access Site: Used for drawing saline.

Needleless Access Site Precautions:

1. Use a standard male luer syringe for administering medication.
2. To disinfect injection site use 70% alcohol or 10% Povidone-Iodine solution.
3. Insert male luer syringe straight into the injection site and twist using a clockwise motion. Twist counterclockwise to disconnect.

VIRAL-RETENTIVE TRANSDUCER PROTECTOR

The set contains one or more pre-attached TP's on the pressure monitoring lines. It contains a 0.2-micron hydrophobic filter, which helps prevent the passage of bacteria, viruses, and particulate matter; as well as preventing the passage of fluid to the machine at pressures of 600 mmHg or less. In vitro testing was performed by an independent testing laboratory using a ΦX174 bacteriophage with the size of 25nm to 27nm and a spherical morphology similar to HBV,HCV, and HIV.

TRANSDUCER PROTECTOR PRECAUTIONS:

CAUTION: Ensure that the TP is securely connected to the pressure monitoring line as well as the machine, or the following may result:

- Pre-pump arterial fluid level will drop.

1. Do not over-tighten the TP to the machine as this may cause the female luer to crack, resulting in a leak.
2. In the event that fluid should completely fill the bloodline side of the TP, the transmission of pressure will be blocked. If this occurs, clamp the pressure monitoring line and remove the TP from the machine. Use a syringe to clear any fluid from the monitoring line and reset the proper blood level in the blood chamber. Then securely attach replacement TP, reattach to the machine, and unclamp monitoring line.
3. If fluid is visible on the side of the TP that faces the machine, have qualified personnel open the machine and check for contamination after the treatment is completed. If contamination has occurred, the machine must be taken out of service and disinfected before further use according to manufacturer recommendations.

DIRECTIONS FOR USE

WARNING: Review all warnings and precautions in this document before performing directions listed below.

NOTE: Reference the 2008® Series K, K² and T Hemodialysis Machine Operator's Manual for Additional information. Refer to Figures 1 and 7 for identification of key bloodline and machine components.

Setup Bloodline:

Dialyzer:

1. Push the dialyzer into holder arterial end down, with the clamp in the middle of the dialyzer. Position dialysate ports to the right, facing outwards away from the machine.

Arterial Line:

1. Close the arterial chamber "pigtail" access site clamp.
2. Close heparin line clamp.
3. Place the arterial drip chamber into the holder.
4. Insert blood pump segment into blood pump. Close door.
5. Connect the dialyzer end of the arterial line to the bottom/arterial port of the dialyzer. Ensure connection to the port is finger tight. See Figures 7a and 7b.

   CAUTION: Do not twist the blood chamber by the lens or body.

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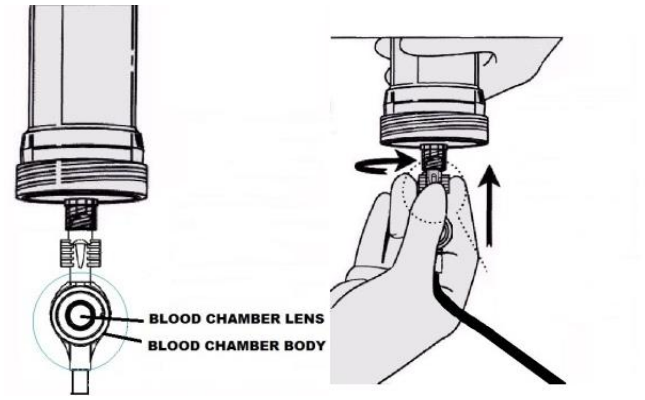
6. Connect monitor line to arterial pressure port with a transducer protector and verify the line is unclamped. Aseptically place the patient end of the arterial line into priming bucket clip.



Figures 7a and 7b

Venous Line:

1. Close the venous chamber "pigtail" access site clamp.
2. Roll the venous drip chamber into the venous level detector with filter below sensor heads. See Figure 8. Close and latch door.
3. Connect the venous line dialyzer connector to the top/venous port of the dialyzer. Ensure connection to the port is finger tight.
4. Connect monitor line to venous pressure port with a transducer protector and verify the line is unclamped.
5. Aseptically place patient end of the venous line into priming bucket clip.

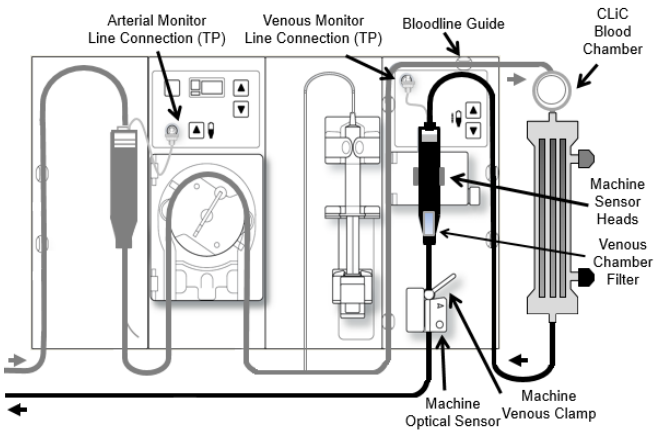


Figure 8: Bloodline/Machine Interface

Prime Extracorporeal Circuit:

NOTE: Priming of the extracorporeal circuit requires approximately 300 mL of saline depending on the size and model of the dialyzer.

1. Hang a saline bag. Close all three saline priming set clamps. Aseptically spike the saline bag.
2. Open the saline "T" and administration clamps on the priming set. Gravity prime the patient end of the arterial bloodline below the saline "T" with saline. When primed, close the patient end clamp of the arterial bloodline.
3. If the heparin pump is to be used: connect the heparin syringe, unclamp the heparin line, prime heparin line, re-clamp and load heparin syringe into heparin pump. If heparin pump is not used, leave the heparin line clamped.
4. Press the **Prime** key.
5. Set blood rate to 150 mL/min. Ensure the blood pump is running.
6. Fill arterial drip chamber approximately 90% full using level adjust key.
7. Clamp the arterial monitor line and disconnect from machine so pressure port is open to atmosphere.
8. The blood pump will continue to run until the pre-set amount of saline has been flushed through the circuit.
   - While priming is occurring, intermittently pinch and release the bloodline between the blood pump segment and the dialyzer to help purge air.
   - Air removal from dialyzer should be performed as per manufacturer's recommendation.
9. Fill venous drip chamber approximately 70% with **level adjust key**, clamp venous monitor line and disconnect from machine so pressure port is open to atmosphere.
10. When blood pump stops, clamp the patient end of the venous bloodline.
11. Aseptically connect patient ends of arterial and venous bloodlines together via the recirculation connector and open arterial and venous Blood Tubing Set clamps.
12. Insert the venous bloodline into the machine venous line clamp and optical detector and close the optical detector door. See Figure 8.
13. Press **RESET** to clear any alarms.

Machine Test:

Refer to machine testing procedure as per the 2008® Series K, K^2 and T Hemodialysis Machine Operator's Instructions.

Recirculation:

1. Verify conductivity, pH and residual disinfectant testing requirements; refer to instructions provided by the dialyzer manufacturer, 2008® Series K, K^2 and T Hemodialysis Machine Operator's Instructions and concentrate manufacturer.
2. Rotate the dialyzer so the arterial end is up.
3. Ensure the bloodline segments connected to the dialyzer are unrestricted and free of kinks.
4. Attach dialysate connectors to dialyzer as per manufacturer recommendations and 2008® Series K, K^2 and T Hemodialysis Machine Operator's Instructions. Fill dialysate compartment per dialyzer manufacturer recommendations.
5. Connect the arterial and venous pressure monitor lines to their respective pressure ports, ensuring each connection is finger tight. Unclamp the arterial and venous pressure monitor lines.
6. Rotate the dialyzer so the arterial end is down.
7. Press **RESET** to clear any alarms. Set the blood pump rate to 350-400 mL/min.
8. During recirculation intermittently pinch and release the bloodline between the blood pump segment and the dialyzer to help purge air.
9. Use the up arrow key to raise the venous drip chamber fluid level, if needed.
10. Check blood tubing to ensure there are no kinks. Replace saline bag with a fresh bag if necessary.
11. Check for a normal dialysate flow as per 2008® Series K, K^2 and T Hemodialysis Machine Operator's Instructions.
12. Set treatment parameters as prescribed.

Starting Dialysis:

1. Complete patient assessment per unit policy.
2. Verify the venous line is in the machine venous clamp and the optical detector. Verify that the optical detector door is closed.
3. Press **RESET** to clear any alarms.

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NOTE: Do not infuse recirculated saline into patient. Discard recirculated saline and fill the entire extracorporeal circuit with fresh saline prior to connecting to the patient. The volume of the saline used to fill the extracorporeal circuit should be equal to the volume of the dialyzer and blood tubing set (approximately 300 mL depending on the size and model of the dialyzer).

4. Lower the blood pump rate to 150 mL/min and press the **Start/Stop** key to stop blood pump.
5. Clamp the saline "T" and saline administration clamps. Clamp patient ends of the arterial and venous bloodlines.
6. Connect the patient. Unclamp the arterial and venous patient access clamps, unclamp the patient ends of the arterial and venous bloodlines and unclamp heparin line, if using heparin pump. Initiate treatment per unit protocol.
7. Press the **Start/Stop** key to start blood pump and set blood pump to prescribed blood flow (Qb) rate.
8. Rotate the dialyzer to arterial end up.
9. Support bloodline to create a bloodline loop above the blood chamber to prevent kinking.
10. Place the sensor clip of the CLiC Device on the blood chamber lens. Refer to the start-up instructions for the CLiC Device.
11. Select the Tx Clock button and press CONFIRM to start treatment, the Status Box will now show "Dialysis".
12. Verify treatment parameters and absence of alarms.

Completion of Dialysis:

1. Replace saline bag with a fresh bag, if necessary.
2. When the dialysis is completed, press the **Start/Stop** key on the blood pump to stop the pump.
3. Disconnect the sensor clip of the CLiC Device from the blood chamber.
4. To return 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 "T" and saline administration clamps and rinse the blood in the tubing below the saline "T" back to the patient. When the blood in the line has been returned back to the patient, close both the arterial patient clamp and arterial patient access clamp.
5. To return the remaining blood in the bloodline back to the patient:
   - Move the hemostat from above the saline "T" and clamp directly below the saline "T".
   - Set blood pump rate to 150-200 mL/min. Press the blood pump **Start/Stop** key to start the pump.
   - When the blood has been returned to the patient, turn the blood pump off.
   - Close both the venous patient clamp and patient access clamp. Close the saline "T" clamp.
6. Aseptically disconnect the patient's arterial and venous access.
7. Discard the extracorporeal circuit according to unit policy.
8. Clean or disinfect the machine exterior according to unit policy.

GENERAL INFORMATION

1. Generic names of materials that directly or indirectly contact the fluid path are available to the user upon request.
2. This product is not made with natural rubber latex.
3. This product is sterilized by ethylene oxide gas (EtO).

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