Roles of Technicians/Technologist in Patient Outcome

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The findings and conclusions in this presentation are those of the author and do not represent the views of St. Joseph Hospital or any professional organizations

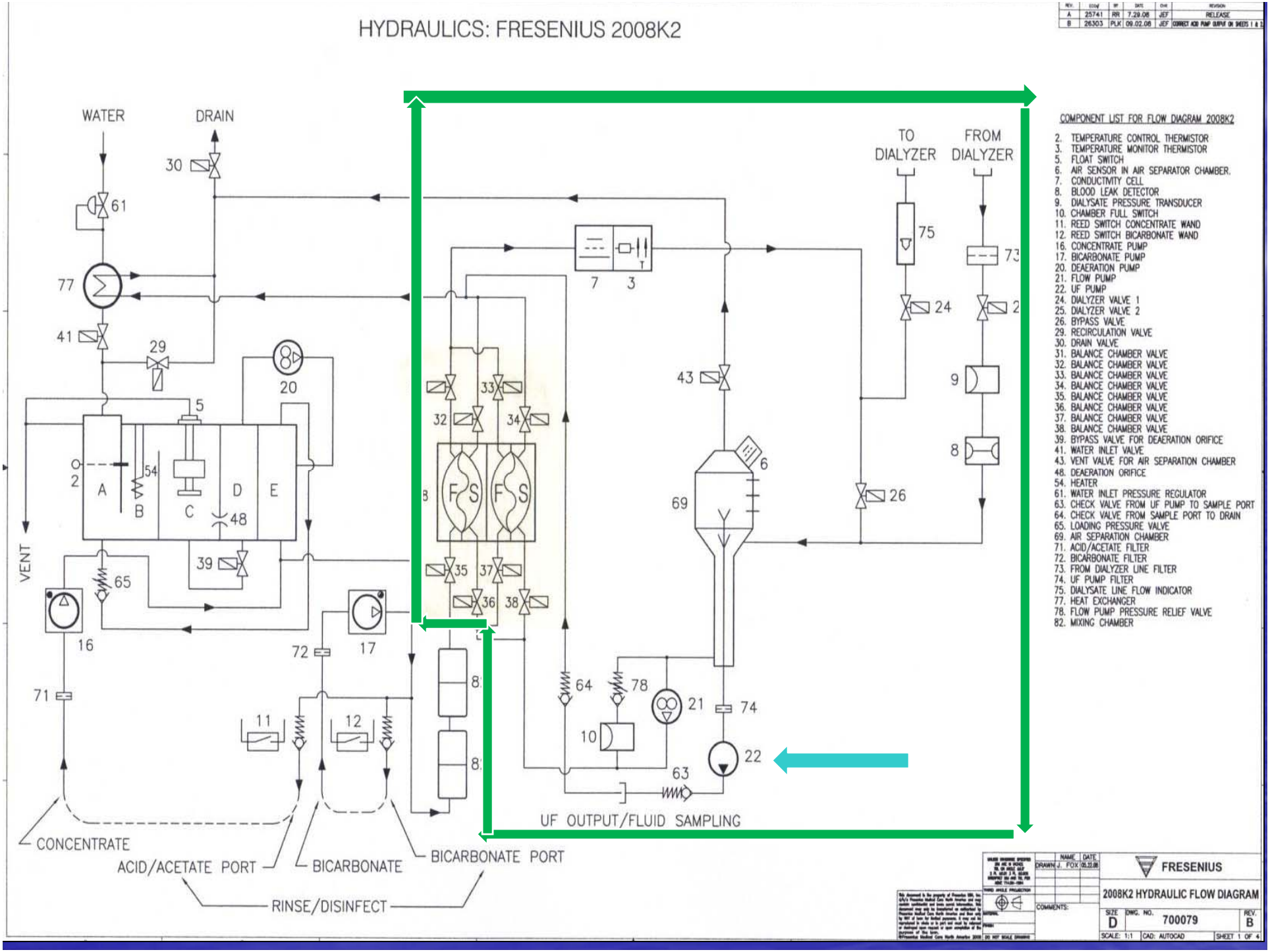
St. Joseph Hospital
ST. JOSEPH HEALTH SYSTEM

CNBT Role in Patient Outcome

- Properly functioning equipment
- Water Treatment
- Ancillary Functions
  - Supply order/inventory/distribution
  - Environment of Care
  - Reprocessing

UF System

HYDRAULICS: FRESENIUS 2008K2



REV.	ECO#	BY	DATE	CHK	REVISION
A	25741	RR	7.29.08	JEF	RELEASE
B	26303	PLK	09.02.08	JEF	CORRECT ACID PUMP OUTPUT ON SHEETS 1 & 2

COMPONENT LIST FOR FLOW DIAGRAM 2008K2

2. TEMPERATURE CONTROL THERMISTOR
3. TEMPERATURE MONITOR THERMISTOR
5. FLOAT SWITCH
6. AIR SENSOR IN AIR SEPARATOR CHAMBER.
7. CONDUCTIVITY CELL
8. BLOOD LEAK DETECTOR
9. DIALYSATE PRESSURE TRANSDUCER
10. CHAMBER FULL SWITCH
11. REED SWITCH CONCENTRATE WAND
12. REED SWITCH BICARBONATE WAND
16. CONCENTRATE PUMP
17. BICARBONATE PUMP
20. DEAERATION PUMP
21. FLOW PUMP
22. UF PUMP
24. DIALYZER VALVE 1
25. DIALYZER VALVE 2
26. BYPASS VALVE
29. RECIRCULATION VALVE
30. DRAIN VALVE
31. BALANCE CHAMBER VALVE
32. BALANCE CHAMBER VALVE
33. BALANCE CHAMBER VALVE
34. BALANCE CHAMBER VALVE
35. BALANCE CHAMBER VALVE
36. BALANCE CHAMBER VALVE
37. BALANCE CHAMBER VALVE
38. BALANCE CHAMBER VALVE
39. BYPASS VALVE FOR DEAERATION ORIFICE
41. WATER INLET VALVE
43. VENT VALVE FOR AIR SEPARATION CHAMBER
48. DEAERATION ORIFICE
54. HEATER
61. WATER INLET PRESSURE REGULATOR
63. CHECK VALVE FROM UF PUMP TO SAMPLE PORT
64. CHECK VALVE FROM SAMPLE PORT TO DRAIN
65. LOADING PRESSURE VALVE
69. AIR SEPARATION CHAMBER
71. ACID/ACETATE FILTER
72. BICARBONATE FILTER
73. FROM DIALYZER LINE FILTER
74. UF PUMP FILTER
75. DIALYSATE LINE FLOW INDICATOR
77. HEAT EXCHANGER
78. FLOW PUMP PRESSURE RELIEF VALVE
82. MIXING CHAMBER

	NAME	DATE
DRAWN	J. FOX	05.22.08

FRESENIUS

2008K2 HYDRAULIC FLOW DIAGRAM

SIZE	DWG. NO.	REV.
D	700079	B

SCALE: 1:1 | CAD: AUTOCAD | SHEET 1 OF 4


NALGENE

ENERAL INFORMATION

dications: Optiflux F200NR, F180NR and F160NR dialyzers are designed for single use ute and chronic hemodialysis.

SA only: Federal law restricts this device to sale by or on order of a physician.

AUTION: The operator should strictly adhere to the manufactures recommended ocedures, warnings and cautions as listed in these instructions for use.

ontraindications: Specific contraindications for the dialyzer are unknown. Generally, e contraindications for hemodialysis are applicable. The dialyzer should only be used directed by a physician.

ecautions: Dialyzers may leak resulting in patient blood loss or contamination with alysate. In the event of a blood leak during dialysis, the health care provider should spond according to the facility's established protocol.

r entering the extracorporeal circuit during dialysis can result in serious injury or death. neck the security of all extracorporeal connections prior to the initiation of dialysis and riodically throughout the treatment. The venous drip chamber should be continuously onitored with a level detector.

arning: Due to the high water flux capability of high permeability membranes with an trafiltration coefficient > 8, it is necessary to use such dialyzers only in conjunction th dialysis machines that are equipped with precise ultrafiltration control, such the Fresenius 2008 series. We recommend that dialyzers with an ultrafiltration efficient > 6 should only be used with such UF control machines. In any case, the fety instructions for the hemodialysis machine must be followed.

ne user is cautioned to regularly monitor the patient's chemistry values using quantitative easurements and analysis to ensure that the prescribed therapy is delivered. The clinical rameters monitored should at least include urea, hemoglobin and serum albumin.

alysate: The dialysate must meet AAMI standards for dialysis (RD5).

de effects: In rare cases, hypersensitivity reactions to the dialyzer or other elements the extracorporeal circuit may occur during hemodialysis. If a hypersensitivity reaction curs, the source of the hypersensitivity should be identified and that component of the tracorporeal circuit should be excluded from future use in hemodialysis treatments for at patient. With severe reactions, dialysis must be discontinued and aggressive first line erapy for hypersensitivity reactions must be initiated. The decision to return the patient's ood in the event of a hypersensitivity reaction is the decision of the physician.

eparinization: It is recommended to systemically heparinize the patient. Systemic parinization is defined as administering the prescribed loading dose of heparin into e patient's vascular access and waiting 3 to 5 minutes prior to initiating the treatment. uring dialysis, the dose of heparin and method of administration is the decision of the ysician.

erile/Non-pyrogenic: The dialyzers are sterilized using the electron beam (ebeam) ethod of sterilization. The dialyzer blood pathway is sterile and non-pyrogenic if the ood port caps are in place and undamaged. Do not use if the dialyzer is damaged in y way. Use aseptic technique for all blood side connections. Structural integrity of the modialyzer is warranted for the first use only when prepared as directed.

ecommended storage: Between 5 and 30 degrees C (41 - 86 degrees F).

alyzer reuse: Optiflux F160NR, F180NR and F200NR dialyzers are not designed for or ended for reuse.

REPARATION FOR DIALYSIS - DRY PACK

Place the dialyzer in the dialyzer holder in the vertical position, arterial end downward.

nstall the arterial and venous bloodlines on the hemodialysis machine.

Note: Refer to dialysate delivery machine manufacturer's instructions for use for setting up bloodlines.

Remove blood port caps from the dialyzer and aseptically connect the arterial and venous dialyzer ends of the bloodlines to the dialyzer. Check to be sure connections are secure.

Aseptically spike a 1 liter bag of 0.9% sterile saline solution with a clamped dialysis priming set.

f not already attached, attach the dialysis priming set to the saline "T" connection located just before the blood pump segment on the arterial bloodline. Check to be sure he connection is secure.

Open the clamp on the dialysis priming set and allow saline to gravity prime the portion of the arterial bloodline from the saline "T" to the patient end.

Clamp the main line tubing on the arterial bloodline between the patient end and the saline "T" connection.

Start the blood pump and set a **pump speed of 150 mL/min**. Prime the rest of the arterial bloodline, dialyzer and venous bloodline with saline. While the extracorporeal circuit is filling with saline, **intermittently pinch and release the bloodline between the blood pump and the dialyzer** to help to purge air from the dialyzer. **Tap the dialyzer** to facilitate air removal from the dialyzer.

Fill the dialyzer and blood lines with 300 mL sterile 0.9% saline solution. The drip chambers in the bloodlines should be set to and maintained at ¾ full.

Stop the blood pump. Clamp the arterial and venous bloodlines. Aseptically connect the patient ends of the arterial and venous bloodlines together in preparation for recirculation of the extracorporeal circuit. Unclamp main line clamps on arterial and venous bloodlines.

Perform Pressure Holding Test on Fresenius 2008 machine.

Verify that the dialysate is within the prescribed conductivity limits with a calibrated conductivity monitor. To identify situations where the acetate or acid and bicarbonate concentrates are not properly matched, use a calibrated pH meter to verify that the pH of the dialysate is within the appropriate physiologic range.

Rotate the dialyzer so the venous end is down. Attach the dialysate lines to the dialyzer. Fill the dialysate compartment with the dialyzer in the venous end down position. In order to maximize the efficiency of the dialyzer, the dialsate flow must be countercurrent to the blood flow.

When the dialysate compartment is filled, turn the dialyzer back to the arterial end down position and place back in dialyzer holder.

Recirculate the extracorporeal circuit at a blood flow rate of 300 to 400 mL/min and a dialysate flow 500 mL/min until all air has been purged from the dialyzer and bloodlines.

During recirculation, to assist in removing air from the dialyzer, intermittently pinch and release the blood tubing between the blood pump and the dialyzer. From the bloodline

- If the dialysate delivery system was chemically disinfected or sterilized prior to patient use, be sure to test for the absence of germicide residuals with a test intended for this application, according to the test manufacturer's instructions.

INITIATION OF DIALYSIS

- To initiate dialysis; stop the blood pump, clamp the dialysis priming set and the arterial and venous bloodlines.
- Aseptically attach the patient ends of the bloodlines to the patient's arterial and venous access. Open the arterial and venous bloodline clamps and the clamps on the patient access.
- Increase the blood pump speed slowly to the prescribed blood flow rate. Be sure to monitor the arterial and venous blood pressures carefully during this process to note any possible flow restrictions or inappropriate pressure readings.
- Once the prescribed blood flow rate has been achieved, set the prescribed ultrafiltration rate and rotate the dialyzer to the arterial end up position.

DURING THE DIALYSIS TREATMENT

- If a blood leak should occur during the treatment, the operator should follow the facility's established procedure for a dialyzer blood leak.
- Air entering the extracorporeal circuit during dialysis is a very serious event and should be avoided. A routine check of all connections prior to initiation of dialysis and periodically throughout the dialysis treatment is recommended. Constant monitoring of the venous drip chamber with a level detector is required. Should air get into the venous line during the treatment, the dialysis treatment must be discontinued without returning any of the blood mixed with air.

TERMINATION OF DIALYSIS

- When the dialysis treatment is completed, turn the blood pump off and set the UF rate to the recommended minimum. Check to see that there is enough 0.9% sterile saline solution in the bag for rinsing the blood in the extracorporeal circuit back to the patient.
- Using a hemostat, clamp the arterial bloodline between the saline "T" and the blood pump. Rinse the blood in the tubing between the saline "T" and the patient end back to the patient.
- Clamp the arterial bloodline between the patient connection and the saline "T". Remove the clamp on the bloodline between the saline "T" and the blood pump.
- Start the blood pump and set at a 150 to 200 mL/min pump speed. Intermittently pinch and release the blood tubing between the blood pump and the dialyzer to help to efficiently rinse the blood in the extracorporeal circuit back to the patient. Do not let air enter the extracorporeal circuit during rinse back.
- Once the blood has been returned to the patient, turn the blood pump off. Clamp the arterial and venous bloodlines and the patient's arterial and venous access. Aseptically disconnect the arterial and venous bloodlines from the patient's access.
- **Discard the extracorporeal circuit in an appropriate biohazard waste receptacle.** References: 29CFR, 1910.145, 1910.1030 (Code of Federal Regulations) and appropriate state and local codes.

Technical data: These data represent typical *in vitro* performance. Actual *in vivo* performance may differ.

	F160NR	F180NR	F200NR	
Ultrafiltration coefficient (*in vitro* bovine blood 32%)	50	60	62	mL/hr/mmHg
Clearance **Qb 300/Qd 500, Qf=0**				
Urea*	266	274	277	mL/min
Creatinine	238	251	253	mL/min
Phosphate	230	238	250	mL/min
Vitamin B_{12}	152	168	173	mL/min
Lysozyme**	70	74	84	mL/min
Priming volume blood	83	98	112	mL
Flow resistance blood (Qb = 200 mL/min)	50	51	55	mmHg
Maximum TMP	600	600	600	mmHg
Maximum blood flow	600	600	600	mL/min
Maximum dialysate flow	1000	1000	1000	mL/min
Surface area	1.5	1.8	2.0	m^2

*Sodium used as a marker for urea.
**Lysozyme, MW 14,300 Da, used as surrogate for MM
Note: Clearance tests performed using aqueous solutions of sodium, creatinine, phosphate, Vitamin B_{12} and Lysozyme

Membrane material:	Advanced Fresenius Polysulfone®
Fiber inner diameter (nominal):	200 microns
Membrane wall thickness:	40 microns
Housing:	Polycarbonate
Potting compound:	Polyurethane
O-ring:	Silicone
Blood connections:	DIN 13090 Part 3
Dialysis fluid connections:	DIN 58352 Part 2
Sterilization Method	Electron Beam

Dialyzer K_{UF} = ml/mmHg/hour

K_{UF} = 50

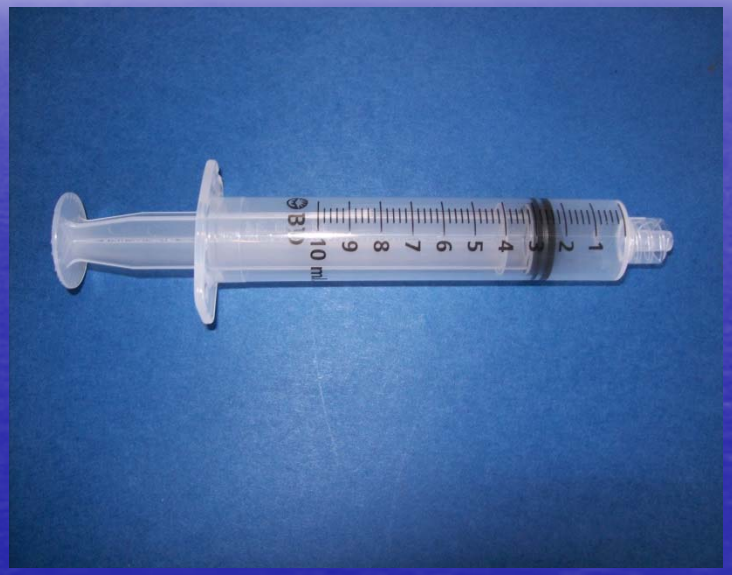
Vp = 250 mmHg

50 x 250 = 12.5L = 27.5 lbs.

TMP tolerance = 600 mmHg

50 x 600 = 30000 mL = 30.0 L x 2.2 = 66 lbs.

=


10 ml

Chloramine

- 33 patients admitted to the hospital in a 14 day period for anemia with at least one patient reportedly diagnosed with hemolytic anemia and myocardial infarction
- Test strips used to detect total chlorine were found to be not reactive to chlorine.

Chloramine Breakthrough

- >0.1 ppm
  - Turn the water system off???

  Or

  - Dialysate by-pass???

Dialysate is the largest contact material a patient's blood touches

- The more pure and endotoxin free the water and dialysate, the fewer Chronic Inflammatory Disease (CID) processes seen in patients over time

Chronic Inflammatory Disease Causes

- Plastics and Residual Sterilants
  - Dialyzers
  - Bloodlines
  - Syringes
- Endotoxins From
  - Dialysate
  - Water
  - Medications
  - Reprocessed Hemodialyzers
- In other words, *all* blood contact materials

Sudden Cardiac Death

- ESRD patients are 10 – 100 times more likely for CVD
  - >20 % annual mortality rate
  - Sudden Cardiac Death number one cause of death for patients on dialysis
    - High levels of hsCRP or IL-6 (2x)
    - Low albumins (1.35X)
    - Combined (4x)

Kidney International Nov. 2 issue, John Hopkins

Definitions of Quality for Dialysis

Reference	Allowable water TVC	Action level water TVC	Allowable Level water EU	Action Level water EU	
RD52:2004	<200	50	2	1	
ANSI/AAMI/ISO 13959	<100	50	<0.25	0.125	
ANSI/AAMI/ISO 23500	<100	50	<0.25	0.125	
ANSI/AAMI/ISO 11663	<100	50	<0.25	0.125	
Ultrapure	<0.1		<0.03		
Infusable	Not listed in the standards				

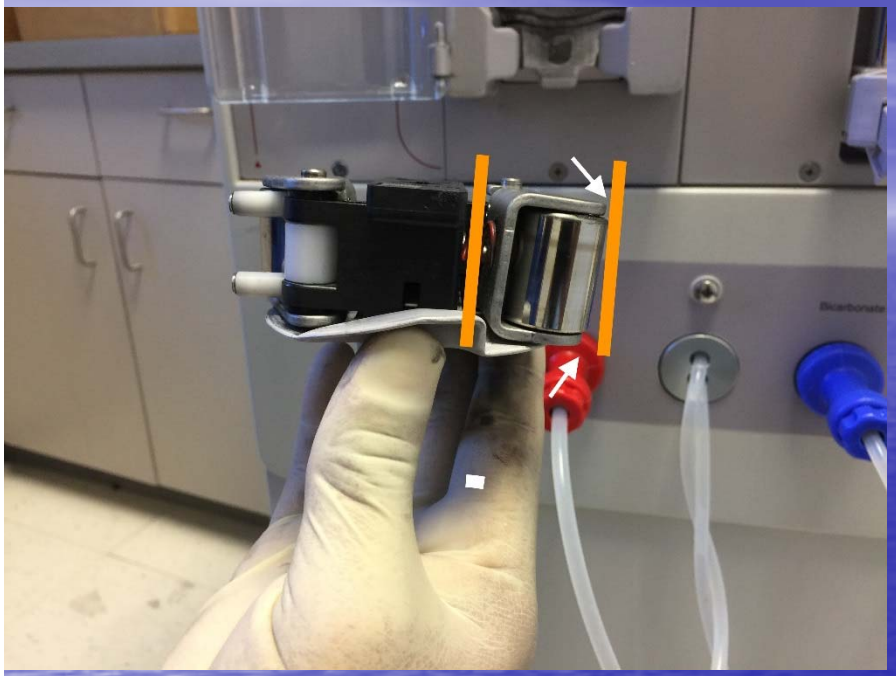
Reference	Allowable dialysate TVC	Action level dialysate TVC	Allowable Level dialysate EU	Action Level dialysate EU	
RD52:2004	<200	50	2	1	
ANSI/AAMI/ISO 13959	<100	50	<0.5	0.25	
ANSI/AAMI/ISO 23500	<100	50	<0.5	0.25	
ANSI/AAMI/ISO 11663	<100	50	<0.5	0.25	
Ultrapure	<0.1		<0.03		
Infusable	10^{-6}		<0.03		

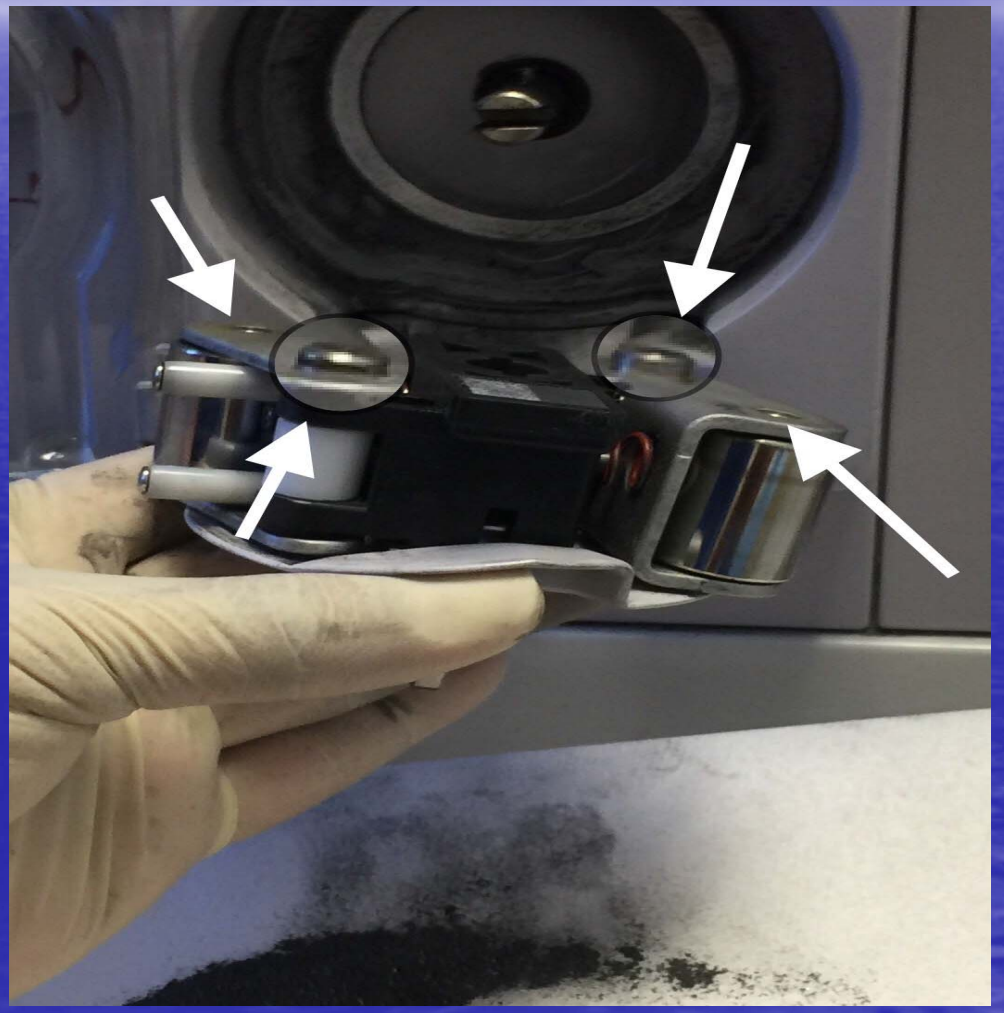
Chemical Contaminant maximum allowable levels equal in all references.


TO DIALYZER
FROM DIALYZER
COVERED BY ONE OR MORE PATENTS:
OF THE FOLLOWING US 4583924
US 4108575 US 4702829
US 4251769 US 4770769
US 4267040 US 4834888
US 4530758 PENDING
OTHER PATENTS

Rotor

- Arterial resistance decrease
- Venous pressure decrease
- Decrease in Kt/V





CP Arrest and Alkalosis

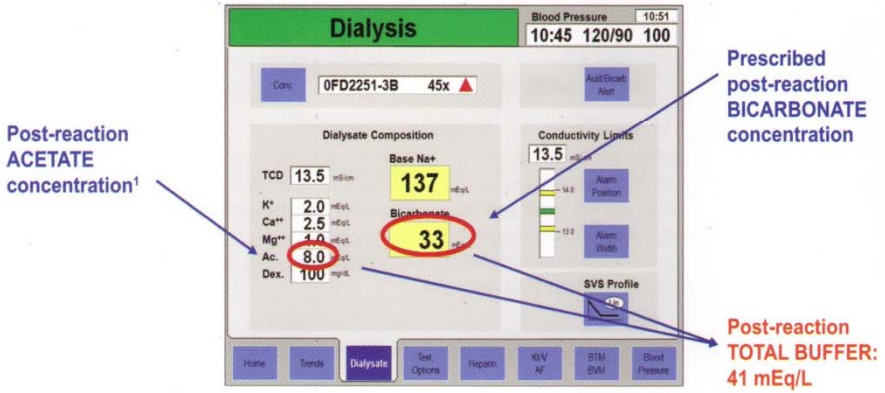
Analyses performed using HD patient safety data confirms that alkalosis is a significant factor associated with cardiopulmonary (CP) arrest in the dialysis unit, independent of an additive to the risk of CP arrest associated with pre-dialysis hypokalemia.

Setting and Display on the Dialysis Machine[1]

The final composition of the dialysate will always match the concentrations of the post-reaction buffer components as prescribed, set and displayed on the dialysis machine. The total buffer is determined by adding the numbers displayed in the corresponding fields.

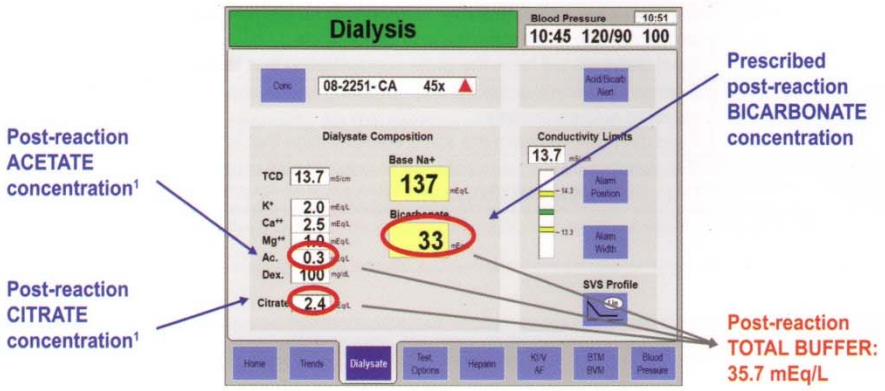
Example of buffer components and total buffer (e.g., Granuflo®).

A conceptual dialysis screen is depicted below illustrating the use of Granuflo® acid concentrate. The screen may differ depending on the dialysis machine used. The example would look similar for NaturaLyte® with the only difference being that the post-reaction value of acetate would be 4 mEq/L and total buffer 37 mEq/L.



Example of buffer components and total buffer (e.g., Citrasate®)

A conceptual dialysis screen is depicted below illustrating the use of Citrasate® acid concentrate. The screen may differ depending on the dialysis machine used.



[1]All information provided in this brochure refers to the Fresenius 2008 machine series and a 45x bicarbonate dialysis fluid.