Targeting Zero Infections: Water Systems in the Dialysis Setting

What Nephrologists Need to Know

A micro-webinar series for fellows: section 2

August 2022

MAKING DIALYSIS SAFER COALITION

NTDS
Transforming Dialysis Safety

Speaker

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Objectives

- Discuss the nephrologist's responsibilities regarding water/dialysate.
- Explain the critical water system components directly impacting water/dialysate quality
- Review Ultrapure Dialysate
- Clarify the composition of dialysate and how it is proportioned

Objectives

- Discuss the nephrologist's responsibilities regarding water/dialysate.

Responsibility: Quality

V177 IG: The medical director is ultimately responsible for the safety and quality of the water used for patient treatments.

The medical director must be knowledgeable of the water treatment system installed and assure that the system as installed will produce Association for the Advancement of Medical Instrumentation (AAMI) quality water.

Source: Centers for Medicare & Medicaid Services - ESRD Interpretive Guidance; Part 494 Conditions for Coverage for End-Stage Renal Disease Facilities

Responsibility: Bacteriology

V178 IG: Product water used to prepare dialysate or concentrates at a dialysis facility, or to process dialyzers for reuse, need to be monitored for colony forming units and endotoxin levels. The final decision of whether to discontinue dialysis rests with the medical director of a facility.

V179 IG: Facilities must monitor the water chemical analysis and microbial testing and take action promptly if results are outside of the AAMI standards.

"Promptly" would be met if action is taken within 48 hours of receiving the results of testing. Examples may include:

- Repeat cultures
- Disinfection and re-culturing

Responsibility: Staff

V696 IG: Any staff member who operates the water treatment system must complete a training program approved by the medical director and the governing body prior to independently performing water treatment system tasks.

Source: Centers for Medicare & Medicaid Services - ESRD Interpretive Guidance; Part 494 Conditions for Coverage for End-Stage Renal Disease Facilities

Responsibility:
Corrective Action & Quality Assessment Performance Improvement (QAPI)

V274 IG: Water and dialysate monitoring must be reported in the QAPI materials, and the medical director must be involved in analyzing and addressing test results outside of expected parameters.

Source: Centers for Medicare & Medicaid Services - ESRD Interpretive Guidance; Part 494 Conditions for Coverage for End-Stage Renal Disease Facilities

Sample Technical Quality Report

Water System (WS)						
	1. RC RO Check performed daily					
	2. RC cultures within AAMI standard Collected:	100%				
	3. RC endotoxin within AAMI standard Collected:	100%				
	4. Monthly RO and distribution loop disinfect	100%				
	5. Acute RO Central System routine check performed	100%				
	6. Acute RO culture within AAMI standard. Collected:	100%				
	7. Acute RO endotoxin within AAMI standard. Collected:	100%				
	8. Monthly Acute RO and distribution loop disinfect	100%				
	9. All Water analysis within AAMI levels	100%				

Renal Technology Department Quality Management Report

St. Joseph Hospital Renal Center **Period Covered:**

Technology Aspect	Item	Expected Outcome	Jan/Feb/ Mar Results	Apr/May/ June Results	Jul/Aug/ Sep Results	Oct/Nov/ Dec Results
Medical Device and Equipment Safety (MDE)	1. Acid concentrate/bicarb lot # documented at time of use	100%				
	2. Medical device problem/issues or recalls (trend not to exceed 3x in 3 mos.)	NT				
Equipment Maintenance (EM)	1. P.M. is current	100%				
Environmental (EV)	1. HVAC	NT				
	2. Plumbing	NT				
	3. Infrastructure	NT				
Water System (WS)	1. RC RO Check performed daily					
	2. RC cultures within AAMI standard Collected:	100%				
	3. RC endotoxin within AAMI standard Collected:	100%				
	4. Monthly RO and distribution/loop disinfect	100%				
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	6. Acute RO culture within AAMI standard. Collected:	100%				
	7. Acute RO endotoxin within AAMI standard. Collected:	100%				
	8. Monthly Acute RO and distribution loop disinfect	100%				
	9. All Water analysis within AAMI levels	100%				
Mobile Systems (MS)	1. Quarterly Portable RO cultures/endotoxin used for diagnostic purpose. Critical value is based on paired dialysis machine results.	Trend with # 10/11				
	2. Dialysis machine cultures paired with mobile RO	100%				
	3. Dialysis machine endotoxin paired with mobile RO	100%				
	4. Tablo dialysate culture result	100%				
	5. Tablo dialysate endotoxin result	100%				
	6. R.O. portable system disinfect weekly/PRN	100%				

Analysis/Evaluation:

Action/Improvement Plan/Goal Date/ Individual Responsible:

Miscellaneous:

Results documented in red indicate explanation required.

NT = No Trend

Reviewed by Medical Director:_____Date_____

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Disinfection Concept

Disinfection should be proactive, rather than retroactive, with schedules designed to prevent bacterial proliferation, rather than to eliminate bacteria once they have proliferated to an unacceptable level. Levels of bacteria and endotoxins should be monitored to demonstrate that the disinfection program is effective, rather than to indicate when disinfection should be performed

Responsibility: Quality Report Review

- Do not accept “positive” or “negative” as a result
  - Want a full count of every viable colony
  - Ex: 200 cfu/mL
- Watch for results that consistently have “no growth” or “0” cfu/mL results
  - This may indicate the lab is using a calibrated loop or the wrong medium
  - Error in obtaining sample
- Do trend analysis
  - Can see problems arising

Evolving Standards

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 23500	<100	50	<0.25	0.125	

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 23500	<100	50	<0.5	0.25	

Responsibility: Required Testing and Maintenance

- Total chlorine prior to each patient shift or every 4 hours
- Monthly L.A.L. and colony counts of water and dialysate
- Annual AAMI Water Chemical analysis
- Minimum monthly R.O. system disinfection
- Daily disinfection dialysis machine

Objectives

- Explain the critical water system components directly impacting water/dialysate quality

Dialysis Water Purification System Components

- Backflow preventer
- Temperature Blending Valve
- Sediment Filter
- Water Softener and Brine Tank
- Carbon Filter
- RO Membrane
- Storage Tank
- RO Water Distribution Loop
- UV Light
- Ultrafilters

Carbon Filters
(aka GAC Granulated Activated Carbon)

GAC Specifications

- Tanks sized for Empty Bed Contact Time (EBCT)
  - 10 minutes EBCT for chloramine removal
  - Two tanks in series for total EBCT, worker and polisher
- Monitoring
  - Check total chlorine post first tank
    - Before every shift
    - Or every four hours
  - Pre and post pressures
    - 10 psi delta pressure

Total Chlorine/Free Chlorine/Chloramine Explained

The maximum allowable level for total chlorine (the free and bound chlorine combined) is ≤0.5mg/L (ppm) for post bleach disinfection residual test. The maximum allowable level for chloramine is ≤ 0.1 mg/L (ppm). There is no direct test for chloramine. The level of chloramine is determined by two separate measurement that include a total chlorine and free chlorine measurement. The chloramine level is the difference between total chlorine and free chlorine. Performing the dual test and calculation has led to errors in determine chloramine concentration. CMS is allowing the simplification of the test to the one method of performing total chlorine. If a facility is doing only one test for total chlorine, then the ≤0.1mg/L (ppm) limit must be used for the maximum allowable level, to ensure patient protection from chloramine exposure.

GAC Breakthrough

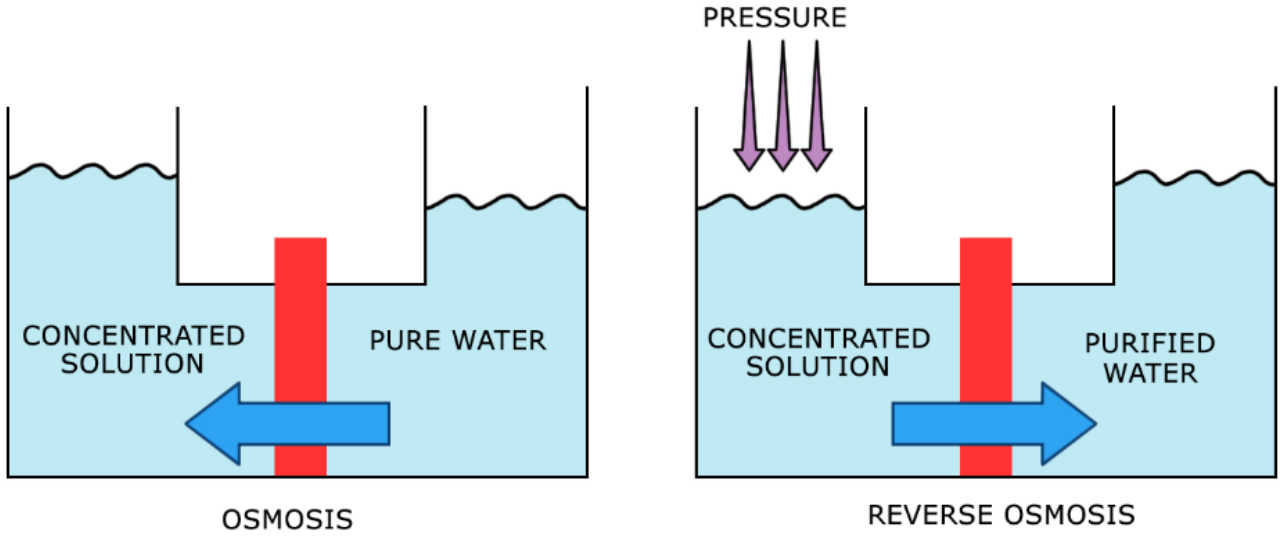
- In the event that the sample from the first carbon tank is >0.1 ppm for Total Chlorine, the water can be tested after the second tank.
- If the second tank sample is ≤0.1 ppm, dialysis can be continued with frequency of testing performed at every half hour until replacement of the first tank can be performed.
- Operation dependent only on the secondary tank cannot exceed 72 hours.

Importance of Total Chlorine Testing: Case Review

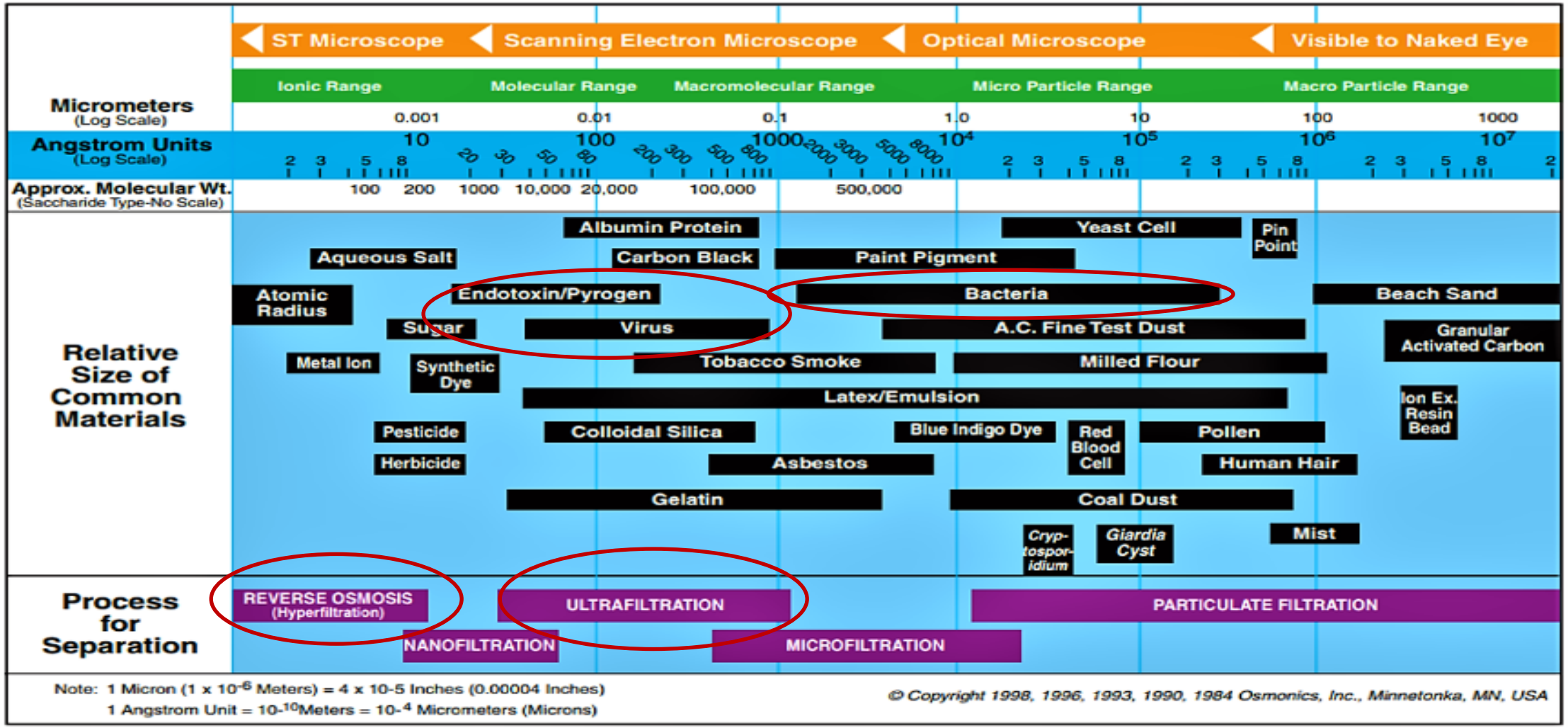
- 33 patients admitted to the hospital in a 14-day period for anemia with at least one patient reportedly diagnosed with hemolytic anemia and myocardial infarction.
- Test strips used by staff to detect total chlorine were found to be not reactive to chlorine.
- If using test strips, they should be validated upon opening, dated, kept dry, and used according to manufacturer recommendations.

Reverse Osmosis (R.O) Membrane

- Will remove an average of 96-99% of all incoming solute. This includes dissolved inorganic, large organic (>200 molecular weight), endotoxins, viruses, and bacteria
- Thin Film Composite (TFC) is the most commonly used membrane material in dialysis today
- Average service life is 1 to 5 years



Filtration Spectrum



Filtration spectrum of reverse osmosis, nanofiltration, ultrafiltration, microfiltration and particulate filtration relative to the pore size of the common material. Source: RADCLIFF and ZARNADZE(2004)

Objectives

- Review Ultrapure Dialysate

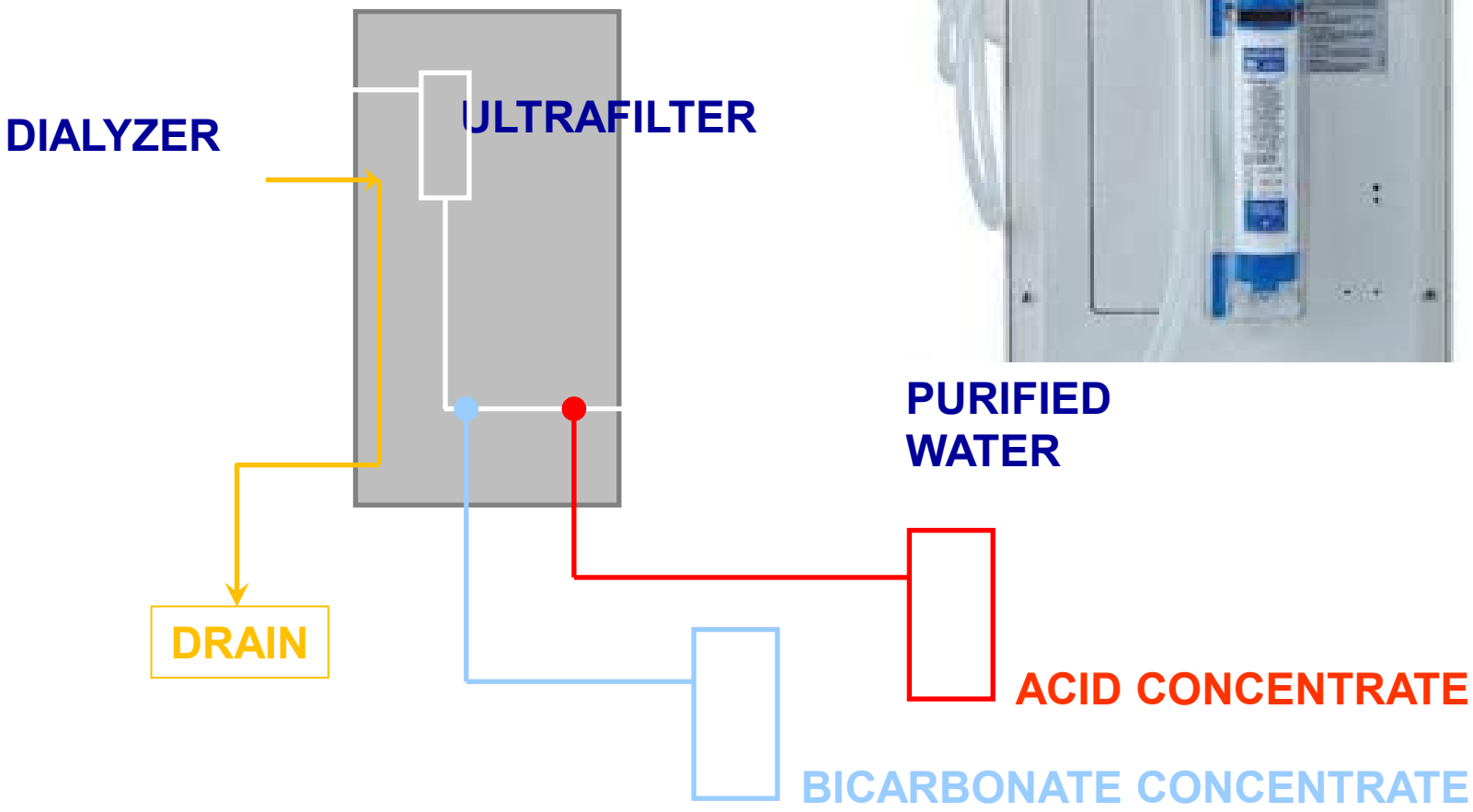
Ultrapure Dialysate Standard

Reference	Allowable dialysate TVC cfu/mL	Action level dialysate TVC	Allowable Level dialysate EU Endotoxin Units	Action Level dialysate EU	
RD52:2004	<200	50	2	1	
ANSI/AAMI/ISO 23500	<100	50	<0.5	0.25	
Ultrapure	<0.1		<0.03		

Ultrafilters (UF)

- Prevents patient from being “final filter”
- Removes Bacteria and endotoxin
  - Validated medical filter (absolute rating)
    - Pore size in the range of 0.001µ to 0.05µ
  - Rated in nominal Molecular Weight Cut Off (MWCO)
    - Typically at a nominal 20,000 daltons
- Place at points of use:
  - Bicarbonate filling station
  - Dialysis machine

Example Point-of-Use Ultrafiltration



Potential Advantages of Ultrapure Dialysate

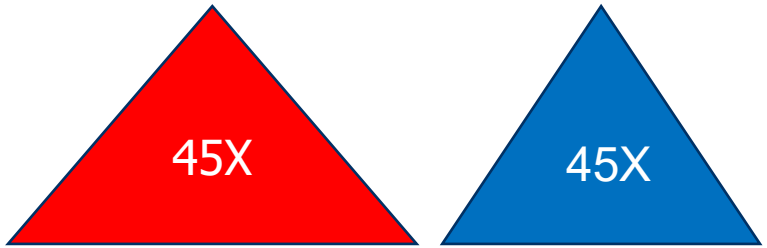
- Less inflammatory stimulus
- Less morbidity associated with inflammation
  - Reduced incidence of β_2-microglobulin amyloid disease.
  - Improved responsiveness to erythropoietin.
  - Improved nutritional status.
  - Improved preservation of residual renal function.

Objectives

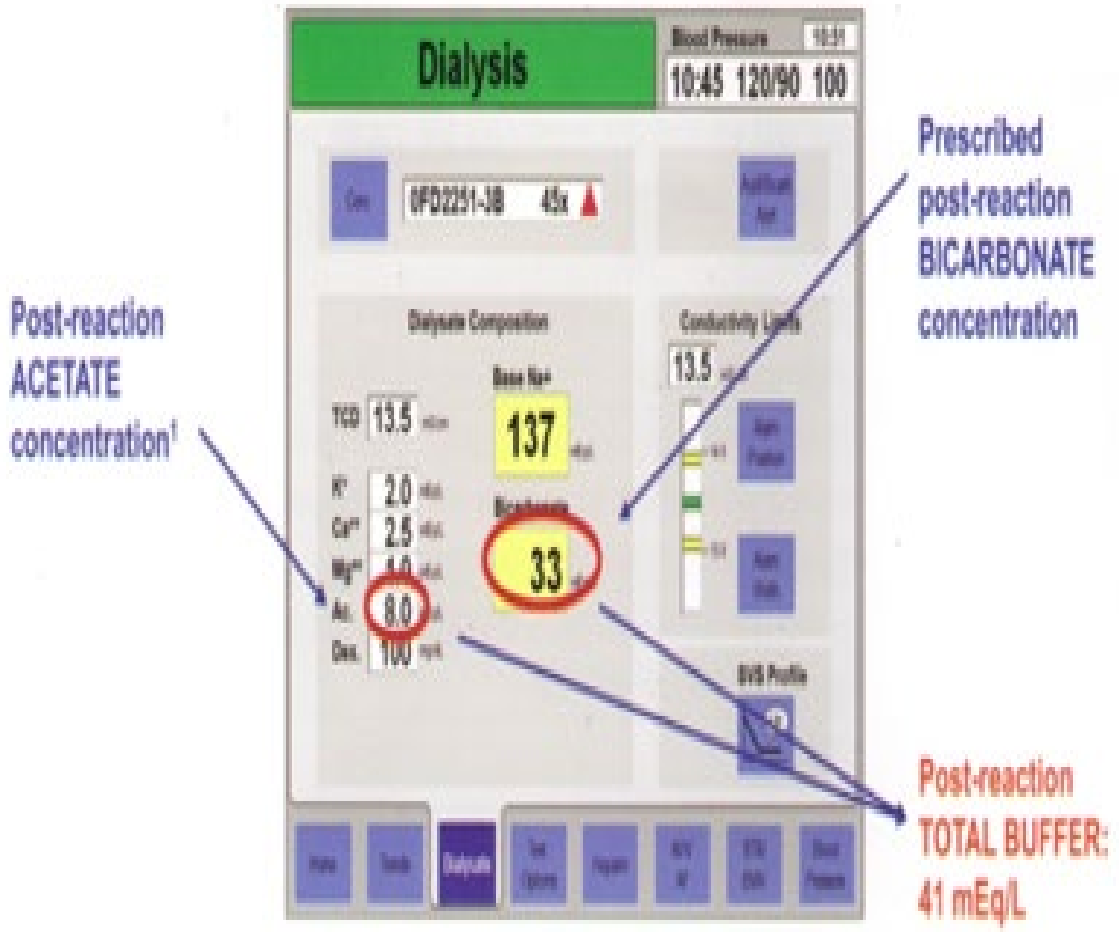
- Clarify the composition of dialysate and how it’s proportioned

Proportioning Systems

- 45x
  - 1 part acid (2.2%)
  - 1.72 parts sodium bicarbonate (3.8%)
  - 42.28 parts purified water (94%)



Sodium Bicarbonate



- Sodium bicarbonate settings
  - Prescribed
  - Post reaction acetate

Alkalosis

HD patient safety data have shown 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.

Summary

- The nephrologist must be intimately involved in the water purification process and has many responsibilities.
- Carbon filters and RO membrane are crucial components of the water system and ensure patient safety.
- R.O. membrane, ultrafilter and dialyzer can effectively block bacteria, endotoxin and virus.
- Ultrapure dialysate can benefit patients.
- Understanding the relationship of the sodium bicarbonate, acid and machine setting can mitigate issues with alkalosis.

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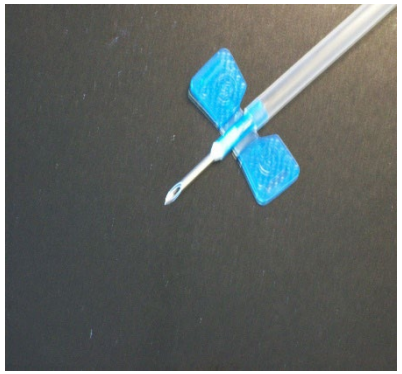

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