

HOSPITAL WATER STANDARDS & REGULATIONS

**DOES YOUR WATER MAKE THE
GRADE?**

By Jeff Lee

Total Water Treatment Systems, Inc.

(100% Employee Owned)

The logo for Total Water Treatment Systems, Inc. features the words "Total" and "Water" stacked vertically in a dark blue, sans-serif font. To the right of the text is a stylized graphic of a blue wave or splash, with the top part being a lighter shade of blue and the bottom part being a darker shade.

Total
Water

About Your Speaker



- Business degree from The University of Iowa
- Water Quality Specialist IV certified through WQA
- Member of Bioforward, Milwaukee Water Council, WHEA, ASHE, ASCLS, ANNA, WQA, and WWQA
- 15 years of experience in the industry.

Customers

- 40 % of Hospitals - WI
- 45% of Dialysis Clinics - WI
- 30% of Laboratory Clinics - WI
- 50% of Biotech Companies - WI
- GE Healthcare
- Marquette University
- Medical College of Wisconsin
- SC Johnson & Family
- University of Wisconsin & UW Hospital



Tap Water Contaminants

- **Chlorine or Chloramines**
- **Ionic Material or Dissolved Solids**
- **Organics**
- **Bacteria**
- **Particulate**
- **Hardness and silica**

Water Standard's Brochure - Handout

AAMI Standards	
Contaminant	AAMI Suggested Maximum Levels
Aluminum	0.010 mg/L
Antimony	0.005 mg/L
Arsenic	0.05 mg/L
Boron	0.100 mg/L
Beryllium	0.001 mg/L
Cadmium	0.005 mg/L
Calcium	1.000 mg/L
Chromium	0.014 mg/L
Copper	0.100 mg/L
Cyanide	0.020 mg/L
Fluoride	0.200 mg/L
Iron	N/A
Lead	0.005 mg/L
Magnesium	4.000 mg/L
Mercury	0.001 mg/L
Nitrate (as N)	1.000 mg/L
pH	N/A
Potassium	1.000 mg/L
Resistivity	N/A
Selenium	0.040 mg/L
Silver	0.050 mg/L
Sodium	10.000 mg/L
Sulfate	100.000 mg/L
Thallium	0.001 mg/L
Total Dissolved Solids	N/A
Zinc	0.100 mg/L

Conductivity and Resistivity (NaCl and CaCO ₃ Solutions at 25° C)				
* 1 µmho/cm = 10 ⁻⁶ S/cm (CaCO ₃)				
Conductivity µmho/cm	ppm as CaCO ₃	ppm NaCl	Conductivity microhm/cm	Resistivity megohm/cm
100	1.00	2.00	1000	0.00010
200	2.00	4.00	2000	0.00020
300	3.00	6.00	3000	0.00030
400	4.00	8.00	4000	0.00040
500	5.00	10.00	5000	0.00050
600	6.00	12.00	6000	0.00060
700	7.00	14.00	7000	0.00070
800	8.00	16.00	8000	0.00080
900	9.00	18.00	9000	0.00090
1000	10.00	20.00	10000	0.00100
1500	15.00	30.00	15000	0.00150
2000	20.00	40.00	20000	0.00200
2500	25.00	50.00	25000	0.00250
3000	30.00	60.00	30000	0.00300
3500	35.00	70.00	35000	0.00350
4000	40.00	80.00	40000	0.00400
4500	45.00	90.00	45000	0.00450
5000	50.00	100.00	50000	0.00500
5500	55.00	110.00	55000	0.00550
6000	60.00	120.00	60000	0.00600
6500	65.00	130.00	65000	0.00650
7000	70.00	140.00	70000	0.00700
7500	75.00	150.00	75000	0.00750
8000	80.00	160.00	80000	0.00800
8500	85.00	170.00	85000	0.00850
9000	90.00	180.00	90000	0.00900
9500	95.00	190.00	95000	0.00950
10000	100.00	200.00	100000	0.01000

Semiconductor		
Test	Attainable	Acceptable
Resistivity @ 25° C	100	100
(% stress)	100	95
TUC (ppb)	<1	<2
OC-120*	<1	<2
FTM (ppb)	<1	<5
Particles /cc/Liter		
SEMI	-	-
0.1-0.1µm	<150	100
0.1-0.1µm	<150	100
0.2-0.2µm	<10	100
0.5-1.0µm	<10	10
>0.1µm	<10	10
0.1-0.1µm	<150	100
0.2-0.2µm	<120	100
0.5-1.0µm	<10	10
0.2-1.0µm	<1	1
>0.1µm	<1	1
Oxygen (ppb)		
O ₂ Flow System	<10>1	<10>1
Bacteria (cfu/sample volume)		
1 Liter	<1	<1
Wash (ppb)		
Total	<1.0	1.0
Dissolved	<0.1	<0.1

AAMI Bacterial Contamination Limits	
Parameter	AAMI Recommended Limit
Purified Water	<10 cfu/ml
Dialysis	<10 cfu/ml
Endotoxins	<1 end by LAL

ASTM			
Water Specifications:			
Water Type	I	II	III
Maximum Turbidity, NTU (20°C)	1.00	1.00	4.0
Total Organic Carbon, mg/L (ppm)	100	10	100
Chlorine, mg/L (ppm)	1	1	10
Total Nitrate, mg/L (ppm)	1	1	10
Total Nitrite, mg/L (ppm)	1	1	10
Water Type	A	B	C
Maximum Bacteria Count (cfu/ml)	<100	<100	<100
Endotoxins (end/ml)	<0.1	<0.1	N/A

CLRW (Clinical Laboratory Reagent Water)		
Water Specifications:		
Water Type	CLRW	SRW
Maximum Bacteria Count (cfu/ml)	10	100
Maximum Turbidity, NTU (20°C)	1.0	1.0
Maximum Resistivity, µmho/cm (25°C)	10	10
Pyrogenic Matter	0.25	0.25
Cryptosporidium (TC ₈₀)	100 ppb	100 ppb

USP 31 NF 26 WATER		
** Distill from Distill		
(TOC) Total Organic Carbon N.E.	500 ppb	500 ppb
Conductivity	1.5 µmho/cm @ 25°C	1.5 µmho/cm @ 25°C
Bacteria (cfu/ml)	100**	100**
WFI	10-100	0.1
Endotoxins (end/ml): LAL		
Purified WFI	—	Discharged
WFI	25	Discharged



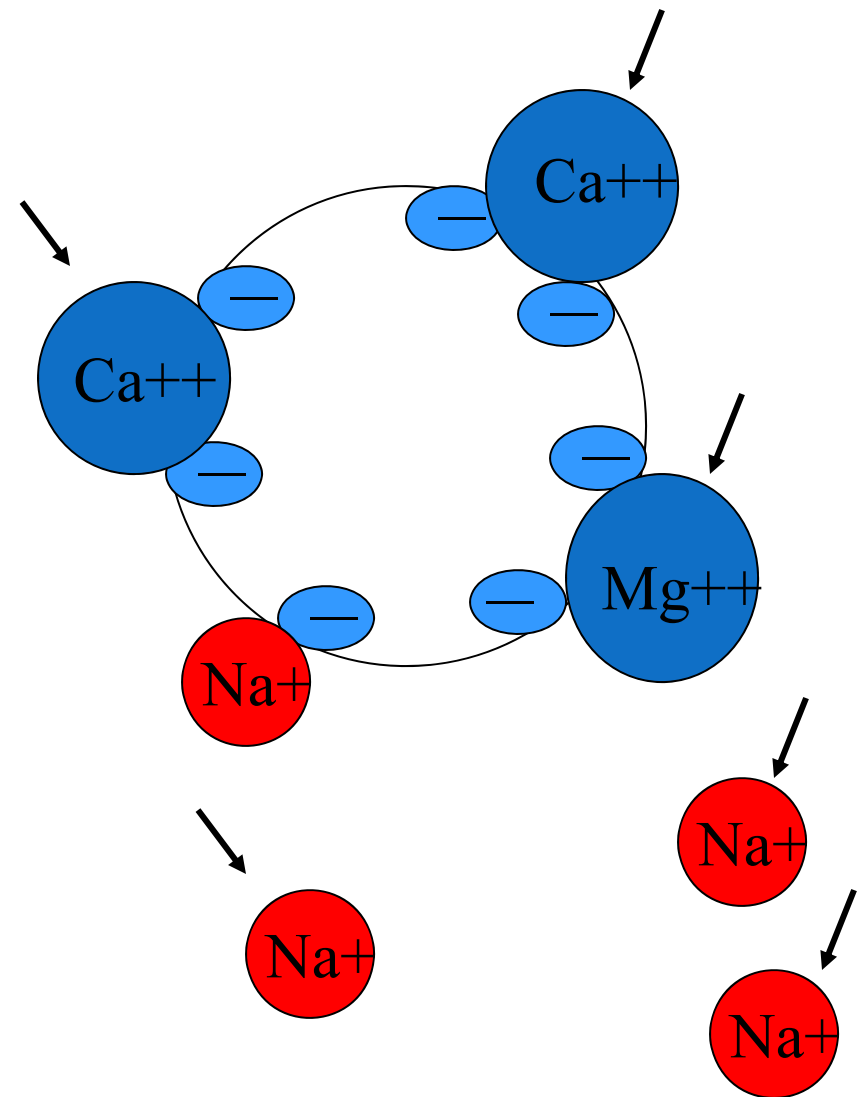


Purified Water Systems

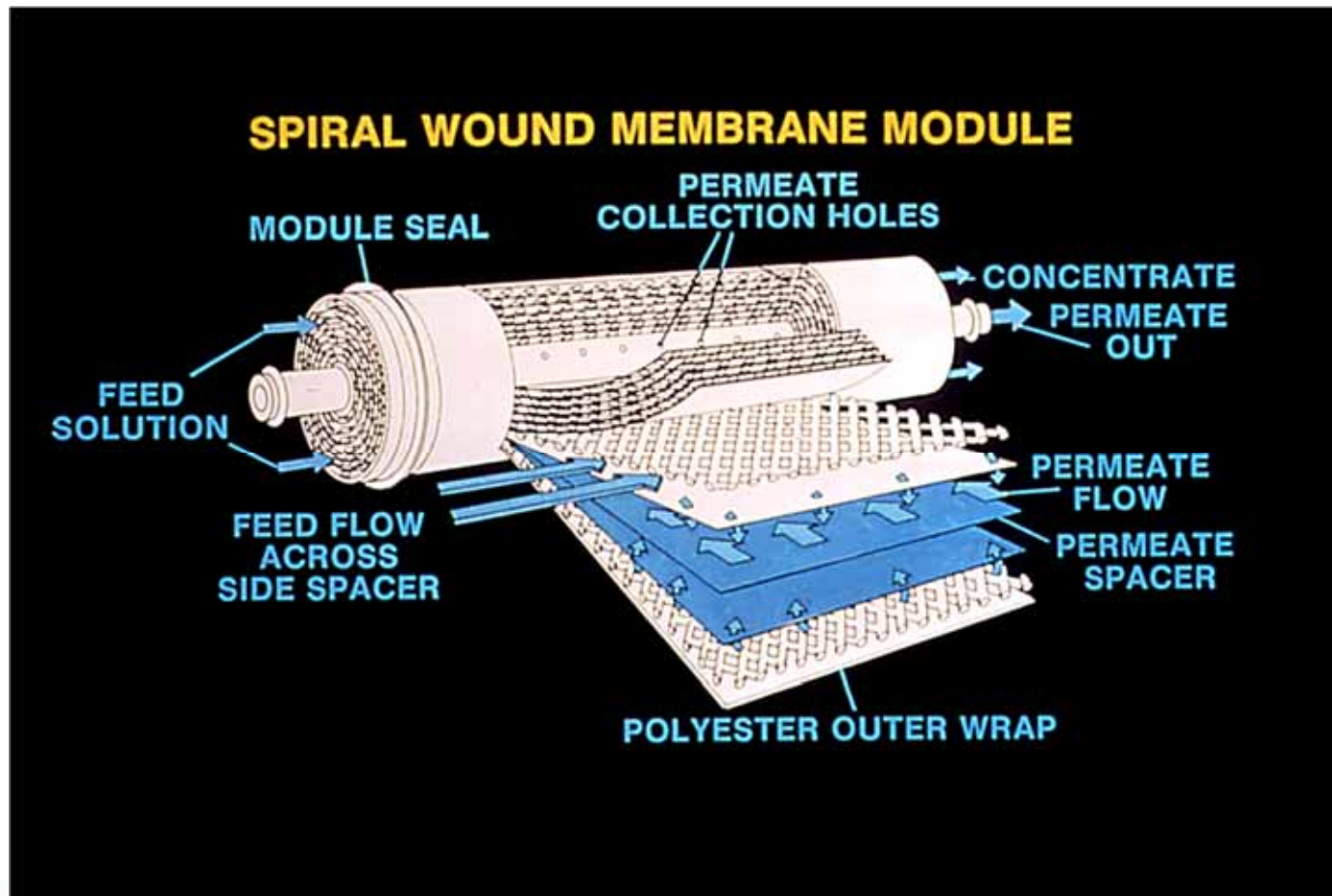
- Softened
- Reverse Osmosis
- Distilled - Still
- Deionized

Water Softening

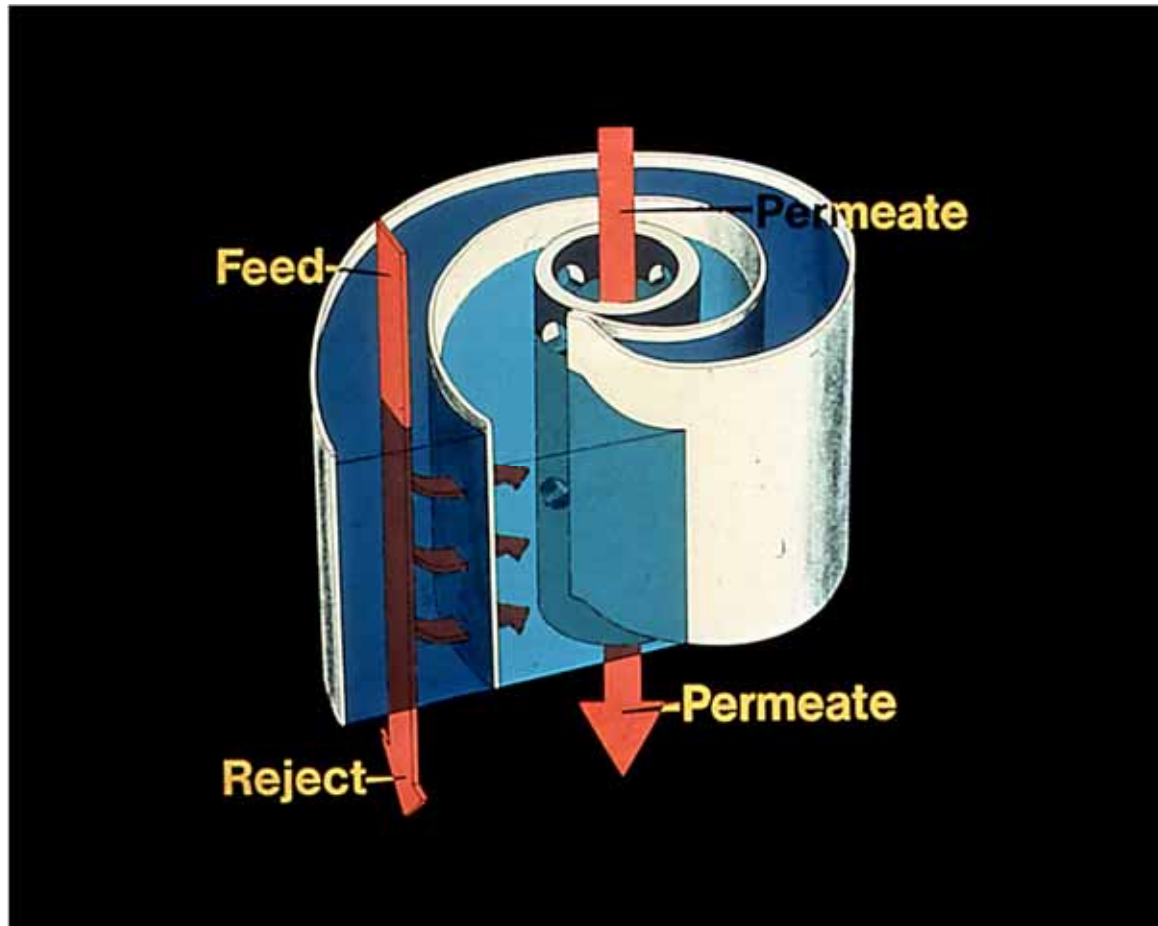
- The resin has a higher affinity for the more highly charged calcium and magnesium ions.
- As hard water passes through the resin bed, the calcium and magnesium ions attach to the resin.



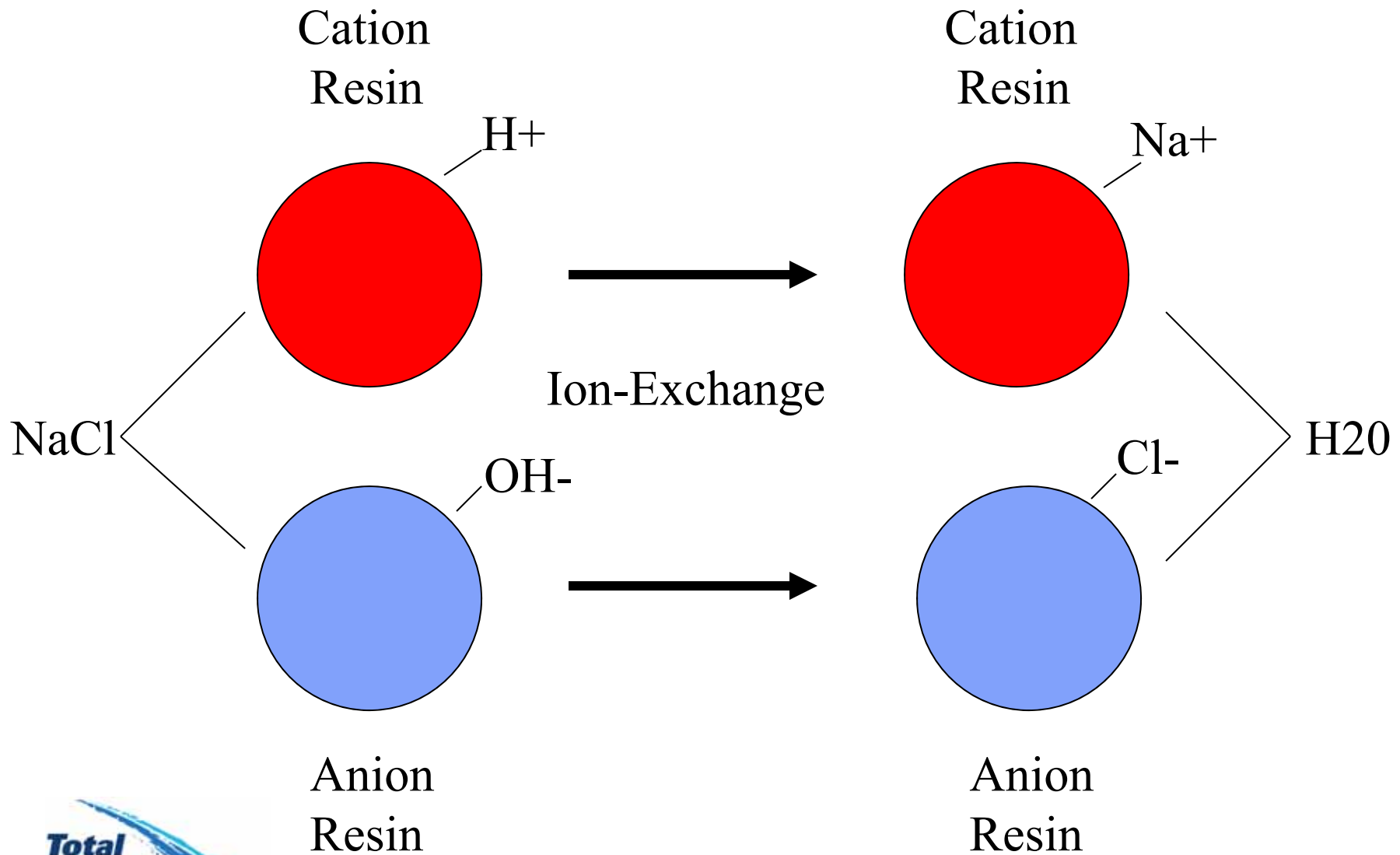
Reverse Osmosis Membrane



Reverse Osmosis Membrane



Deionization Process



Quality Ranges of Purified Water

- Polishing System 18.2 MΩ/cm @ 25° C (pH 7)
- Mixed Bed DI 2 - 18 MΩ/cm @ 25° C (pH 7)
- Two Bed DI 200k to 800k ohms (pH 8.5-9.0)
- Weak Base DI 20k to 200k ohms (pH 6.2)
- Reverse Osmosis 100k – 200k ohms (pH 6.2)

Difference - RO vs. DI

Description	DI	RO
Removes inorganics effectively	yes	yes
Removes organics effectively	no	yes
Removes CO ₂	yes	no
Removes O ₂	no	no
Requires pre-treat of carbon filtration	yes	yes
Total Dissolved Solids	yes	yes
Total Suspended Solids	no	yes
Reactive Silica	yes	yes
Non-reactive Silica	no	yes

Hospital Water Standards

- AAMI – Kidney Dialysis Water Std
- CLRW – Clinical Lab Reagent Water Std
- Decontamination
- Sterilizer Water



CLSI - Clinical Lab Reagent Water Std. (CLRW):

- Resistivity 10 meg-ohm
- Total Organic Carbon 500 ppb
- Bacteria (cfu/ml) 10 cfu/ml
- Particulate Matter 0.22

CLRW Water System



Purified Water Lab Quality Standards

- Type I Water
 - 18.2MΩ/cm @ 25° C
 - TOC < 10 PPB
- Type II Water
 - 5.0 MΩ/cm @ 25° C
 - TOC < 30 PPB
- Type III Water - Reverse Osmosis Water



Type I Water

- Recommended for Critical Laboratory Applications
 - HPLC
 - Blanks and sample dilution in GC, HPLC, AA, ICP-MS, and other advanced analysis techniques
 - Preparation of buffers and culture media for mammalian cell culture
 - Reagents for molecular biology

Millipore Advantage



Barnstead Diamond



Type II Water

- Recommended for Regular Laboratory Applications
 - Buffers
 - pH solutions
 - Microbiological media preparation
 - Feed to clinical analyzers and weatherometers
 - Preparation of reagents for chemical analysis or synthesis
 - Feed to Type I ultrapure water systems

Type II Deionized Water System





Type III Water

- Recommended for General Non-Critical Laboratory Applications
 - Feed to glassware washing machines final rinse
 - Heating baths
 - Autoclaves
 - Solution - RO Water, Two-Bed DI, or Mixed Bed DI

AAMI Water Standards

What are the AAMI contamination levels

Hemodialysis Water Quality - Chemical Contaminant Levels

Maximum allowable chemical contaminant levels in water used to prepare dialysate and concentrates and to reprocess dialyzers for multiple use.

Contaminant	Maximum Concentration (mg/L)	Contaminant	Maximum Concentration (mg/L)
Calcium	2 (0.1 mEq/L)	Mercury	0.002
Magnesium	4 (0.3 mEq/L)	Selenium	0.09
Potassium	8 (0.2 mEq/L)	Silver	0.005
Sodium	70 (3.0 mEq/L)	Aluminum	0.01
Antimony	0.006	Chloramines	0.10
Arsenic	0.005	Free Chlorine	0.50
Barium	0.10	Copper	0.10
Beryllium	0.0004	Fluoride	0.20
Cadmium	0.001	Nitrate (as N)	2.0
Chromium	0.014	Sulfate	100
Cyanide	0.02	Thallium	0.002
Lead	0.005	Zinc	0.10



AAMI Chlorine Standard

**What are the AAMI suggested
maximum contaminant levels
for chlorine and chloramines?**

Chlorine 0.5 mg/L

Chloramines 0.1 mg/L

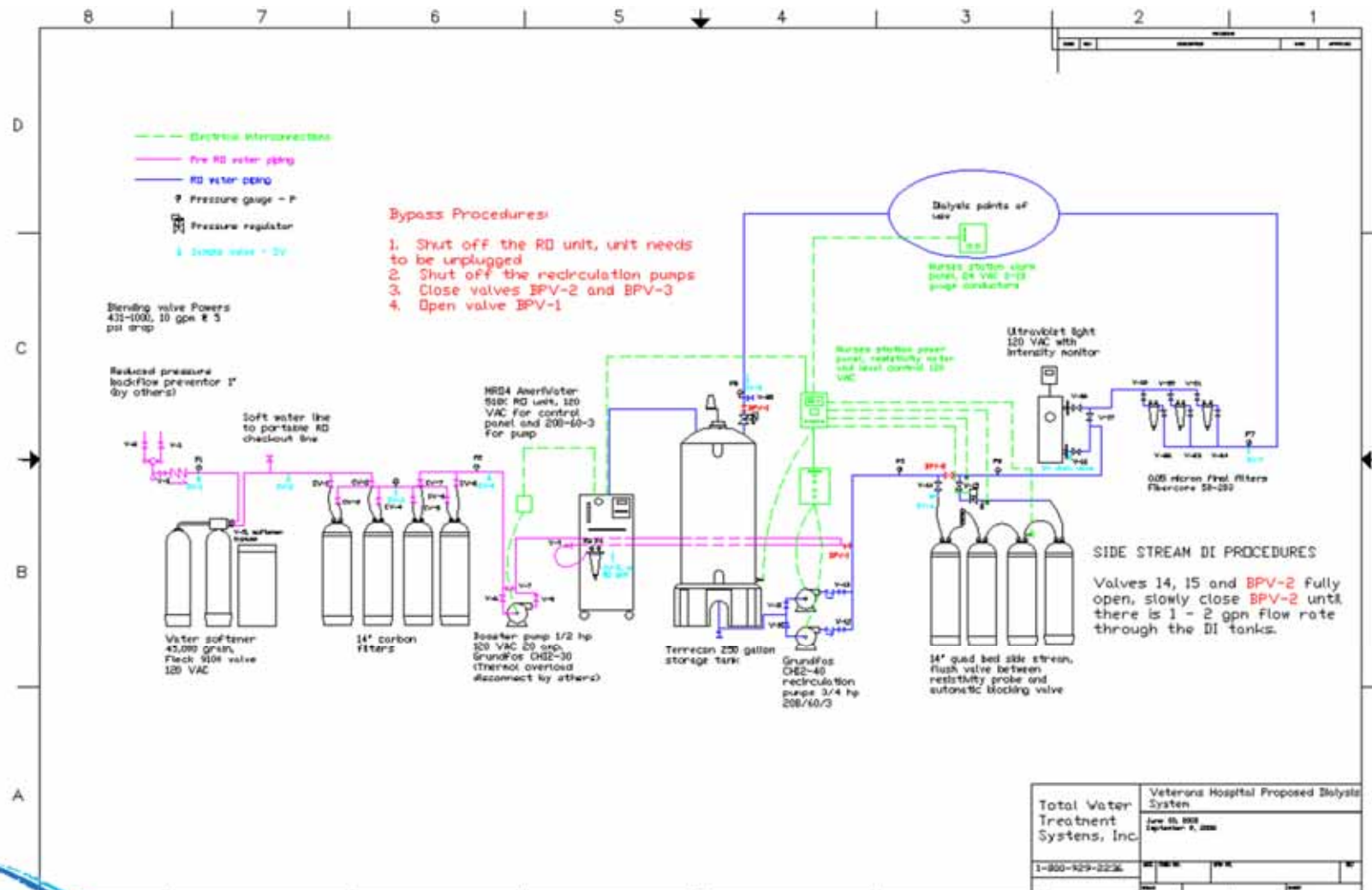
AAMI Bacteria Standard

- Maximum Bacteria in Water < 200 cfu/ml
- Maximum Bacteria in Dialysate < 200 cfu/ml
- Maximum Endotoxin Level < 2 EU

Dialysis Water System



Dialysis Process Water Drawing



Total Water Treatment Systems, Inc.	Veterans Hospital Proposed Dialysis System		
	June 25, 2008	Revision 1	Sheet 1 of 1
1-800-829-2226	DATE	BY	APP



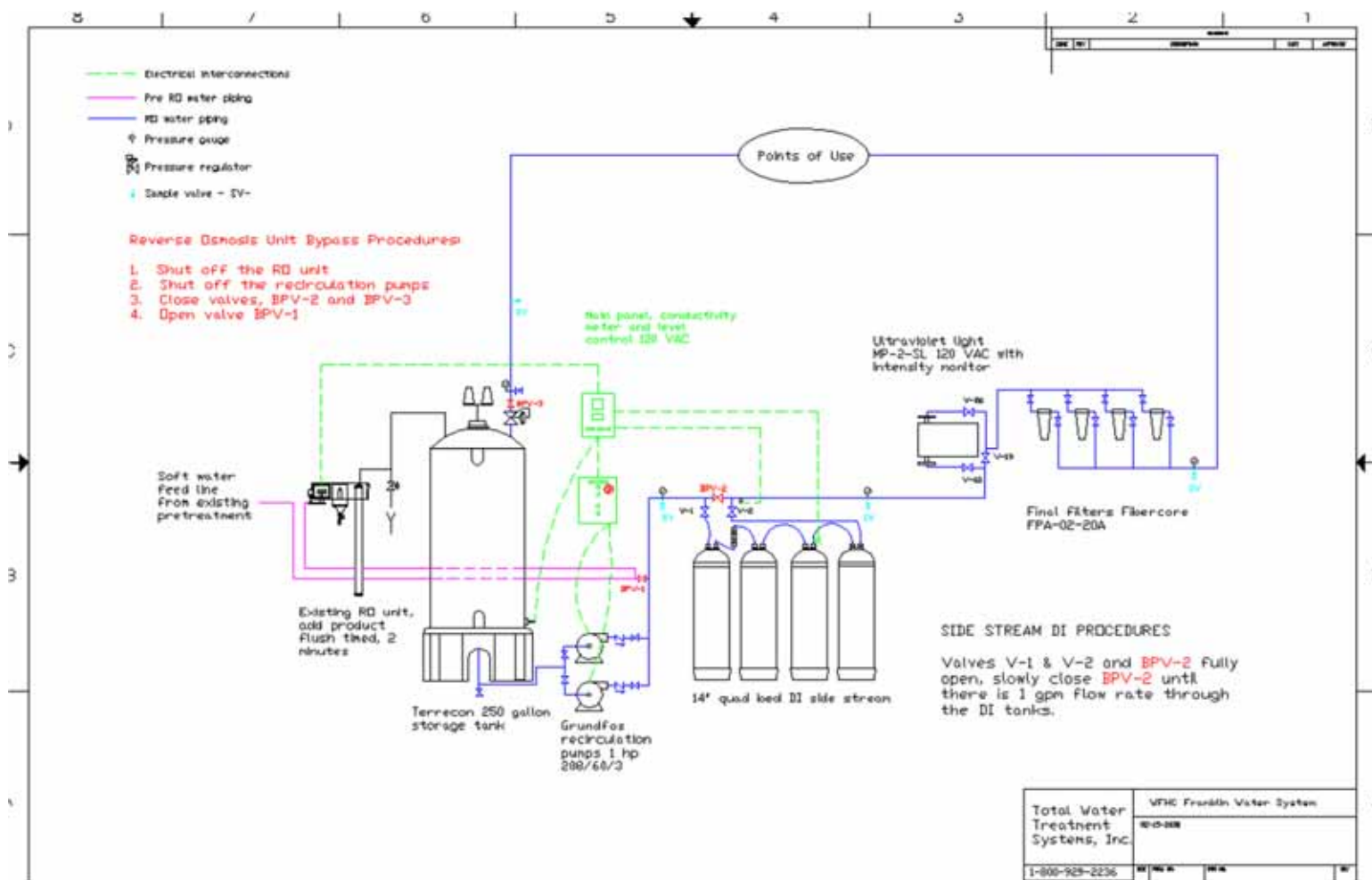
Decontamination/Sterilizer Water Quality

- Conductivity Better than 200k
 - Reverse osmosis polished by deionized mixed bed resin tanks
- TOC No standard
- Bacteria Minimum – no std
 - Ultraviolet light and 0.2-micron final filtration

Sterilizer & Decontamination System



Sterilizer & Decontamination Process Drawing

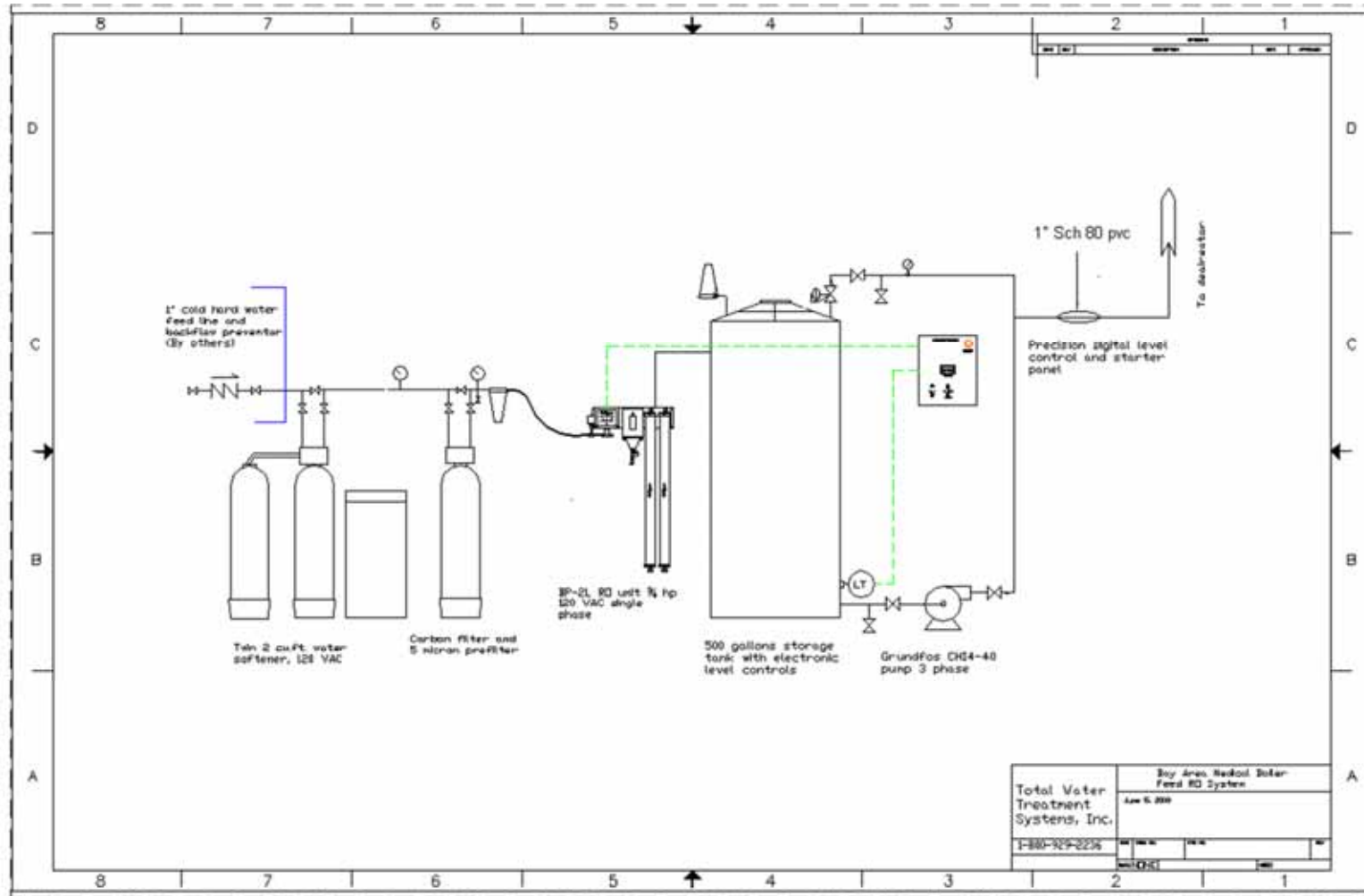




Boiler Water Standard

- Conductivity < 20 uS/cm
 - Reverse osmosis water is ideal

Boiler Treatment System



USP Water System



Questions





Additional Questions?

Feel free to contact me with any additional questions.

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Thank you!