Bridge of Life

Water Treatment for Hemodialysis



Water Treatment

Rationale for Treating Water
 Patient safety issues

 Very large exposure volume
 Little or no renal excretion
 Dialyzer membrane is sole barrier
 Prevention of equipment damage

Water Treatment

Regulatory Agencies

- AAMI standards
 - Association for the Advancement of Medical Instrumentation

- ISO Standards

- International Organization for Standardization
- Local regulations

Old Maximum Standards for Water

Hemodialysis and reuse water

- < 200 colony count or CFU/ml
- < 5 EU of bacterial lipopolysaccharide "LAL" assay

Dialysate Effluent
 - < 2000 CFU/ml

Current Maximum Standards for Water

 ◆ Hemodialysis and reuse water

 ≤ 100 colony count or CFU/ml
 ≤ .25 EU of bacterial lipopolysaccharide "LAL" assay

 ◆ Dialysate Effluent

 ≤ 100 CFU/ml

DQW Acceptable, Action and Unacceptable Range

Water/ Dialysate Culture Parameters

- Acceptable level: below 50 cfu/ml
- Action level: 50-99 cfu/ml
- Unacceptable level: 100 cfu/ml or greater

Water Endotoxin Parameters

- Acceptable level: below 0.12 EU/ml
- Action level: 0.12 EU/ml
 to less than 0.25 EU/ml
- Unacceptable level:
 0.25 EU/ml or greater

Dialysate Endotoxin Parameters

- Acceptable level: below 0.25 EU/ml
- Action level: 0.25 EU/ml to less than 0.50 EU/ml
- Unacceptable level:
 0.50 EU/ml or greater

Symptoms and Contaminants

<u>Symptoms</u>	<u>Water Contaminant-</u> <u>Related Cause</u>
Anemia	Aluminum, chloramines, copper, zinc
Bone disease	Aluminum, fluoride
Hemolysis	Chloramines, copper, nitrates
Hypertension	Calcium, sodium
Hypotension	Bacteria, endotoxin, nitrates

More Symptoms and Contaminants

<u>Symptoms</u>	Water contaminant-related cause
Metabolic acidosis	Low pH, sulfates
Muscle weakness	Calcium, magnesium
Nausea and vomiting	Bacteria, calcium, copper, endotoxin, low pH, magnesium, nitrates, sulfates, zinc
Neurological deterioration and encephalopathy	aluminum

Water Treatment Processes

Pre-treatment

 Before the RO

 Purification

 Removes organic, inorganic and bacterial contaminants
 Distribution

Typical Pre-Treatment System



Water Softener



Water Softeners

Primarily for RO protection
Remove "hardness" ions (calcium & magnesium) and add sodium
Sized for at least 1 day's operation
Regenerate with pellet salt

Water Softener Monitoring

- Off-line hardness testing at end of day
- On-line monitoring of pressure drop with pressure gauges
- Verify timer setting
- Verify brine tank salt pellets are above liquid level

Ion Exchange Softening



Carbon Filters

Essential for free chlorine and chloramine removal



Paired Carbon Filters



Carbon Filter Monitoring

When do we test?
Where do we get the sample?
What are acceptable limits?
Total chlorine limit is 0.1 mg/L

Carbon Filter Monitoring, cont.

What do you do if levels checked after first tank are too high?
If post-second tank levels are within limits, how often do we monitor?
If post-second tank levels become too high, what do we do?

Reverse Osmosis

 Use semi-permeable membrane and pump to overcome (reverse) osmotic pressure and produce purified water

♦ Remove

- Organic and inorganic contaminants
- Bacteria and endotoxin

 Nearly ideal device for dialysis water purification

Reverse Osmosis



RO Monitoring

Continuous on-line monitoring Off-line monitoring

- Product water laboratory analyses for AAMI contaminants
- Product water bacterial counts & endotoxin levels

Ultraviolet

♦ Action

Destroys bacteria or makes them incapable of reproducing
Is used only in conjunction with other water treatment systems

Ultrafilter/Endotoxin Filter

 Last component before water is distributed to patient stations
 Submicron filter for small particles
 Extracts bacteria and endotoxin

Distribution Systems

- Convey purified water to points of use
- Must maintain purified water quality
- Components include pipes, valves, regulators & other piping fixtures
 May be indirect feed (holding tank) or direct feed design

Indirect Feed Design



Direct Feed Design



Daily Water System Check and Monitoring

	FACILITY:		Date:								8		
	Monitored Process or Component	Acceptable Limit(s)	Monitor Location	MON	TUE	WED	THU	FRI	SAT	SUN			
1	Is RO On? (RO must be running for 15 minutes)	YES (Y)	RO Pump										
2	Pretreatment Feed Water Pressure	Enter Facility Specific	Pressure Gauge #										
3	Feed Water Temperature	> 60 F but < 85 F	Temp Gauge #	5		8		8					
4	All Pretreatment Timers are Set for the	YES (Y)	Timer Controls										
5	Multimedia filter pressure (Pre - Post)	Delta pressure < or = to 15 psi Y / N / NA	Pre-treatment										
6	Scavenger Tank pressure (Pre - Post)	Delta pressure < or = to 15	Pre-treatment										T
7	Scavenger Brine Tank Salt Level	Tank at least half full , Above the waterY / N / NA,	Brine Tank										
8	Cartridge filter pressure (Pre - Post)	Delta pressure < or = to 15 psi Y / N / NA	Pre-treatment										ľ
9	Water softener pressure (Pre - Post)	Delta pressure < or = to 15 psi	Pre-treatment										
10	Salt Level in Brine Tank?	Tank at least half full , Above the waterY / N / NA,	Brine Tank								Signature	Signature	Signature
11	Primary carbon pressure (Pre - Post)	Delta pressure < or = to 15 psi	Pre-treatment										
12	Secondary carbon pressure (Pre - Post)	Delta pressure < or = to 15 psi	Pre-treatment								initials.	initials	with the
13	Is RO Bypass Valve Closed?	YES (Y) or N/A	Bypass Valve (V#)								100		
14	RO Pre-filter Inlet Pressure	Enter Facility Specific	Pressure Gauge #										
15	RO Pre-filter Outlet Pressure	Enter Facility Specific	Pressure Gauge #										
16	RO Pre-filter Delta Pressure	< 20 psi	Line 16 - Line 17										
17	RO Product Water Quality	Enter Facility Specific	RO Monitor										
18	RO Percent Rejection	>/= 90%	RO Monitor or Independent Meter										
19	RO Product Water Flow Rate	Enter Facility Specific	RO Monitor or Flow Meter										
20	RO Reject Water Flow Rate	Enter Facility Specific	RO Monitor or Flow Meter										
21	Final Product Water Quality	Enter Facility Specific	Final Quality Monitor										
22	Ultrafilter Inlet Pressure	Enter Manufacturer Specific	Pre UF Gauge #								- 24	1	Ē
23	Ultrafilter Outlet Pressure	Enter Manufacturer Specific	Post UF Gauge #										
24	Ultrafilter Delta Pressure (Pre - Post)	Enter Manufacturer Specific	Line 24 - Line 25										
25	If In Use, Is UV light(s) On?	YES (Y) or N/A	UV Controller										
26	Time When Checks Above Completed	Prior to Start of Patient Treatment Day	Time of Day										
27	If Required, Time When Biomed Contacted for Direction or Assistance	Contact Time or N/A	Time of Day								roture	nature	radure
28	Initials of Teammate Performing Above Checks	Teammates Initials	Match Signature on Side								8	8	18
29	Initials of Licensed Nurse	Licensed Nurses Initials	Match Signature on Side										
30	End of Day Hardness Test Result	= 1 gr/gal / NA</th <th>Post Softener Sample Port</th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th></th> <th>Initials</th> <th>Initials</th> <th>Initials</th>	Post Softener Sample Port								Initials	Initials	Initials
31	Time and initials of Teammate Performing End of Day Hardness Test	Time & initials	Match Signature on Side										

MONTH

Empty Bed Contact Time (EBCT)

Empty Rod Contact Timos

Amount				LIII	ptyl	Deu	001	llau		162						
to Order				Gall	on per	Minute	RO u	sage (p	permea	te and	concen	trate)				
cu.ft.	7.48 factor	1 gal	2 gal	3 gal	4 gal	5 gal	6 gal	7 gal	8 gal	9 gal	10 gal	11 gal	12 gal	13 gal	14 gal	15 gal
1	7.5	7.5	3.7	2.5	1.9	1.5	1.2	11	0.9	0.8	0.7	0.7	0.6	0.6	0.5	0.5
2	15.0	15.0	7.5	5.0	3.7	3.0	2.5	2.1	1.9	17	1.5	1.4	1.2	1.2	11	1.0
3	22.4	22.4	11.2	7.5	5.6	4.5	3.7	3.2	2.8	2.5	2.2	2.0	1.9	1.7	1.6	1.5
4	29.9	29.9	15.0	10.0	7.5	6.0	5.0	4.3	3.7	3.3	3.0	2.7	2.5	2.3	2.1	2.0
5	37.4	37.4	18.7	12.5	9.4	7.5	6.2	5.3	4.7	4.2	3.7	3.4	3.1	2.9	2.7	2.5
6	44.9	44.9	22.4	15.0	11.2	9.0	7.5	6.4	5.6	5.0	4.5	4.1	3.7	3.5	3.2	3.0
7	52.4	52.4	26.2	17.5	13.1	10.5	8.7	7.5	6.5	5.8	5.2	4.8	4.4	4.0	3.7	3.5
8	59.8	59.8	29.9	19.9	15.0	12.0	10.0	8.5	7.5	6.6	6.0	5.4	5.0	4.6	4.3	4.0
9	67.3	67.3	33.7	22.4	16.8	13.5	11.2	9.6	8.4	7.5	6.7	6.1	5.6	5.2	4.8	4.5
10	74.8	74.8	37.4	24.9	18.7	15.0	12.5	10.7	9.4	8.3	7.5	6.8	6.2	5.8	5.3	5.0
11	82.3	82.3	41.1	27.4	20.6	16.5	13.7	11.8	10.3	9.1	8.2	7.5	6.9	6.3	5.9	5.5
12	89.8	89.8	44.9	29.9	22.4	18.0	15.0	12.8	11.2	10.0	9.0	8.2	7.5	6.9	6.4	6.0
13	97.2	97.2	48.6	32.4	24.3	19.4	16.2	13.9	12.2	10.8	9.7	8.8	8.1	7.5	6.9	6.5
14	104.7	104.7	52.4	34.9	26.2	20.9	17.5	15.0	13.1	11.6	10.5	9.5	8.7	8.1	7.5	7.0
15	112.2	112.2	56.1	37.4	28.1	22.4	18.7	16.0	14.0	12.5	11.2	10.2	9.4	8.6	8.0	7.5
				Minim	um Co	ntact T	ime 3.5	5 . If Ch	lorami	ne, min	imum is	6.5 Ide	al is 5 8	10		

MONTH

	FACILITY:	(š	Date:							
	Monitored Process or Component	Acceptable Limit(s)	Monitor Location	MON	TUE	WED	THU	FRI	SAT	SUN
1	Is RO On? (RO must be running for 15 minutes)	YES (Y)	RO Pump							
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3	Feed Water Temperature	> 60 F but < 85 F	Temp Gauge #							
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6	Multimedia filter pressure (Pre - Post)	Delta pressure < or = to 15 psi Y / N / NA	Pre-treatment							
6	Scavenger Tank pressure (Pre - Post)	Delta pressure < or = to 15 psi / NA	Pre-treatment							
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26	Time When Checks Above Completed	Prior to Start of Patient Treatment Day	Time of Day		-					
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31	Time and initials of Teammate Performing End of Day Hardness Test	Time & initials	Match Signature on Side							

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RO OPERATION

RO MEMBRANES WILL BECOME DIRTY AND FOULED WITH: •DIRT •ORGANICS •SCALE •IRON AND OTHER METALS •COLLOIDS •MICRO-ORGANISMS (ALIVE & DEAD)

IT WILL BE NECESSARY TO CLEAN AND DISINFECT THE RO SYSTEM PERIODICALLY CLEANING VERSUS DISINFECTION

CLEANING OBJECTIVES •INCREASE REJECTION •REDUCE PRODUCT TDS •INCREASE PRODUCT FLOW

BY REMOVING DIRT, SCALE, IRON, OTHER METALS, ORGANICMATERIALS AND MICRO-ORGANISMS

•GET AS MUCH STUFF OFF THE MEMBRANE AS POSSIBLE

RO MAINTENANCE - DISINFECTION

DISINFECTION OBJECTIVES

•REDUCE OR ELIMINATE VIABLE BACTERIA FROM THE WATER FLOW PATH
•ESPECIALLY THE PURIFIED WATER FLOW

•FOR INDIRECT FEED SYSTEMS (STORAGE TANKS) THE RO IS USUALLY DISINFECTED SEPARATELY

•FOR DIRECT FEED SYSTEMS (NO STORAGE TANK), THE WATER LOOP IS DISINFECTED WITH THE RO

CLEANING AND DISINFECTION

THE GOAL OF BOTH PROCEDURES IS TO PROVIDE CLEAN, SAFE WATER TO THE PATIENTS

WHEN TO CLEAN

WHEN PRODUCT WATER <u>FLOW RATE</u>: •DECREASES BY 10 PER CENT.

WHEN <u>REJECTION</u> DECREASES: •"DOUBLING" OF THE SALT PASSAGE RATE

EXAMPLE: NEW RO REJECTION RATE = 97% SALT PASSAGE RATE = 3% SO, CLEAN WHEN REJECTION FALLS TO 94%

WHEN TO CLEAN

ROUTINE PREVENTIVE MAINTENANCE EVERY 60 TO 90 DAYS

WHEN TO CLEAN

•FEED WATER DEPENDENT
•PRE-TREATMENT HELPS REDUCE FREQUENCY
•INCREASE FREQUENCY WHEN UPSETS OCCUR
•CITY WATER PROBLEMS
•HIGH PH
•HIGH HARDNESS
•TEMPORARY PRE-TREAT BREAKDOWNS

RO MAINTENANCE - DISINFECTION

WHEN TO DISINFECT

CURRENT AAMI/ISO RECOMMENDATION •ACTION LEVEL: 50-99 CFU •MAXIMUM LEVEL: >100 CFU

•WHENEVER COLONY COUNT TEST RESULTS INDICATE INCREASING CFU PER ML

RO MAINTENANCE - DISINFECTION

REGULARLY SCHEDULED DISINFECTION, DILIGENT SURVEILLANCE (TESTING) AND TIMELY RESPONSE (DISINFECTING) IS THE BEST WAY TO MAINTAIN MICROBIOLOGICAL CONTROL CLEANING THE RO SYSTEM **CLEANING - GENERAL**

ACID & BASE '2-STEP' CLEANING PROCESS

•LOW PH (ACID) FOR CALCIUM AND IRON
•HIGH PH (BASE) FOR SILT AND ORGANICS

ALWAYS USE LOW PH (ACID) SOLUTION FIRST •REMOVES MINERAL SCALE AND METALS •<u>ALWAYS</u>: WHEN USING PERACETIC ACID FOR DISINFECTION

CLEANING - IRON

•IRON IS A PARTICULAR PROBLEM

IRON ABOVE 0.05 MG/LMAY ACCUMULATE ON MEMBRANE

•MEMBRANE DAMAGE MAY OCCUR WHEN IRON IS PRESENT AND PERACETIC ACID IS APPLIED

•OTHER "TRANSITION METALS" ALSO A PROBLEM

USE ACID CLEANER WHICH IS FORMULATED TO REMOVE IRON!

CLEANING PROCEDURE - GENERAL

MIX REQUIRED VOLUME OF CLEANER
FOR RO'S UP TO 3 MEMBRANES: 20 GALLONS
EACH ADDED MEMBRANE, ADD 5 GALLONS
READ MANUFACTURER'S LABEL

CONNECT LINES TO CLEANING CONTAINER
USE AN AUXILIARY CLEANING PUMP
USE LARGE HOSES - ESP. SUCTION HOSE
WASTE LINE
PRODUCT LINE
CLOSED LOOP FOR RECIRCULATION

CLEANING PROCEDURE - RECIRCULATION -

BEGIN RECIRCULATION
ENERGIZE BOTH AUXILIARY & RO PUMPS
CHECK FLOWS & PRESSURES
ADJUST AS NECESSARY

•USE LOW PRESSURE
•LESS THAN NORMAL MEMBRANE PRESSURE
• ~ 50-100 VS 250 PSI

•USE HIGHER FLOW •7-10 GALLONS PER MIN (FOUR INCH MEMBRANES)



CLEANING PROCEDURE - RECIRCULATION -

RECIRCULATE FOR 5 TO 20 MINUTES •FOLLOW RO MANUFACTURER'S RECOMMENDATION

MONITOR SOLUTION TEMPERATURE
SOLUTION WILL GET WARMER!
STOP RECIRC IF TEMP APPROACHES 82-84 F.
MAXIMUM 'CLEANING' TEMP FOR MOTOR IS 86 F (NOTE: MAX TEMP FOR PERACETIC ACID IS 75 F.)

 SOUTHERN LOCALES & SUMMER TEMPS
 MAY BE NECESSARY TO ADD ICE BLOCK IN SOLUTION TO KEEP TEMP DOWN

CLEANING PROCEDURE (ALTERNATE)

IF AUXILIARY CLEANING PUMP IS NOT USED CONNECT SUCTION DIRECTLY TO RO PUMP INLET **•**USE LARGE HOSE & FREE-FLOWING CONNECTIONS •NO RESTRICTIONS, NO KINKS •ENERGIZE RO PUMP RECIRCULATE AS PREVIOUSLY INSTRUCTED VERIFY FLOWS ON START (LOWER PRESSURES, HIGHER FLOWS) MONITOR TEMP AND RE-CIRC TIME CLOSELY •SHORT RE-CIRC TIME, LONGER DWELL



CLEANING - GENERAL

•USE LOW PH CLEANER FIRST•RINSE THOROUGHLY & RECORD RESULTS

•USE HIGH PH CLEANER SECOND•RINSE THOROUGHLY & RECORD RESULTS

PERFORM DISINFECTION PROCEDURE
RINSE THOROUGHLY & VERIFY ABSENCE
SHUT OFF FOR 10-15 MIN
RINSE UNIT ADDITIONAL 15-30 MIN
VERIFY ABSENCE OF CHEMICAL
'TWO-PERSON SIGN-OFF' ON CHEMICAL TEST

RINSE PROCEDURE

SAME AS NORMAL RUN MODE EXCEPT PRODUCT LINE DIRECTED TO DRAIN

NORMAL FEED (FROM PRE-TREATMENT)
WASTE LINE TO DRAIN
PRODUCT LINE TO DRAIN

•RINSE THOROUGHLY - DO NOT USE WATER FOR ANY PURPOSE UNTIL RINSE IS COMPLETE DISINFECTING THE ROSYSTEM DISINFECTION
- CHEMICALS -

RECOMMENDED DISINFECTING CHEMICALS

NOTE: MAY VARY BY RO MANUFACTURER AND TYPE OF MEMBRANES

•PERACETIC ACID (1% SOLUTION)
•MINNCARE™, RENALIN™, PURISTERIL™

DISINFECTION
- CHEMICALS -

EXPOSURE PRECAUTIONS FOR DISINFECTANTS

PERACETIC ACID - PERSONAL SAFETY •SPLASH PROTECTION

DISINFECTION - PERACETIC ACID -

RO SYSTEM CONSIDERATIONS

•USE-DILUTION STRENGTH MUST BE 1% (1:100)
•TEMPERATURE MUST NOT EXCEED 75 F.
•MEMBRANES MUST BE FREE OF IRON
•DWELL TIME: 2 HOURS MINIMUM 12 HOURS MAXIMUM

•USE THE MINIMUM DWELL TIME THAT RESULTS IN ACCEPTABLE MICROBIOLOGICAL CONTROL

DISINFECTION

RECALL THAT OUR OBJECTIVE IS TO FORCE THE DISINFECTING / SANITIZING AGENT THROUGH THE MEMBRANES INTO THE PURIFIED WATER FLOW PATH

DISINFECTING PROCEDURE IS SIMILAR TO THE CLEANING PROCEDURE, EXCEPT FOR THE PRESSURES AND FLOWS USED

•NEAR-NORMAL TO NORMAL PUMP OPERATING PSI•NEAR-NORMAL TO NORMAL PRODUCT & WASTE FLOW





DISINFECTION PROCEDURE - RECIRCULATION & DWELL -

RECIRCULATION PERIOD MUST BE LONG ENOUGH TO THOROUGHLY DISTRIBUTE THE DISINFECTANT THROUGHOUT THE RO

•TEST THE PRODUCT WATER TO ASSURE THAT AN ADEQUATE LEVEL OF DISINFECTANT IS PRESENT

•BEGIN DWELL TIME AS APPROPRIATE FOR THE DISINFECTANT USED

TIPS FOR SUCCESS RO UNITS

•CLEAN & DISINFECT ON A REGULAR BASIS BEFORE PROBLEMS ARISE AND BACTERIA/ENDOTOXIN BECOMES ENTRENCHED

•CLEAN MEMBRANES PRIOR TO DISINFECTION PROCEDURE

•ENSURE THAT CHEMICAL CONTACTS EVERY PART OF RO UNIT •OPEN AND CLOSE EVERY BALL VALVE, SAMPLE VALVE, PRESSURE RELIEF VALVE, ETC. •DO THIS WITH PUMP OFF!

•ENSURE MINIMUM DWELL TIME REQUIREMENT IS MET (AT LEAST)
•PURGE EXISTING WATER FROM RO BEFORE RECIRCULATING
•INCREASE VOLUME OF DISINFECTING SOLUTION
•ALLOW ONE-THIRD TO ONE-HALF TO FLUSH TO DRAIN BEFORE CONNECTING WASTE HOSE TO CONTAINER

TIPS FOR SUCCESS STORAGE TANKS - LOOPS

•WHILE CHEMICAL IS RE-CIRCULATING, OPEN EVERY OUTLET TAP IN THE PLUMBING SYSTEM AND DRAW OUT 500-1000 ML

•OPEN AND CLOSE EVERY BALL VALVE, SAMPLE PORT, NEEDLE VALVE, ETC. SEVERAL TIMES TO ENSURE CONTACT •DO THIS WHILE LOOP DISTRIBUTION PUMP IS OFF •REPEAT ALSO DURING RINSE-OUT PROCEDURE

•LOOP PRESSURE RELIEF VALVES: BACK OFF THE SETTING TO MAKE SURE THE VALVE VENTS CHEMICAL TO DRAIN •DON'T FORGET TO RE-SET

•OCCASIONALLY RUN DISINFECTANT OUT THROUGH DIALYSIS MACHINES (CHECK WITH MANUFACTURER FIRST) •ENSURES CONTACT IN CONNECTION PORT, MACHINE HOSE •BE SURE TO MAKE SUFFICIENT QUANTITY OF SOLUTION! •RINSE LOOP AND DIALYSIS CONTROLLERS THOROUGHLY!



INCLUDE TANK FILL PIPE WHEN DISINFECTING

DISINFECTION PROCEDURE - RINSE & VERIFY -

AFTER THE DWELL PERIOD, RINSE THE **ROAS PREVIOUSLY INSTRUCTED** NORMAL FEED STREAM PRODUCT LINE TO DRAIN •DO NOT USE THE THE WATER FOR ANY PURPOSE UNTIL THE RINSE IS COMPLETED RINSE THOROUGHLY - 2 TO 3 HOURS + •TEST PRODUCT WATER TO VERIFY ABSENCE •SHUT OFF FOR 10-15 MIN •RINSE ADDITIONAL 15-30 MIN •RE-TEST & VERIFY ABSENCE OF DISINFECTANT • 'TWO PERSON SIGN-OFF' ON ABSENCE TEST

AND THEN . . .

IT BEGINS AGAIN.....

RO MEMBRANES WILL BECOME DIRTY AND FOULED WITH: •DIRT •ORGANICS •SCALE •IRON AND OTHER METALS •COLLOIDS •MICRO-ORGANISMS (ALIVE & DEAD)

IT WILL BE NECESSARY TO CLEAN AND DISINFECT THE RO SYSTEM PERIODICALLY