Water Quality for Health Care

An AmeriWater White Paper Authored By
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Background

Health care processes require specific water quality specifications that improve the outcomes of the process. In addition, the desire for sustainable and eco-friendly health care operations means not using disposable products. Instead, the products have to be washed and cleaned with a high purity water that will not cause contamination.

This paper discusses water quality, requirements and application of high purity water in health care facilities.

The topics that will be covered in this white paper include:

- Water Isn't Just Water
- Water Quality
- Water Treatment System Design, Maintenance and Monitoring
- Applications That Require High Purity Water
- Water Quality Specification Charts

Water Isn't Just Water

Water is the universal solvent. It has the ability to dissolve anything it comes in contact with. In fact, the only place pure water exists in nature is when a water drop forms in clouds and starts to fall as rain. As it falls it picks up gases and particles in the air. As it continues to the tap, it picks up even more contaminants from the earth.

There are generally five types of contaminants found in water that may interfere with a use of the water. These contaminants include:

- Particulate
  Sand, silt, rust, sediment, grit, colloids

- Organic
  Chemicals, chlorine, chloramines, solvents, etc…

- Inorganic
  Salts or minerals, calcium, magnesium, chlorides, iron, etc…

- Microbiological
  Bacteria, pyrogens, endotoxin, viruses, spores

- Gases
  Carbon dioxide, hydrogen sulfide, methane

Each of these contaminants require a different water treatment technology or group of technologies to remove and control them.

Technology	**Function**
Sediment Filter	Captures Particulate
Carbon Filter	Adsorbs Chlorine / Organics
Anti-Scalant Feed	Contain Water Hardness
Water Softener	Remove Water Hardness
Reverse Osmosis	Remove Inorganics
Deionization	Remove Inorganics
Ultraviolet Light	Kills Bacteria / Viruses
Submicron Filter	Removes Bacteria
Pyrogen Filter	Removes Endotoxin
Storage Tank	Pure Water Storage
Distribution Pump	Distribution / Recirculation

Water Quality

Water quality requirements are different based on the type and level of the contaminant that will interfere with the process for which the water is being used. Many of these contaminants are fine to drink, so the municipal water treatment plant does not remove them.

A high purity water treatment system has to be designed to remove the residual contaminants from tap water that will provide the specified water for the specific application.

For example: Nuclei are enzymes that are an inorganic or organic catalyst that degrade DNA and RNA and interfere with microbiological and DNA testing.

Water Treatment System Design, Maintenance and Monitoring

There are many different specifications for the applications used in health care facilities. This means that there will be many different components that make up a “high purity water” system. The feed tap water will be a factor in the determination of the component chosen as well as the application specifications.

Water treatment systems must be designed to produce the desired quality and quantity of water.

The design should allow for:

- routine equipment maintenance and monitoring of water quality
- requirements for the system for incoming water quality
- maximum and minimum pressure
- inlet flow rate
- drain size
- electrical needs

So that the length and complexity of the distribution piping can be minimized, the water treatment system should be located, if possible, in a secure area immediately adjacent to use.

Schematic diagrams should be displayed identifying components, valves, sample ports, gauges and meters. Flow direction should be indicated on the drawing.

Microbial Considerations

In addition to the organic and inorganic removal, the design may have microbial considerations. The water treatment system components will usually have storage and distribution loop considerations that need to be addressed in the design.

Bacterial contamination is a persistent problem with high purity water systems. Bacteria grow well in the nutrient-poor environment of a high purity water system. They establish and build biofilm structures that provide a self-sustaining community that can be very difficult to remove. Maintenance and monitoring of these systems is critical to their long term quality performance. Procedures must be established for maintenance and replacement of components that will ensure that the product water continues to meet specifications.

Monitoring

Monitoring of the water treatment equipment is part of a quality assurance program and should be performed by water maintenance personnel daily.

Monitoring and measurement equipment needs to be inspected and calibrated on a regular schedule.

Logs should be kept on monitoring, maintenance, replacement and disinfection of the high purity water system.

The following table is a general layout of what should be monitored on each component, how often and what parameters should be met. The equipment manufacturer works with the customer to set up a specific log.

Monitoring Water Treatment Equipment

Device	What to Monitor	Frequency	Parameters
Sediment and Cartridge Filters	Pressure Drop Across the Filter (ΔP)	Daily	<10 psig. (ΔP)
Water Softener	Outlet Water Hardness	Daily	<1 GPG
Anti-Scalant Feed	Usage and Container Level	Daily	Liquid level
Carbon Adsorption	Outlet Chlorine Level (free chlorine or total chlorine)	Daily	<0.1 ppm
Reverse Osmosis	Product Conductivity Product Flow Rate Reject Flow Rate Pump Pressure	Daily Daily Daily Daily	* uS * GPM * GPM * PSIG
Deionizer	Product Resistivity	Daily	* ohms or megohms
Submicron and Ultrafilters	Pressure Drop Across the Filter (ΔP)	Daily	* (ΔP)
Ultraviolet Disinfector	Energy output	Monthly	* mJ
Distribution Piping or Loop	Bacteria (and endotoxin)	Monthly	* CFU / EU
* Levels are set by the application and/or manufacturers recommendation.			

Applications That Require High Purity Water

Endoscope Reprocessors (AER)

Potable water is usually used for the initial flushing and cleaning cycles. The high level disinfectant cycle and final rinse will work more effectively and not leave scaling and staining on the endoscope if high purity water that meets the AAMI water quality for medical device reprocessing is used.

Clinical Laboratory:

This area is more complicated today because of the proliferation of new test methods and equipment. There are a number of purified water standards used in clinical laboratory testing procedures specified*:

- Clinical Laboratory Reagent Water (CLRW)
- Special Reagent Water (SRW)
- Water supplied by a method manufacturer
- Autoclave and wash water
- Commercially bottled, purified water

* CLSI Guidelines – Fourth Edition

The only types that have specifications are the CLRW or CAP / CLSI Type I Water. (See charts under Specifications) The industry consensus today is that the type of water for a particular application needs to be validated for that application.

Stills and Steam Disinfection Boilers:

Feed water that is high purity ASTM Type II will improve the product and prevent scale and maintenance problems.

Medical Washers – Disinfectors:

For both semi-critical and critical devices, the post-flush rinse should be performed with high purity water that meets AAMI water quality standards for medical device reprocessing.

Glassware Washers:

To prevent residue that could interfere with the use of glassware, high purity water that meets ASTM Type IV or CLSI Type III should be used.

Hemodialysis:

FDA 510K process released water treatment equipment for use in hemodialysis.

ANSI/AAMI/ISO 23500:2011 and ANSI/AAMI/ISO 11663:2009 replace AAMI RD52:2004.

ANSI/AAMI/ISO 13959:2009 and ANSI/AAMI/ISO 26722:2009 replace AAMI RD62:2006.

Both of the above (ANSI/AAMI/ISO) establish the standards for high purity water and requirements for maintaining the water treatment system.

Water Quality Specifications Charts

These specifications usually list the various contaminants and their maximum acceptable levels for use with the process or procedure.

Some of these specifications or standards have been developed by standards bodies such as ASTM and AAMI. Some are specified by the manufacturer of the equipment that utilize the high purity water and some standards are generally accepted practices developed over time by users and manufacturers.

On the following pages is a listing of various specifications for health care applications.

WATER PURIFICATION STANDARDS

Laboratory Grade Water (CAP / CLSI)

	Type I	Type II	Type III
Conductivity (MicroSiemens)	<0.1	<0.5	<10.0
Resistivity (Megohm-cm)	>10.0	>2.0	>1.0
Bacteria (CFU/ml)	<10.0	10	N/A
Silicate (mg/L)	<0.05	<0.1	<1.0
Total Solids (mg/L)	0.1	1	5
TOC (mg/L)	<0.05	<0.2	1
PH	-	-	5.0 – 8.0

ASTM Standard for Reagent Grade Water (D1193-99e1)

	Type I	Type II	Type III	Type IV
Electrical Conductivity (MicroSiemens)	0.056	1	0.25	5
Electrical Resistivity (Megohm-cm)	18	1	4	0.2
Endotoxin (EU)	<0.03	0.25		
TOC (ug/L)	50	50	200	No Limit
Sodium (ug/L)	1	5	10	50
Chlorides (ug/L)	1	5	10	50
Total Silica (ug/L)	3	3	500	No Limit
PH				5.0 – 8.0
Special Requirements	0.2 um membrane filter*	Prepared by distillation	0.45 um membrane filter	

	Type A	Type B	Type C
Heterotrophic Bacteria Count	10/1000 ml	10/100 ml	100/10 ml

* Processed by distillation or reverse osmosis followed by mixed bed ion exchange and 0.2 micron filter. Feed water to final polishing must have a maximum conductivity of 20 uS/cm at (25° C)

Pharmacopeia Grade Water

	USP 24 – Purified	EP – Purified
Conductivity (MicroSiemens)	<1.3 uS/cm at 25°C	<4.3 uS/cm at 20°C
Bacteria	<100 CFU/ml	<100 CFU/ml
Endotoxin (EU)	-	<0.25 EU/ml
TOC	<500 ug/L	<500 ug/L
Nitrates	-	<0.2 ppm
Heavy Metals	-	<0.1 ppm

Water Quality for Medical Device Reprocessing
AAMI TIR34:2007

Contaminant	Level
Bacteria	≤10 CFU/mL
Endotoxin	<10 EU/mL
Total Organic Carbon (TOC)	<0.05 mg/L (ppm)
PH	N/A
Water Hardness	<1 ppm as $CaCO_3$
Resistivity	>1,000,000 ohm/cm
Conductivity	<1 uS
Ionic Contaminants	
Chloride	<0.2 mg/L (ppm)
Iron	<0.2 mg/L (ppm)
Copper	<0.1 mg/L (ppm)
Manganese	<0.1 mg/L (ppm)

CLSI Guide Line

CLRW (Clinical Laboratory Reagent Water) Type Water

Resistivity	10 megohm-cm
Bacteria	10 CFU/mL
TOC	500 ppb (ng/g)
Particulate and Colloid	Final 0.22 um Absolute Filter

ASTM Standard for Biomedical Grade Water (D5196)

Electrical Resistivity (Megohm-cm)	
Measured at production point (no air)	10.0
Measured at storage tank (with air)	1.0
TOC (ug/L)	20.0
Heterotrophic Bacteria Count	<10/1000 mL
Endotoxin (EU/mL)	<0.03
Volatile Chlorinated Hydrocarbon (ug/L)	5.0
Arsenic (ug/L)	0.1
Cadmium (ug/L)	0.1
Chromium (ug/L)	1.0
Cobalt (ug/L)	1.0
Copper (ug/L)	1.0
Fluoride (ug/L)	1.0
Iron (ug/L)	1.0
Lead (ug/L)	1.0
Nickel (ug/L)	0.1
Potassium (ug/L)	2.0
Silica (Total) (ug/L)	6.0
Sodium (ug/L)	0.5
Titanium (ug/L)	1.0
Zinc (ug/L)	0.5
Acetate (ug/L)	3.0
Ammonia (ug/L)	1.0
Chloride (ug/L)	1.0
Chloroform (ug/L)	6.0
Formate (ug/L)	2.0
Nitrate (ug/L)	1.0
Phosphate	1.0
Phthalates (ug/L)	0.1
Sulfide (ug/L)	1.0
Sulfate (ug/L)	1.0

Dialysis Grade Water

	AAMI
Calcium (mg/L)	2 (0.2 mEq/L)
Magnesium (mg/L)	4 (0.3 mEq/L)
Potassium (mg/L)	8 (0.2 mEq/L)
Sodium (mg/L)	70 (3.0 mEq/L)
Antimony (mg/L)	0.006
Arsenic (mg/L)	0.005
Barium (mg/L)	0.1
Beryllium (mg/L)	0.0004
Cadmium (mg/L)	0.001
Chromium (mg/L)	0.014
Lead (mg/L)	0.005
Mercury (mg/L)	0.0002
Selenium (mg/L)	0.09
Silver (mg/L)	0.005
Aluminum (mg/L)	0.01
Chloramines (mg/L)	0.1
Free Chlorine (mg/L)	0.5
Copper (mg/L)	0.1
Fluoride (mg/L)	0.2
Nitrate (as N) (mg/L)	2
Sulfate (mg/L)	100
Thallium (mg/L)	0.002
Zinc (mg/L)	0.1
Total Viable Microbial Counts	<100 CFU/ml
Endotoxin	<0.25 EU/ml
Resistivity (Deionization Only)	>1 Megohm-cm at 25°C

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