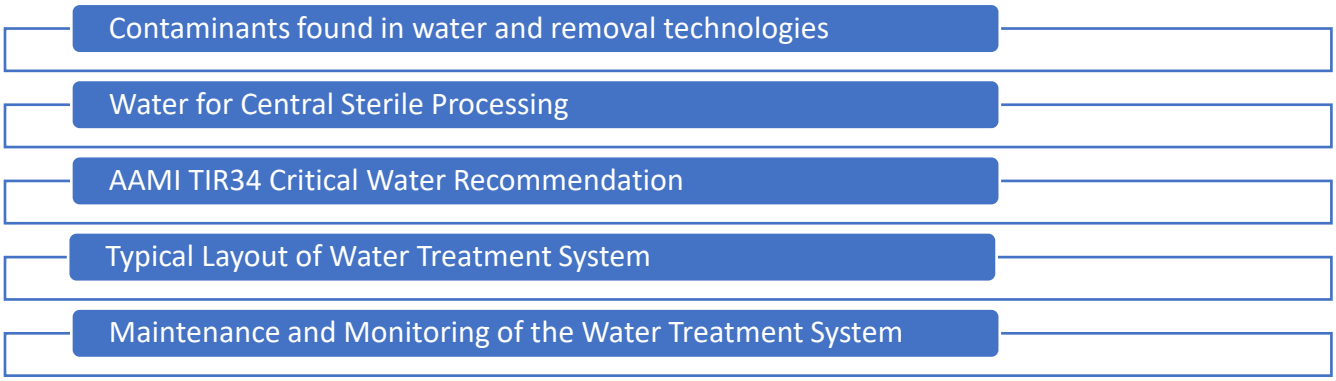
A valuable resource for Central Sterile Processing Professionals

Water Quality for Processing of Medical Devices

James W. Baker, MWS
NuStream Filtration
7/1/2021

Introduction

Surgical site infections are a leading cause of hospital re-admissions, many times due to the water quality. Most sterilizers, washers and disinfectors used in the cleaning of surgical instruments are considered medical devices and require treated water within standards set by AAMI. This paper provides information on:



Contaminants in Water and Technologies for Removal

Water is the universal solvent because it has the ability to dissolve almost everything it comes into contact with. The properties of water is constantly changing. Wherever it flows, it takes along chemicals, minerals, and nutrients whether it be from the air, the ground and even our bodies.

Although municipalities remove these contaminants to meet US Drinking Water Standards, water becomes re-contaminated as it travels to the final point of use. Additional treatment may be needed based on the specifications for use. Chart A contains a list of contaminant categories and the technology required for treatment.

Water for Processing Medical Devices

Water that has been treated to be suitable for drinking is not necessarily suitable for the Central Sterile Processing department. This is especially true during the final rinse cycle where high quality / low endotoxin water is needed.

Within the department treated water is for both instrument processing, and final flushing at the sink. The manufacturers of the processing equipment (sterilizers, washers, etc.) each have their own set of specifications and instruction for use (IFU) specifying the quality and quantity of water required for their specific piece of equipment. Reference Chart B for a list of equipment and the water quality specifications.

Chart A - Contaminants and Treatment Technologies

TYPE OF CONTAMINANT	WATER TREATMENT TECHNOLOGY
Particulates • Sand • Silt • Rust • Colloids	Sediment Filtration Note: the micron size determines the level of removal
Organics • Chemicals • Chlorine • Chloramines • Solvents	Carbon Filtration Activated carbon block or granular activated
Inorganics • Salts • Minerals • Chlorides	Reverse Osmosis Deionization Electro-Deionization
Microbiological • Bacteria • Endotoxin • Viruses • Spores • Biofilm	Ultra-Filtration
Gasses • Carbon Dioxide • Hydrogen Sulfide • Methane • Oxygen	Degassifier

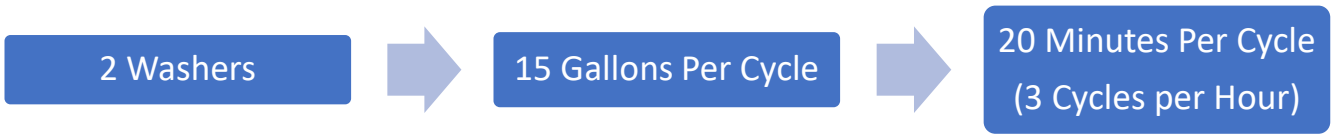
Chart B – Water Quality Requirements for Central Sterile Processing Equipment

STERILE PROCESSING EQUIPMENT	WATER QUALITY
Steam Sterilizer for Case Iron Boilers	Softened Water (<1 grain per gallon)
Clean Steam from SS Boilers or SS Heat Exchangers	0.1 Microsiemens /cm (1 meg ohm/cm)
Clean Up Sink (last sink)	10 Microsiemens/cm (100,000 ohms/cm)
Washers / Disinfectors	10 Microsiemens/cm (100,000 ohms/cm)
Ultrasonic Cleaners	10 Microsiemens/cm (100,000 ohms/cm)
Tee Probe and Endoscope Processor	10 Microsiemens/cm (100,000 ohms/cm)

Properly Sizing Water Treatment Equipment

A water treatment company will use the manufacturers specifications to properly size the correct system based on quality and usage. To guarantee no down time, the water treatment system should be sized to supply all of the sterile processing devices for one hour. This can be determined by multiplying the water usage per cycle by the number of cycles per hour by the quantity of devices in the department. Sizing this way guarantees there will be enough water whether the department is running 10 or 24 hours a day.

Sizing Example Based on the Following:



2 x 15 = 30 x 3 = 90 Gallons Per Hour

AAMI TIR34 Critical Water Standards

Water quality for Central Sterile Processing is currently under two regulatory recommendations.

One of them being AAMI recommendation of TIR34 for medical device processing. The other is FDA guidance for devices requiring high level disinfectants that contact the patients blood stream or other sterile body sites. There are two categories of water, each with different recommendations for quality. Utility water (tap water that may have some level of treatment) and Critical Water that is treated and used for the final rinse.

AAMI has added endotoxin to their recommended microbiological levels for medical device processing using critical water. The source of endotoxin is bacteria. Bacteria sheds its “skin” to get rid of waste products and when it dies, the skin (or endoderma) becomes endotoxin which can cause pyrogenic reaction. The association between gram negative bacterial endotoxin and sepsis has been recognized for many years. A large proportion (79%) of sepsis patients also exhibit endotoxemia.

For removal of both bacteria and endotoxin, final filtration is required.

Categories and Recommended Levels of Water Quality for Medical Device Processing*

It's important to understand the difference between the two categories of water treatment required for central sterile processing.

Utility Water is the hospitals water source coming straight from the tap. Since this water is used only for flushing, washing, and rinsing the acceptable contaminant levels are less stringent than for Critical Water.

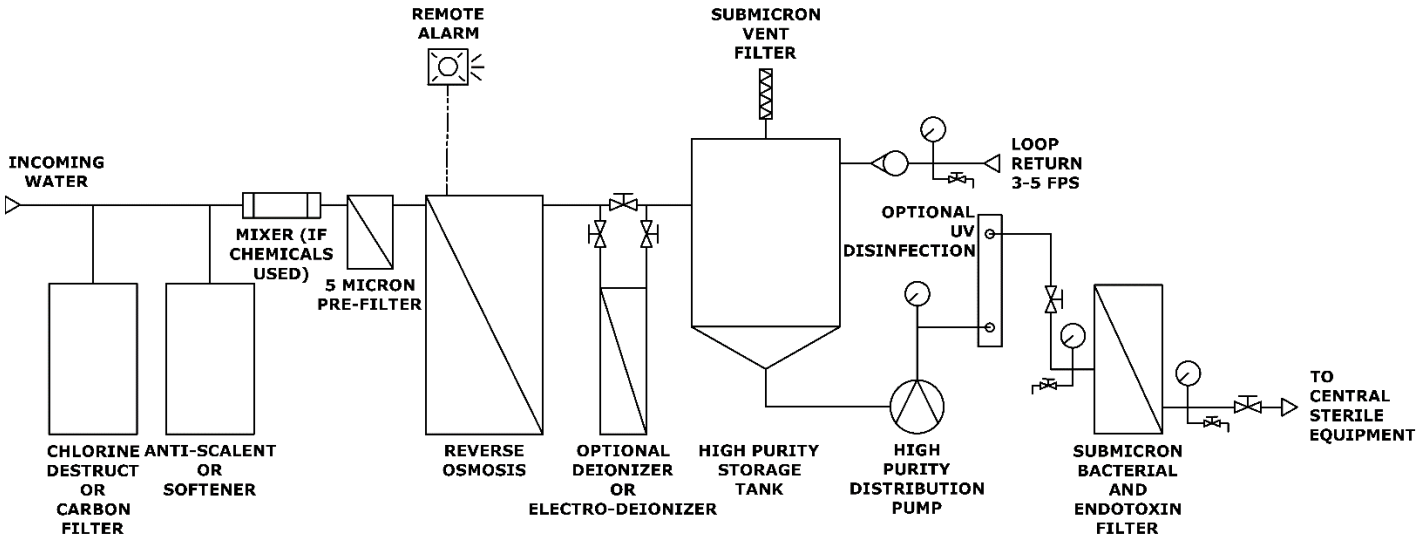
Critical Water is used for the final rinse on a washer/disinfector and steam generation. For the health and safety of the patient, it's important to remove microorganisms such as bacteria and endotoxin.

	Utility Water	Critical Water
Contaminant	**Flushing / Washing / Rinsing**	**Final Rinse**/Steam**
Hardness, mg/l	<150	<1
Conductivity, mg/l (ppm)	<500	<10
pH	6-9	5-7
Chlorides, mg/l	<250	<1
Bacteria, cfu/ml	n/a	<10
Endotoxin, EU/ml	n/a	<10

*2020 Association for Advancement of Medical Instrumentation

**Final rinse on a washer/disinfector, prior to sterilization of a critical device

Typical Layout of Water Treatment System for Critical Water



PRETREATMENT

In order to extend the life of the RO membranes, the RO system requires water that is treated for organics and hardness minerals.

MAIN TREATMENT

Reverse Osmosis with deionization polisher provides the highest quality water.

DISTRIBUTION

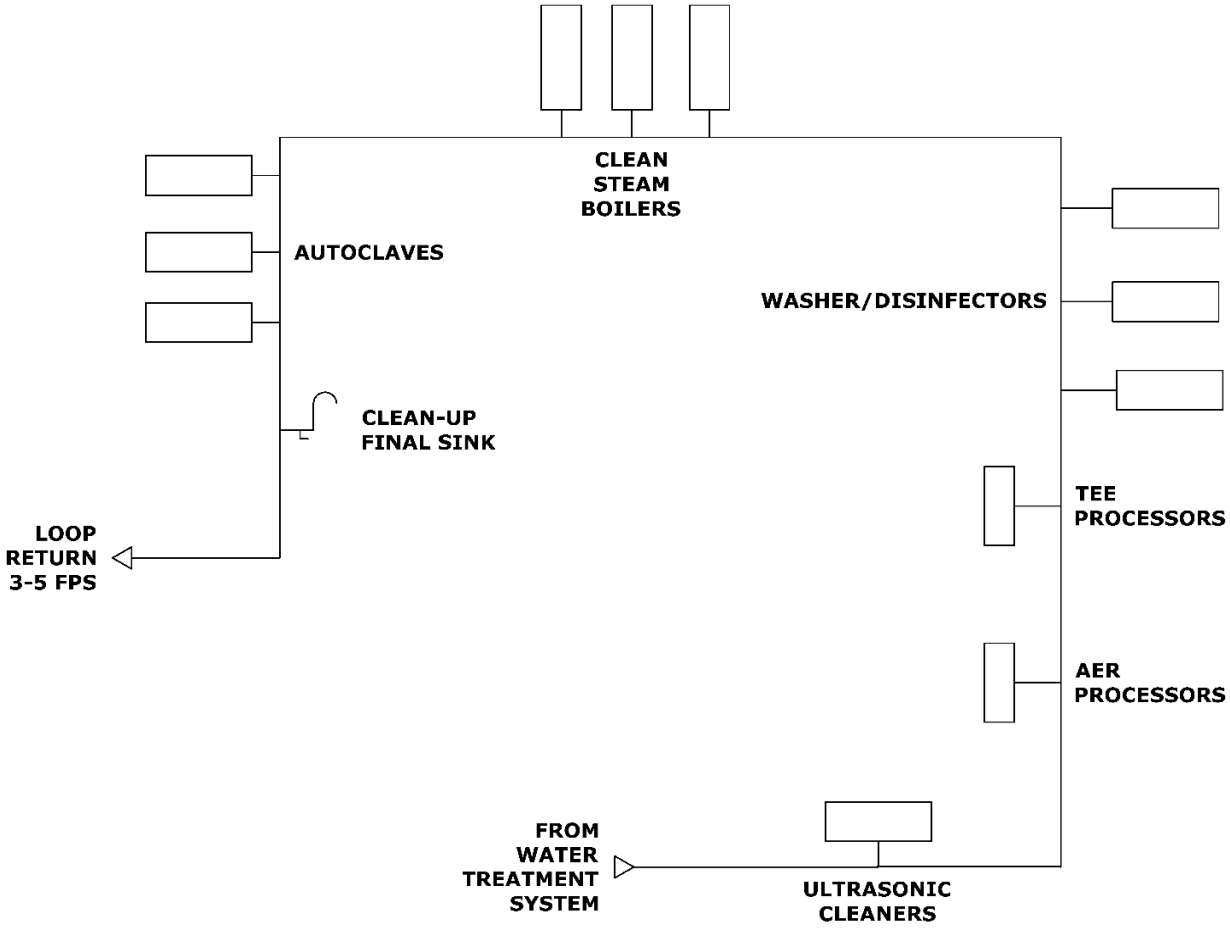
Cone bottom high purity storage tank with vent filter, followed by a high purity distribution pump and optional UV system keeps the treated water fresh.

POST TREATMENT

To protect patients from the harmful effects of bacteria and endotoxin, validated submicron filters are used to remove microbiological contaminants.

.

Typical Layout of Central Sterile Processing Medical Devices



The Importance of a Proper Loop Design

Recirculation and prevention of dead legs is important for regular disinfection of the distribution system. To prevent biofilm in the piping and connections, distribution loops should recirculate at a continuous rate of 3-5 feet per second and the pipe feeding the device should be less than six times the pipe diameter of the loop. See chart below for recommended recirculation rates in distribution loop:

	Gallons Per Minute Flow Required @ 3 or 5 Ft. Per. Sec.	
Pipe Size (ID)	**3 Feet Per Second**	**5 Feet Per Second**
½”	2 GPM	3 GPM
¾”	3.5 GPM	6 GPM
1”	6 GPM	10.5 GPM
1-1/4”	11.5 GPM	18 GPM
1-1/2”	16 GPM	27 GPM

Maintenance and Monitoring of a Critical Water Treatment System

A critical water treatment system requires monitoring, testing, disinfection, and on-going maintenance including consumable component replacements.

Every day that the Sterile Processing is operating, parameters should be logged assuring that the equipment is performing properly.

Device	What to Monitor	Parameters*
Sediment Filter Cartridges	Pressure Drop Across the Filter	< 10 PSIG
Water Softener	Outlet Hardness	< 1 Grain per Gallon
Anti-Scalant Feed	Container Level	Liquid to minimum line
Carbon (GAC) Filter	Outlet Chlorine Level	< 1 Part Per Million (PPM)
Chlorine Destruct	Container Level	Liquid to minimum line
Reverse Osmosis**	Product Conductivity Product Flow Rate Reject Flow Rate Pump Membrane Pressure	Microsiemens uS/cm Gallons Per Minute (GPM) Gallons Per Minute (GPM) Pressure (PSIG)
Electro Deionizer Exchange Tank Deionizer	Product Resistivity	>1 megohms / cm
Ultraviolet	Indicator Light	On
Final Filter	Pressure Drop Across	<20 PSIG

*levels are set by standard and manufacturers IFU

**levels are set by feed water quality and manufacturers IFU

Microbiological Testing

Sampling should always be taken before disinfection. If results are above level, disinfect and rinse to the level of no detection, then retest. The best disinfectant for reverse osmosis, storage tank and distribution loop is 1% Peracetic Acid.

Contaminant	Sample Sites	Frequency
Bacteria	RO Product	Monthly
Colony Forming Units (cfu/ml)	End of Loop	Monthly
Endotoxin (EU/ml)	End of Loop After Final Filter Before Final Filter	Monthly Monthly Monthly

Conclusion

Water quality varies from season to season, place to place, and even day to day.

Because it plays a significant role in the sterilization process, it is important to team up with a knowledgeable water treatment company who specializes in the health care industry and follows the guidelines set by AAMI TIR34. In addition, and possibly most important, the team of central sterile processing professionals must remain informed and vigilant in following all procedures to ensure the safety of their patients.

James W. Baker
BS, MWS

President
NuStream Filtration
Dayton, Ohio

With over 40 years of water treatment experience, Jim is highly respected in the industry. Past accomplishments include the design of many water treatment products for the industry, creation of several continuing education programs for healthcare professionals, Past President of the International Water Quality Association and induction into the Water Quality Hall of Fame. Jim is an active member of the AAMI Water Quality for Processing Medical Devices group.

References

Clean Steam Systems, Tim Latham, *Pharmaceutical Engineering*, Vol.15, No. 2, 1995

ASHRAE Standard 188-2018. Legionellosis: Risk Management for Building Water Systems

Kober P. The Implications of Endotoxins for Sterilization of Surgical Instruments. Central Sterile, 14:372-373, 2006.

Phillips G, McEwan H, and Butler J. Quality of Water in Washer-Disinfectors. *J Hosp Infect*, 31"152-154, 1995

Roslansky PF, Dawson MR and Novitsky TJ. Plastics, Endotoxins and the Limulus Amebocyte Lysate Test, *J Parenteral Sci Technol*, 45: 83-87, 1991.

British Standards Institute. *Washer-Disinfectors for Medical Purposes*. BS2745. BSI: London, 1993

Duffy RE, Couto B. Pessoa JM, Starling C, Pinheiro S, Pearson ML, Arduino MJ, Mattson BJ and Jarvis WR, Improving Water Quality Can Reduce Pyrogenic Reactions Associated with Reuse of Cardiac Catheters*. Infect Control Hosp Epidemiol*, 24 (12)" 955-960, 2003.

Flocard V, Goullet D, and Freney J. Evaluation of Endotoxin Risk Posed by Use of Contaminated Water During Sterilization of Surgical Instruments, *Zentr Steril*, 14: 26-29, 2005.

U.S. Food and Drug Administration and Centers for Disease Control and Prevention. *FDA and CDC Public Health Advisory: Infections from Endoscopes Inadequately Reprocessed by and Automated Endoscope Reprocessing System*: Rockville, MD: FDA, September 10, 1999.

U.S. Pharmacopeial Convention. *The United States Pharmacopeia*. Current ed. Rockville MD: USP.

Water Quality Association. *Glossary of terms*. Lisle, IL. 1997.

Association for Professionals in Infection Control and Epidemiology, *APIC Text of Infection Control and Epidemiology,* Washington DC, APIC, 2005.

Association for the Advancement of Medical Instrumentation. *Water for Hemodialysis and Related Therapies. ANSI. AAMI/ISO 13959:2009*. Arlington, VA: AAMI, 2011.

Assn. for the Advancement of Medical Instrumentation. *Water for the Reprocessing of Medical Devices*. AAMI TIR34:2014.

Association for the Advancement of Medical Instrumentation. *Bacterial Endotoxin – Test Methodologies, Routine Monitoring and Alternatives to Batch Testing.* ANSI/AAMI ST72:2002. Arlington VA, AAMI, 2002.

Association for the Advancement of Medical Instrumentation. *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. ANSI.AAMI ST79:2006. Arlington VA. AAMI, 2006.

ASTM International. *Standard Guide for Biomedical Grade Water*. ASTM D5196-91 (1999). Philadelphia, PA. ASTM International, 1999.

CSA International. *Decontamination of Reusable Medical Devices*. CSA Z314.8-00(R2005). Toronto, ON: CSA International, March 2020.

International Organization for Standardization. *Washer-Disinfectors, Part 5: Test Soils and Methods for Demonstrating Cleaning Efficacy of Washer-Disinfectors*. ISO/TS 15883-5:2005. Geneva, Switzerland. ISO, 2005.