

A primer on water quality for sterile processing

WATER QUALITY DEFINED

Water, which can exist as a solid, liquid, or vapor, consists of one atom of oxygen and two atoms of hydrogen bonded together by their shared electrons. In terms of water purity, anything that is not an H⁺ or OH⁻ ion is considered a contaminant or impurity.

The Environmental Protection Agency (EPA) identifies contaminants to regulate in drinking water to protect public health.¹ The Agency sets regulatory limits for the amounts of certain contaminants in water provided by public water systems. Local public water systems treat water to these standards to make it potable. However, despite this treatment, water can become re-contaminated with chemicals and microorganisms as it is distributed through the municipality's piping infrastructure. This contamination can be problematic for many applications that use this potable water. Sterile Processing in hospitals is one such application.

WATER QUALITY IS IMPORTANT IN STERILE PROCESSING

Water quality is an important consideration in all stages of medical device reprocessing. Poor water quality can lead to adverse effects, such as medical device corrosion, decreased effectiveness of cleaning agents, and patient infection.²

It is important that personnel who reprocess medical devices (or use them in procedures) understand how the quality of the facility's water can have an impact on the reprocessing equipment, as well as the devices and instruments themselves. It is also important that personnel recognize that the quality of water should



be regularly monitored to ensure that the control measures in place are working properly.

WATER TREATMENT

Water treatment includes a collection of water purification devices and associated piping, pumps, valves, and gauges that together produce purified water of a specified quality and deliver it to the point of use. Water purity is an indication of the extent to which impurities (e.g., dissolved organic and inorganic solids and microbial contaminants, ionic, and chemical) have been removed.

¹ United States Environmental Protection Agency. <https://www.epa.gov/dwstandardsregulations>; 2018

² ANSI/AAMI ST108:2023—Water for the Processing of Medical Devices

Note: This primer is intended to provide a general overview of the importance of water quality for sterile processing, as well as the ANSI/AAMI ST108:2023 standard. It is not intended to act as a substitute for healthcare personnel reading the full ANSI/AAMI ST108:2023 standard, additional industry, guidelines, or medical device manufacturers' Instructions for Use (IFU).

ADVERSE EFFECTS OF POOR WATER QUALITY

Water impurities can have adverse effects to medical device reprocessing.

Adverse effects to the product:

- Corrosion, pitting, scaling
- Biomass build-up
- Increase microbial load or endotoxin content

Adverse effects to the process:

- Decreased effectiveness of detergents
- Degradation of the water system (biofouling or scaling)

Adverse effect to the patient (indirect):

- Infection
- Toxicity

It is important that Sterile Processing personnel understand the water quality issues that can contribute to adverse patient events and be aware of some of the gross indicators that suggest that there may be problems with the water quality. Monitoring water quality is a process meant to confirm that control strategies are working properly.

In the preparation of water for use in medical device reprocessing, two general characteristics need to be considered:

- The microbial level in water
- The inorganic and organic components of water

Ensuring adequate water quality in device reprocessing requires collaboration between the personnel who reprocess medical devices and the personnel who establish and maintain the water treatment system.

ANSI/AAMI ST108:2023—WATER FOR THE PROCESSING OF REUSABLE MEDICAL DEVICES

In order to educate and provide guidance to healthcare facility personnel, the Association for the Advancement of Medical Instrumentation (AAMI) publishes a standard called ANSI/AAMI ST108:2023—Water for the Processing of Medical Devices. This new standard replaces AAMI TIR34:2014.

ST108 has binding requirements on the quality of water that should be used in each stage of medical device reprocessing for each category of medical device. It also includes annexes that provide technical information to water maintenance personnel (i.e., personnel such as Facilities Engineering/Management who are involved in water treatment and distribution in the facility) to guide them in configuring and monitoring water treatment systems. More specifically, ANSI/AAMI ST108:2023 includes the following:

- Covers the quality of the water used to clean, rinse, disinfect, and sterilize medical devices.
- Defines water types on the basis of hardness, pH, microorganism levels, endotoxin levels, and other characteristics. The following topics are covered:
 - Importance of water quality and effective water treatment
 - Categories of water quality for medical device reprocessing
 - Selection of water quality
 - Water treatment systems
 - Monitoring of water quality
 - Strategies for microorganism control
 - Personnel considerations
 - Continuous quality improvement
 - Troubleshooting water quality issues
- Provides definitions of terms and a bibliography
- Annexes contain technical details pertaining to water treatment and monitoring for the benefit of water maintenance personnel

KEY CHANGES WITH AAMI ST108

- Requirement for the facility to establish a multi-disciplinary team responsible for water quality and the water management program
- Expansion of water quality types to include steam
- Establishment of expanded water quality criteria for system performance qualification
- Routine water quality monitoring requirements at both the water generation system and at departmental points-of-use

AAMI ST108: Key Highlights

WATER GENERATION SYSTEM PERFORMANCE QUALIFICATION SPECIFICATIONS¹

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25°C	pH	6.5-9.5	5.0-7.5	5.0-9.2**
Total Alkalinity	mg CaCO ₃ /L	<400	<8	<8
Bacteria	CFU/mL	<500 [†]	<10	N/A
Endotoxin	EU/mL	N/A [†]	<10	N/A
Total Organic Carbon (TOC)	mg/L (ppm)	N/A	<1	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Ionic Contaminants				
Aluminum	mg/L	<0.1	<0.1	<0.1
Chloride	mg/L	<250	<1	<1
Conductivity	µS/cm	<500	<10	<10
Copper	mg/L	<0.1	<0.1	<0.1
Iron	mg/L	<0.1	<0.1	<0.1
Manganese	mg/L	<0.1	<0.1	<0.1
Nitrate	mg/L	<10	<1	<1
Phosphate	mg/L	<5	<1	<1
Sulfate	mg/L	<150	<1	<1
Silicate	mg/L	<50	<1	<1
Total Hardness	mg CaCO ₃ /L	<150 [‡]	<1	<1
Zinc	mg/L	<0.1	<0.1	<0.1

- ¹ Reprinted from ANSI/AAMI ST108:2023; *Water for the processing of medical devices*, Table 2, with permission from AAMI. No endorsement by AAMI of any content herein is implied or given. For complete information, please refer to the full standard DOI: 10.2345/9781570208737. ©2023 Association for the Advancement of Medical Instrumentation.
- * Steam parameters are for monitoring as steam condensate.
- ** For local steam generation, the condensate pH should be 5.0 to 7.5. For boiler-treated steam, most boilers should be treated to maintain a condensate pH of 7.5 to 9.2.
- † When Utility Water is used after chemical high-level disinfection as a final rinse, the bacteria should be <10 CFU/mL and endotoxin <10 EU/mL.
- ‡ If hardness is greater than 150 mg/L a water softener is recommended unless used for washing where the cleaning chemistry is capable of handling higher levels of hardness.

WATER GENERATION SYSTEM ROUTINE MONITORING SPECIFICATIONS²

Water Quality Measurement	Units	Utility Water	Critical Water	Steam*
pH @ 25°C	pH	6.5-9.5	5.0-7.5	5.0-9.2**
Conductivity	µS/cm	<500	<10	<10
Total Alkalinity	mg CaCO ₃ /L	<400	<8	<8
Total Hardness	mg CaCO ₃ /L	<150	<1	<1
Bacteria	CFU/mL	<500	<10	N/A
Endotoxin	EU/mL	N/A	<10	N/A
Color and Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment

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- * Sampled as steam condensate.
- ** The pH range for steam is wider than for critical water as some steam may not be generated locally but from a centralized/facility system. The need to add chemicals to the boiler and the steam to travel distances over black iron piping may result in higher pH requirements. A pH <7.5 in these systems should be avoided.

CATEGORIES OF WATER QUALITY FOR MEDICAL DEVICE REPROCESSING

Water Category	Definition
Utility water	Water that comes from the tap that may require further treatment. Used for flushing, washing, rinsing.
Critical water	Water that is extensively treated to ensure microorganisms and inorganic and organic materials are removed. Used for the final rinse or steam generation.
Steam	Water that is heated via a boiler or steam generator until it changes from liquid phase to vapor phase. Steam can be fed from a central location within the hospital such as a boiler plant or created via a steam generator within a sterilizer. Used for sterilization of medical devices



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