# What You Need to Know About AAMI ST108

## The New Standard for Water Quality for Medical Device Processing

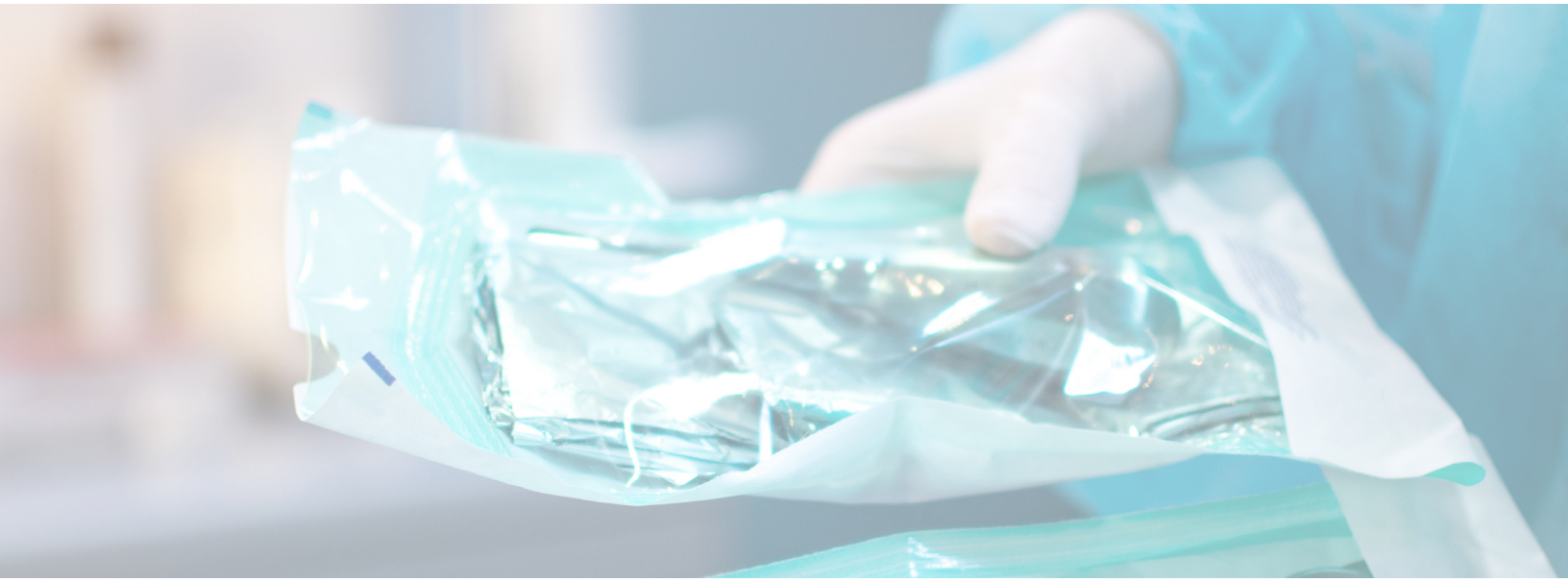
AmeriWater
The Water Purification Specialists

# AAMI ST108: An Overview

**The Association for the Advancement of Medical Instrumentation (AAMI) issued ST108 to provide valuable information to healthcare industry professionals regarding water quality as it pertains to medical device processing. ST108 has become standard as of August 2023 replacing AAMI TIR34.**

Contaminants found in water can vary significantly depending on the source of water utilized by the facility. These contaminants (visible or nonvisible) have created increasing challenges faced by healthcare professionals and can contribute to decontamination issues such as discoloration, corrosion, pitting, and biofilm build up on instruments.

Due to these risks and safety concerns on equipment and instrumentation, AAMI created ST108 to be the standard for monitoring frequencies, system designs, and best practices to mitigate risks with water quality. Historically, regulatory agencies such as CMS (Center for Medicare Services), TJC (Joint Commission), and others will adopt these standards.



# What does ST108 cover?

**ST108 highlights the importance of creating a cross-functional team to address the responsibilities with developing a water management program for the water treatment system.**

The cross-functional team typically consists of Facility Engineering, Infection Prevention, Sterile Processing, Water Treatment Specialists, and others to establish the different responsibilities regarding the water system. A water management program should consist of the following:

- Risk Analysis
- Water Treatment Design
- Validation of the Water System
- Monitoring the Water Quality
- Maintaining the Water System

# What Should a Risk Analysis Entail?

**Conducting a risk assessment requires actively evaluating all potential factors that could adversely impact the medical device, disinfection process, patients, and personnel. This includes considerations such as:**

### Prioritize the risks.

Once the risks have been assessed, the team should prioritize them based on their likelihood and severity. This will help the team focus on the most important risks first.

### Develop and implement risk mitigation strategies.

For each high-priority risk, the team should develop and implement strategies to mitigate the risk.

### Monitor and review the risk assessment.

The risk assessment should be reviewed on a regular basis to ensure that it is up-to-date and that the risk mitigation strategies are effective.

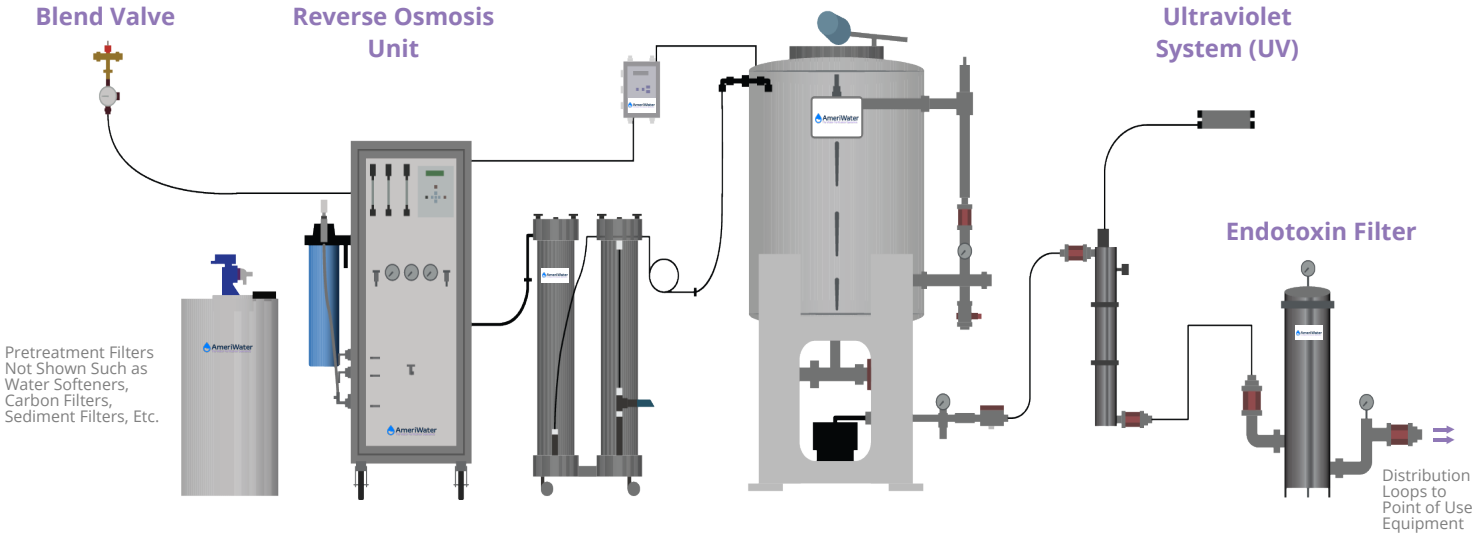
It is important to highlight that the risk assessment is an ongoing process. The cross-functional team should regularly monitor and update it, especially in response to changes like using new medical devices in the disinfection process. For more information on Risk Analysis, refer to Annex B in AAMI ST108.

# Water Treatment Design

## Conducting a comprehensive feed water analysis is crucial before implementing a water treatment system.

This analysis helps identify the specific contaminants present to select the most appropriate pretreatment processes. Engaging water professionals for a thorough analysis ensures that the chosen treatment methods would align with meeting the water qualities needed. For more information on water treatment design and technologies used to remove specific contaminants, refer to Annex E & F in AAMI ST108.

## Components that are typically a part of a water treatment system:




It is crucial to evaluate the distribution piping design that is transferring the water to its points of use, such as washers, ultrasonic cleaners, sinks, and other central sterile devices. If not designed properly, the piping can be susceptible to biofilm growth. The contaminated water can transfer the biofilm to surgical devices during sterilization.

## Distribution piping should be designed to inhibit proliferation of microorganisms which includes:

**Minimization of stagnant areas** within the distribution loop (i.e., dead legs - piping that is more than 3-5 times as long as its internal diameter and that does not have constant water flow).

**Continuous recirculation** with a water velocity at 3 - 5 feet per second (FPS) to ensure all surface area of the piping is preventing biofilm growth.

**Periodic disinfection** of distribution loop.

# Validating Your Water Treatment System

## The cross-functional team should validate the water treatment system before any surgical device reprocessing. Additionally, the team should determine the frequency of subsequent validations once the system is in place.

A validation plan includes qualification procedures for the installation of the system, operation of the system, and evaluating the system's performance to meet the water quality acceptance criteria in Table 1 below. The standard defines water qualities for validation in three categories for medical device reprocessing: utility water, critical water and steam:

### Utility Water

Potable water primarily intended for tasks like flushing, washing, and intermediate rinsing. Additional purification methods may be required to meet the specifications on the table below.

### Critical Water

This water serves primarily as the final rinse following high-level disinfection. Purified water that has been through a multi-step treatment and would need routine disinfection to remove microorganisms, inorganic and organic contaminants.

### Steam

Purified water that is converted to vapor through a centralized boiler located near or on the sterilizer. The steam quality should adhere to the criteria outlined below when tested as a condensate.

**Table 1: Water Quality for Water Treatment System Validation**

| | | Type of Water/Water Use | | |
|---|---|---|---|---|
| Water Quality Measurement | Units | Utility Water[1]/Flushing/Washing/Rinsing | Critical Water/Final Rinse[2] | Steam |
| pH @ 77°F (25°C) | pH[4] | 6.5 – 9.5 | 5.0 – 7.5 | 5.0 – 9.2 |
| Conductivity | µS/cm | <500 | <10 | <10 |
| Total Alkalinity | mg CaCO3/L | <400 | <8 | <8 |
| Bacteria | cfu/mL | <500[5] | <10 | N/A |
| Endotoxin | EU/mL | N/A[5] | <10 | N/A |
| Total Organic Carbon (TOC) | mg/L ( ppm) | N/A | <1.0 | 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 |
| 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 CaCO3/L | <150[3] | <1 | <1 |
| Zinc | mg/L | <0.1 | <0.1 | <0.1 |

Note 1 - This is the quality of water that might come from the tap but might need some form of treatment to achieve specifications.

Note 2 - If this is the final rinse prior to sterilization of a critical device.

Note 3 - If hardness is greater than 150 mg/L, a water softener is recommended unless used for washing and the chemistry is capable of handling higher levels of hardness.

Note 4 - For boiler-treated steam, most boilers are treated to maintain a pH of 7.5 or 8.5. Any treatment of water that boilers should be in accordance with the sterilizer and boiler manufacturers' written IFU.

Note 5 - 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.

# Monitoring Your Water Quality

**Regular monitoring of the water system is essential to prevent deterioration in water quality. Below are the requirements that must be met to ensure consistent quality is maintained.**

| Table 2: Water Quality for Routine Monitoring | | | | |
|---|---|---|---|---|
| | | Type of Water/Water Use | | |
| Water Quality Measurement | Units | Utility Water[1]/Flushing/Washing/ Rinsing | Critical Water/Final Rinse[2] | Steam |
| pH @ 77°F (25°C) | pH[4] | 6.5 – 9.5 | 5.0 – 7.5 | 5.0 – 9.2 |
| Conductivity | µSiemens/cm | <500 | <10 | <10 |
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| Total Hardness | mg CaCO3/L | <150[3] | <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 |
| Note 1 - This is the quality of water that might come from the tap but might need some form of treatment to achieve specifications. | | | | |
| Note 2 - If this is the final rinse prior to sterilization of a critical device. | | | | |
| Note 3 - If hardness is greater than 150 mg/L, a water softener is recommended unless used for washing and the chemistry is capable of handling higher levels of hardness. | | | | |
| Note 4 - For boiler-treated steam, most boilers are treated to maintain a pH of 7.5 or 8.5. Any treatment of water that boilers should be in accordance with the sterilizer and boiler manufacturers' written IFU. | | | | |

It is imperative to follow the guidelines for water sampling locations for routine monitoring to meet the recommended water quality requirements in Table 2. For proper sampling techniques, refer to Annex H.5 in AAMI ST108.

| Table 3: Routine Monitoring Testing at Water Treatment System | | | | |
|---|---|---|---|---|
| | | | Frequency for Each Type | |
| Water Quality Measurement | Type of Testing | Routine Monitoring Sample Site | Utility Water | Critical Water |
| **pH @ 77°F (25°C)** | pH meter or Colorimetric dipsticks | After the last treatment step | Quarterly | Monthly |
| **Conductivity** | Conductivity meter | After the last treatment step | Quarterly | Daily |
| **Total Alkalinity** | Colorimetric dipsticks | After the last treatment step | Quarterly | Monthly |
| **Total Hardness** | Determination of ppm CaCO3 or Colorimetric dipsticks | After the last treatment step | Quarterly | Monthly |
| **Bacteria** | Heterotrophic plate count | Loop Out & Loop Return | N/A | Monthly |
| **Endotoxin** | LAL test | Loop Out & Loop Return | N/A | Monthly |

Table 3 and 4 are the recommended types of testing, sampling location and frequency for water treatment system and reprocessing equipment point of use within the department. For additional information, refer to Annex G in AAMI ST108.

The frequencies listed must be taken as a recommended minimum. If a problem is found or levels exceed recommendations, more frequent monitoring may be necessary.

| Table 4: Routine Monitoring Testing at Point of Use | | | | | |
|---|---|---|---|---|---|
| | | | Frequency for Each Type | | |
| Water Quality Measurement | Type of Testing | Routine Monitoring Sample Site | Utility Water | Water for Steam | Critical Water |
| **pH @ 77°F (25°C)** | pH meter or Colorimetric dipsticks | First Point of Use on the Distribution Loop | Quarterly | Quarterly | Monthly |
| **Conductivity** | Conductivity meter | First Point of Use on the Distribution Loop | Quarterly | Quarterly | Monthly |
| **Total Alkalinity** | Colorimetric dipsticks | First Point of Use on the Distribution Loop | Quarterly | Quarterly | Monthly |
| **Total Hardness** | Determination of ppm CaCO3 or Colorimetric dipsticks | First Point of Use on the Distribution Loop | Quarterly | Quarterly | Monthly |
| **Bacteria** | Heterotrophic plate count | Each Location of Point of Use in Department | Quarterly | N/A | Monthly |
| **Endotoxin** | LAL test | Each Location of Point of Use in Department | N/A | N/A | Monthly |
| **Visual Inspection** | Visual Inspection of inside of equipment - Look for residue, staining, scaling and discoloration (Annex I) | Spray Arms/Inside Chamber Walls/Inside Interior of Machine | Daily | Daily | Daily |

# Maintaining Your Water Treatment System

**Consistently following a maintenance schedule is vital to ensure the smooth operation of the water treatment system. The maintenance program helps prevent system failures and disruptions to the schedule of the central sterile processing unit.**

Consult with the water system manufacturer on their recommended maintenance.

**Below are some examples of what a regular system maintenance schedule would typically include:**

- **Consumable components such as filter, carbon, and DI tank exchanges**
- **Complete water system disinfection including the distribution loop**
- **Membrane cleaning or replacement**
- **Required water quality testing**

AAMI ST108 defines the feed water quality requirements to the steam sterilizers and boilers in Table 1 and 2. For questions on steam quality, processes, and testing procedures, refer to ANSI/AAMI ST79: "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities", or consult your steam sterilizer manufacturer.

# Informative Sections Included in ST108

The Annexes to AAMI ST108 are used as informative sections on how to meet the requirements of the standard. The Annexes cover a wide range of topics including risk analysis steps, water treatment system selection and design, types of water used for disinfection, water quality monitoring and testing, and device issues that can arise for water quality problems.

**BELOW IS EACH ANNEX IN AAMI ST108:**

**Annex A** – Guidance on the application of the normative requirements

**Annex B** – Risk Analysis

**Annex C** – Automated Endoscopy Reprocessor (AER)

**Annex D** – Water used in cleaning and moist heat processes

Annex E – Water treatment technologies

**Annex F** – Water treatment system design

**Annex G** – Routine monitoring of water treatment equipment & produced water quality

**Annex H** – Maintaining microbiological quality

**Annex I** – Typical presentation of water quality issues during the processing of medical devices

To use the full release of ANSI/AAMI ST108:2023 Water for the Processing of Medical Devices at your facility, you can purchase a copy of the standard from AAMI.org

# About AmeriWater

Healthcare facilities require water treatment for a variety of medical applications, each with its own unique standards and requirements. At AmeriWater, we understand these varying needs and have designed a range of water purification systems specifically tailored to the needs of each healthcare application.

Our extensive range of healthcare solutions means you have a reliable single source for all your water treatment needs, saving you valuable time coordinating technical compatibilities between several suppliers.

Our product offering is supported by our in-house expertise, and our nationwide network of sales and service dealers means we can provide same day support to any US location.

For more information on our systems or requests to join your cross-functional team as a water treatment specialist, please contact one of our experts today at 800-535-5585.

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