EASYWATER®

ANSI/AAMI ST108

Your Guide to the New Standard *for* Medical Device **Water Quality**

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ANSI/AAMI ST108 Overview

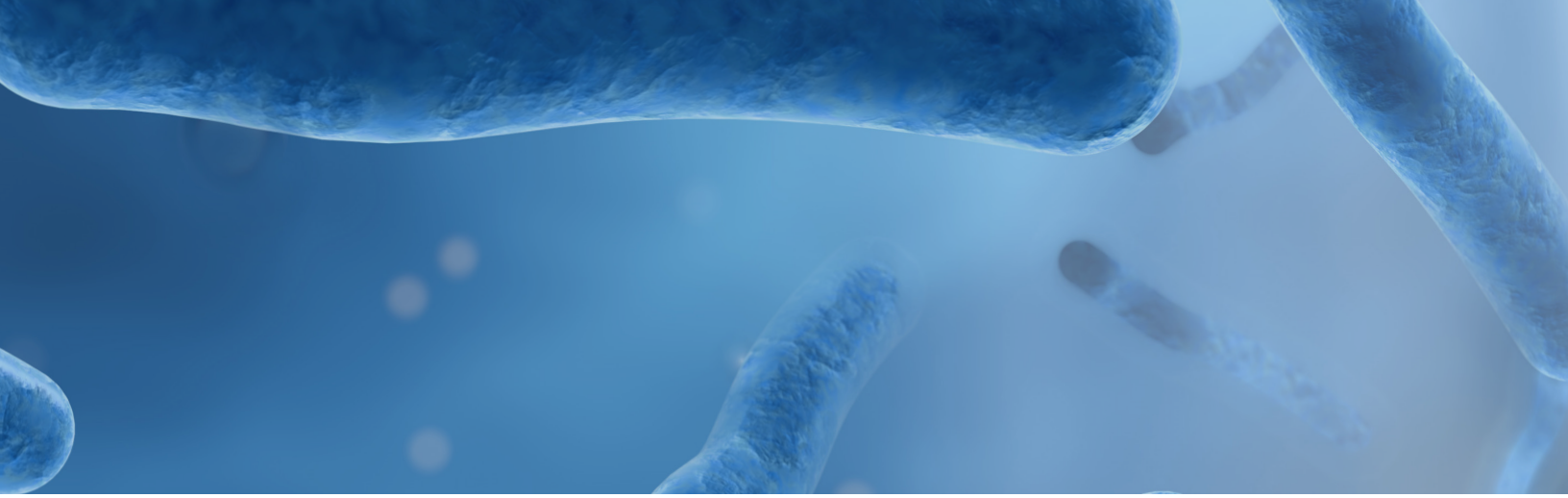
The Association for the Advancement of Medical Instrumentation (AAMI) has released a new standard, AAMI ST108:2023, which outlines the requirements for water quality processing at every stage of medical device handling.

AAMI ST108 focuses on selecting and maintaining adequate water quality by emphasizing proper water system design, monitoring, testing and maintenance. It is pivotal in preventing health care-associated infections (HAIs) and ensuring the functionality and longevity of medical equipment.

AAMI ST108 replaces the previous technical information report TIR34 (TIR) which covered the selection and maintenance of effective water quality suitable for reprocessing medical devices. Unlike TIR34, which offered guidelines around water quality used for medical device reprocessing, ST108 has binding requirements for sterile processing departments.

KEY DIFFERENCES AND UPDATES FROM TIR34 INCLUDE:

- Establishment of a multi-disciplinary team that has responsibility for water quality and the program administration
- Inclusion of steam in water quality categories
- Expanded water quality criteria for performance qualification
- Water quality monitoring requirements at both the water generation infrastructure and at points-of-use



IMPACTS OF POOR WATER QUALITY

Water impurities can have significant impacts to medical device processing.

EQUIPMENT IMPACTS

- Localized corrosion, deposits and fouling
- Biomass accumulation
- Increased microbial burden
- Endotoxin content

APPLICATION IMPACTS

- Reduction in detergent effectiveness
- Degradation of the water system (biofouling or scaling)

PATIENT IMPACTS

- Infection
- Toxicity

A key requirement is that sterile processing personnel understand the water quality issues that can contribute to adverse patient events and be aware of some of the indicators that suggest that there may be problems with the water quality.

3 Categories of Water Quality

UTILITY WATER

The Association for the Advancement of Medical Instrumentation (AAMI) defines utility water as water that is used for routine activities such as cleaning, equipment operation, and other purposes that do not involve direct patient care. It is typically not considered to be sterile and is used in processes where the water does not come into contact with sterile items or environments.

CRITICAL WATER

According to the AAMI ST108 guidelines, "critical water" is defined as water that is used for processes that involve direct contact with sterile items or the preparation of products intended for sterile use. This type of water must meet stringent quality standards to ensure that it does not introduce contaminants that could compromise the sterility of the items being processed.

STEAM

AAMI ST108 defines "steam" as the vapor phase of water, generated when water is heated to its boiling point and beyond. In the context of sterilization, it refers to the saturated steam that is used in steam sterilizers (autoclaves) to achieve the necessary conditions for effective sterilization of medical devices and instruments.

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

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	<1.0	N/A
Color & Turbidity	Visual	Colorless, clear, without sediment	Colorless, clear, without sediment	Colorless, clear, without sediment
Conductivity	us/cm (microsiemens)	<500	<10	<10

Source: Table 2 of the ANSI/AAMI ST108

HEATH CARE FACILITIES IMPACTED

- **Major Medical Centers**
- **Hospitals**
- **Ambulatory Surgical Centers**
- **Doctor's Offices with Outpatient or Same-Day Surgery**

How the New Standards Affect Facility Managers

The introduction of the new ST108 standards will have a direct effect on the responsibilities of facility managers.

The requirements will be in effect for any facility that processes surgical instruments.

Legionella and Other Waterborne Pathogens

Centers supplying Medicaid and Medicare services are now required to have a water management plan that includes verification and validation steps in place for Legionella and other waterborne pathogens.

The only way to validate a plan is through regular Legionella and pathogen testing.

Risks If These Systems Aren't Implemented Properly or On Time

A risk analysis section is included since water quality issues can have an adverse effect on patients.

When a pack of surgical instruments undergoes sterilization, the team checks it for cleanliness. If it does not pass the test, the facility is prohibited from conducting surgeries that day, and operations are suspended until the water quality in the sterilization system meets the required minimum standards.

Risks range from adverse impact on patient health and potential loss of Joint Commission accreditation and litigation, as well as other concerns.

A risk analysis should be performed regularly to reduce or eliminate the risks associated with poor water quality. AAMI ST108 details specific water quality performance indicators that should be monitored to assure the correct water quality is being used.

How Facilities Should Implement AAMI ST108

There are four steps sterile processing departments and hospital facilities teams should immediately take to achieve critical water quality:

1 WATER QUALITY ASSESSMENT

Tap water from a public utility source should be analyzed by an accredited facility with expertise in water quality to determine whether the water requires treatment and, if so, what type of treatment is necessary.

The Joint Commission recommends that the facility's water management program should be performed by a multidisciplinary team. The team should include individuals with authority to allocate resources as well as a water treatment specialist. Interested parties from sterile processing, facilities engineering, infection prevention and control, clinical engineering, and surgery should also be included in the water management team.

2 IMPLEMENTATION OF WATER TREATMENT PLAN

If treatment is required, personnel should ensure that treatment processes are implemented immediately to provide the type of water quality needed for the medical device processing needs of the facility.

3 ASSURANCE OF PROPER WATER QUALITY

Process water used in medical device reprocessing areas should be regularly audited to determine whether water of the correct quality is being used for the devices being reprocessed in each area. If not, the water treatment should be corrected as necessary to meet requirements.

4 GUIDANCE FOR ONGOING WATER MONITORING

The AAMI ST108 standard outlines specific guidelines for water quality monitoring, particularly in healthcare settings. For utility water, it emphasizes the importance of routine monitoring to ensure that the water used for non-sterile processes meets established quality standards.

KEY POINTS OFTEN INCLUDE:

- **Routine Testing:** Regular assessment of water quality parameters such as total microbial counts and specific contaminants.
- **Defined Limits:** Establishing acceptable thresholds for different quality parameters based on their intended use.
- **Documentation:** Maintaining records of water quality testing results and any corrective actions taken if quality standards are not met.
- **Corrective Action:** Procedures should be in place for addressing any water quality failures to ensure continued compliance.

The **utility water** in medical device processing should be monitored for bacteria quarterly at each point-of-use location, such as a sink, using a daily visual inspection of the interior of processing equipment, checking for residues, staining, scaling, and discoloration.

Critical water requires more frequent monitoring. If critical water is not properly maintained, the water treatments can result in heightened microbial levels, biofilm development, and endotoxin. In addition, the making of critical water may affect the chemical attributes of water, including pH, conductivity, total alkalinity, and total hardness. For these reasons, point-of-use critical water should be tested monthly for endotoxins and bacteria. Daily visual inspections should also be performed that include inspection of the interior of processing equipment for residues, staining, scaling, and discoloration.

VIEW SOLUTIONS

AAMI ST108:
EasyWater's Treatment Solutions

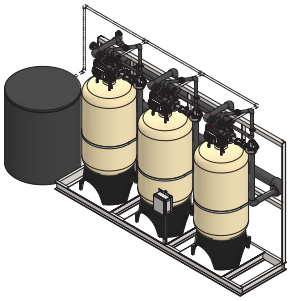
EasyWater offers solutions for all water treatment needs to meet AAMI ST108's new standard for medical device water quality.

Contact EasyWater directly or your local representative today to determine proper solutions for your specific application.

UTILITY WATER

SimplySoft Water Softener

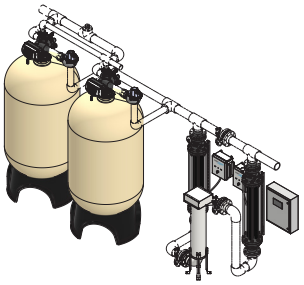
https://easywater.com/commercial/product/**simplysoft**



SimplySoft by EasyWater combines superior design and the highest quality components to deliver a low-maintenance softener that is simple to use and easy to maintain. SimplySoft provides you with soft water while reducing the damaging lime scale deposits and spotting caused by hard water.

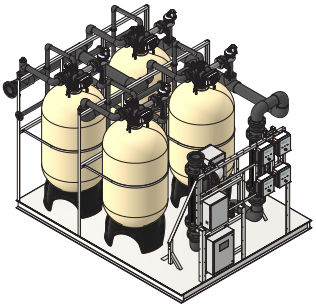
DWP (Domestic Water Protection) Treatment System

https://easywater.com/commercial/product/**dwp-system**



EasyWater's DWP (Domestic Water Protection) System is a unique, three-part solution for domestic water filtration and treatment. The DWP System provides clean, safe water for utility service by using the following technologies:

- **SedimentShield Sub-Micron Filtration** - Utilizes EasyWater's sub-micron SedimentShield media, which is a proprietary blend of media that (1) backwashes clean, (2) does not harbor bacteria, (3) has an expected life of 20+ years, (4) removes over 90+% of bacteria from the water, and (5) reduces turbidity or cloudiness in the water.
- **No-Salt Conditioners** - Minimizes Legionella risk throughout the domestic water system by eliminating scale buildup and reducing or eliminating system biofilm.
- **Ultraviolet (UV) System** - Kills bacteria on contact.



CRITICAL WATER

SmartGuard RO (Reverse Osmosis) Treatment System

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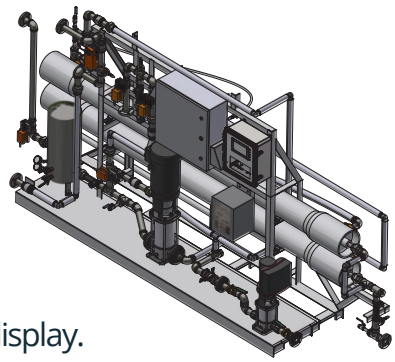

SmartGuard RO is an intelligent water filtration system built to meet the AAMI ST108 requirements for water quality that is needed.

EasyWater's SmartGuard is an intelligent and dependable RO system that doesn't require softener or chemical pretreatment.

SmartGuard is completely microprocessor driven with a touch screen display.

- SmartGuard combines a powerful on-board microprocessor with digital sensors and custom firmware
- Measures and reports performance data, operation alarms and maintenance needs
- Touch screen display keeps you informed of system and filter condition and provides an on-board interface for making adjustments
- Dry contacts provide alarm communication for building management systems

SmartGuard is customizable for ultra-high purity applications using Carbon Pre-Treatment, Mixed Bed DI or EDI, UV, and Endotoxin (.05 micron) Filtration as needed to meet water quality requirements.

- **Sediment and Carbon Pre-Treatment** to remove the chlorine/chloramines so they don't damage RO membranes. Sediment is filtered to 3 microns or less to prevent plugging of membranes.
- **Mixed Bed Deionization (DI) / Electrodeionization (EDI)** are employed to remove impurities such as calcium, magnesium, chloride, and silica, as well as other impurities like lead, chlorine, fluoride, and arsenic are removed. Mixed Bed DI tanks or EDI are combined with SmartGuard RO to meet the water quality requirements.
- **Ultraviolet (UV) Disinfection** is a water treatment method that uses ultraviolet light to inactivate pathogens in water. UV disinfection can remove most forms of microbiological contamination, including viruses, bacteria, and protozoa.
- **Endotoxin (.05 micron) Filters** are large enough to allow water molecules to pass through, but small enough to trap sediment, bacteria, protozoa/cysts and endotoxins. These filters are designed to capture these small organisms and provide protection against waterborne diseases.
- **Pure Water Conical Storage Tank** to store the RO/DI water. The conical shape allows the tank to be effectively drained and sanitized as needed.

STEAM

Depending on the usage of the steam that is produced, it can be used for varying applications. EasyWater can treat both process and clean/pure steam as required. Treatment systems would be either SimplySoft Water Softener or SmartGuard RO Systems.

SimplySoft Water Softener

https://easywater.com/commercial/product/**simplysoft**

SmartGuard RO (Reverse Osmosis) Treatment System

https://easywater.com/commercial/product/**smartguard-ro**

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