

The Association for the Advancement of Medical Instrumentation (AAMI) has finalized and published a new standard, ANSI/AAMI ST108:2023 - Water for the Processing of Medical Devices. This new standard replaces AAMI TIR34. The new standard establishes the requirements for the quality of water used for cleaning, rinsing, disinfection, and sterilization of medical devices.

ANSI/AAMI ST108:2023 places great importance on the following:

- The facility requirement to establish a multi-disciplinary team to oversee the water treatment program.
- Proper Water System Design.
- Establishment of Water Quality Criteria for Performance Qualification.
- Routine maintenance of the water system.
- Water quality monitoring program.

H₂O Solutions provides turnkey systems designed specifically to meet and exceed ANSI/AAMI ST108:2023. We can also assist your team in evaluating the performance of an existing system, make recommendations for improvement, and implement the necessary changes. This includes Validation Documentation for system Performance Qualification.

Let us know how we can assist your team!

Water quality measurement	Units	Critical Water
pH @ 25°C	pH	5.0-7.5
Total Alkalinity	mg CaCO ₃ /L	<8
Bacteria	CFU/mL	<10
Endotoxin	EU/mL	<10
Total Organic Carbon (TOC)	mg/L (ppm)	<1.0
Color and Turbidity	Visual	Colorless, Clear, without sediment
Ionic Contaminants		
Aluminum	mg/L	<0.1
Chloride	mg/L	<1
Conductivity	uS/cm	<10
Copper	mg/L	<0.1
Iron	mg/L	<0.1
Manganese	mg/L	<0.1
Nitrate	mg/L	<1
Phosphate	mg/L	<1
Sulfate	mg/L	<1
Silicate	mg/L	<1
Total Hardness	mg CaCO ₃ /L	<1
Zinc	mg/L	<0.1

