AAMI WATER QUALITY STANDARD FOR HEMODIALYSIS

ANSI/AAMI/ISO 23500-3:2019

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WATER QUALITY STANDARD FOR BETTER PATIENT OUTCOMES

The adoption of higher standards by the American Association for the Advancement of Medical Instrumentation (AAMI) means the quality of water used in dialysis treatment has increased. The latest standard has 2 important aspects to it. First, acceptable microbiological levels have been reduced by more than 50%, as noted in the chart below. Second, the testing protocol used to determine bacteria levels is a much more sensitive cultivation technique yet still allows for other test methods. The net result is that existing water system designs may or may not consistently produce water that meets the latest standards.

AAMI Microbiological Standards for Dialysis Water

Microbiological Level	Previous Standards	New Standards	Previous Action Level	New Action Level
Colony Forming Units	< 200 CFU/mL	< 100 CFU/mL	≥ 50 CFU/mL	≥ 50 CFU/mL
Endotoxin Units	< 2 EU/mL	< 0.25 EU/mL	≥ 1 EU/mL	≥ 0.125 EU/mL

MICROBIOLOGICAL TESTING PROCEDURE

In an effort to harmonize procedures for measuring microbiological levels in dialysis water, AAMI adopted the International Organization for Standardization (ISO) guidance back in 2009 with one deviation. Since then, ISO released a re-designated and revised series of five standards that incorporated dialysis quality and safety related topics into a more cohesive series, thereby helping healthcare professionals, manufacturers and suppliers navigate essential requirements.

The latest standards brings harmonization to the microbiology testing methods where previously a U.S. deviation had been established. As a result, the 23500- series brings a variety of acceptable options for dialysis fluid sample collection and testing.

There are 3 main elements of these procedures: Agar Medium, Incubation Temperatures and Incubation Time. In many cases, the clinic does not perform the procedure but sends the samples to a certified laboratory for processing. Laboratories will need to be instructed as to the clinics stated method of testing.

Methodology using **Agar Mediums** are Tryptone Glucose Extract Agar (TGEA) or Reasoner's 2A supplemented with 4% sodium bicarbonate, or equivalent. Blood or chocolate agar are listed as unacceptable and are not be used. **Incubation Temperatures** that mirror actual water environment are normally between 15-25°C. Therefore this requires the temperature to be maintained between 17°C to 23°C. In order to give the microorganisms time to develop, it has been determined that a longer **Incubation Time** of 168 hours (7 days) provides an accurate indication of viable bacteria.

Another methodology accepts **Agar Mediums** Trypticase Soy Agar (TSA, a soybean casein digest agar) or standards method agar and plate count agar (also known as TGYE). These are to be stored at **Incubation Temperatures** of 35°C for 48 hours of **Incubation Time** prior to assaying.

The standard also allows for other comparative and validated test methods to be used.

Results: The more strict cultivation conditions simulate dialysis water environment and have been demonstrated to produce higher levels of bacteria as compared to previous conditions. Although higher levels of bacteria are expected, some testing has shown little difference between the old and new conditions. However, agreement on using TSA at the 35°C for 48 hours within the 23500- series standards provides a quicker response time should results be outside acceptable parameters.

WHAT CAN YOU DO?

For existing water systems, you should perform testing using the latest standard to ensure that your water system is producing water that meets the new requirements. As a result, you may need to increase the disinfection frequency, or add additional filtration or a combination of both in order to meet the new standard. Evoqua Water Technologies can help you evaluate the options.

For those considering new water systems, the use of heat for daily disinfection of the water distribution loop has been proven to be a state of the art design to minimize bacteria growth. The CWP-100 H/S central and EON® portable Reverse Osmosis Systems are designed for routine heat disinfection. The use of endotoxin retentive filters can also provide a level of safety for the water system.

If you have any questions about the latest AAMI Standards or what can be done to improve your water system's compliance to the standard, a Evoqua Water Technologies representative is available to help. We will be happy to meet with you to review your existing water system and to discuss options for any future water system design. Call us at 1-800-633-3080 or visit us on the web at www.mcpur.com.

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Medical Water Systems

Evoqua Water Technologies is one of the largest and most experienced water purification suppliers to the Medical/Hemodialysis market. We have the largest equipment and service offerings and provides complete, installed, medical device registered water systems throughout North America. Each system is serviced from one of our nationwide service offices, which are stocked with critical medical device spare parts.

Medical Water Products

Evoqua Water Technologies offers a wide variety of medical water products and services, in addition to water systems, to ensure that hemodialysis clinics and their employees have the equipment, products, information, and service to effectively provide their patients with the highest quality water available. From product support, to essential parts, to ongoing education, we have the resources to keep your water treatment system and clinic running smoothly.

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Evoqua Water Technologies is one of the largest and most experienced water purification companies in North America. We have been servicing medical water treatment equipment for over 50 years and have an experienced nationwide team of technicians qualified to work on your medical water systems. We have a service office within 100 miles of over 70% of the U.S. Medical customers.

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