Technical Information Report

AAMI TIR34: 2014/(R)2021

Water for the reprocessing of medical devices

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AAMI Technical Information Report

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Water for the reprocessing of medical devices

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AAMI

Abstract: This technical information report (TIR) covers the selection and maintenance of effective water quality suitable for reprocessing medical devices. It provides guidelines for selecting the water quality necessary for the reprocessing of categories of medical devices and addresses water treatment equipment, water distribution and storage, quality control procedures for monitoring water quality, strategies for bacterial control, and environmental and personnel considerations.

Keywords: carbon filters, deionization, disinfection, distillation, pasteurization, reverse osmosis, sediment filters, sterilization, ultrafiltration, water filtration, water quality, water softening, water treatment

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Ste. 300, Arlington, VA 22203.

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International Standards adopted in the United States may include normative references to other International Standards. AAMI maintains a current list of each International Standard that has been adopted by AAMI (and ANSI). Available on the AAMI website at the address below, this list gives the corresponding U.S. designation and level of equivalency to the International Standard.

www.aami.org/standards/glossary.pdf

Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Water Quality for Medical Device Reprocessing Working Group

This technical information report (TIR) was developed by the AAMI Water Quality for Medical Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. Approval of the TIR does not necessarily mean that all working group members voted for its approval. At the time this TIR was published, the Water Quality for Medical Device Reprocessing Working Group had the following members:

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Foreword

This technical information report was developed by the AAMI Water Quality for Medical Device Reprocessing Working Group under the auspices of the AAMI Sterilization Standards Committee. The objective of this TIR is to provide guidelines to personnel involved in medical device reprocessing on the quality of water that should be used in various stages of medical device reprocessing. It is also intended to provide guidelines to water service maintenance personnel on establishing and monitoring water treatment systems. This second edition has been changed to reflect two water categories instead of the four previously specified. There are also many updates and organizational enhancements.

The concepts incorporated in this TIR should not be considered inflexible or static. The recommendations presented here will be reviewed and updated periodically to reflect new information and technical developments regarding water quality and treatment in medical device reprocessing.

Suggestions for improving this TIR are invited. Comments and suggested revisions should be sent to Technical Programs, AAMI, 4301 N. Fairfax Dr., Ste. 301, Arlington, VA 22203-1633.

Introduction

Water quality is an important consideration in all stages of medical device reprocessing. 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. Because the needs of these two groups are distinct, this technical information report (TIR) contains:

a) sections in the main text that provide guidance for personnel involved in medical device reprocessing on the selection of the recommended water quality for each stage of medical device reprocessing for each category of medical device; and

b) annexes that provide technical information to water maintenance personnel (i.e., personnel who are involved in water treatment and distribution in the facility) to guide them in setting up and monitoring water treatment systems.

Water can be treated by a variety of methods that yield different levels of water quality. In general, as the chemical quality of water improves, its microbial content could increase unless the system is closely monitored to prevent microbial overgrowth. Gram-negative bacteria and nontuberculous mycobacteria can grow in any type of water, including tap, softened, deionized (DI), reverse osmosis (RO) treated, and distilled water. The rate of growth and the microbial levels attained are a function of the amount of organic contaminants in the water. The importance of monitoring water quality to prevent problems with microbial overgrowth cannot be overemphasized.

This TIR defines two levels of water quality suitable for medical device reprocessing, and it describes the water treatment processes that can be used to obtain the correct water quality. To provide optimal water for medical device reprocessing, reprocessing personnel and water maintenance personnel should collaborate with administrative personnel to implement the following procedures:

Step	Procedure	What to Do	Who is Responsible
1	Assessment of water quality	The tap water from the 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. This analysis should take into account seasonal variations in water quality.	Water maintenance personnel
2	Implementation of water treatment process	On the basis of the assessment in Step 1 and in consultation with an accredited facility with expertise in water quality, personnel should ensure that treatment processes are implemented to provide the type of water quality needed for the medical device reprocessing needs of the facility.	Water maintenance personnel in conjunction with device reprocessing personnel
3	Assurance of proper water quality for the various stages in medical device reprocessing	Medical device reprocessing areas should be 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 modified as necessary.	Device reprocessing personnel in conjunction with health care technology management personnel
4	Ongoing monitoring of water quality	Where applicable, monitoring procedures should be established to ensure that the treated water is of adequate quality for medical device reprocessing. Water maintenance personnel and device reprocessing personnel should communicate effectively to ensure that action is taken when inadequate water quality is detected.	Water maintenance personnel in conjunction with device reprocessing personnel

This TIR was developed using information on the reprocessing of medical devices labeled for reuse. There might be regulatory requirements or other issues associated with reprocessing single-use devices that were not considered in developing this TIR (see www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm).

Water for the reprocessing of medical devices

1. Scope

1.1 General

This TIR addresses how to determine the water quality needs for reprocessing various categories of medical devices at various stages of reprocessing and how to assess, generate, monitor, and maintain water meeting those requirements.

1.2 Inclusions

This TIR covers the quality of the water used to clean, rinse, disinfect, and sterilize medical devices. It defines water types on the basis of hardness, pH, microorganism levels, endotoxin levels, and other characteristics. The following specific topics are covered:

a) Importance of water quality and effective water treatment

b) Categories of water quality for medical device reprocessing

c) Selection of water quality

d) Water treatment systems

e) Monitoring of water quality

f) Strategies for microorganism control

g) Personnel considerations

h) Continuous quality improvement

i) Troubleshooting water quality issues

This TIR also provides definitions of terms and a bibliography. The annexes contain technical details pertaining to water treatment and monitoring for the benefit of water maintenance personnel.

1.3 Exclusions

This TIR does not cover the water requirements for hemodialysis applications. See ANSI/AAMI/ISO 13959, ANSI/AAMI/ISO 11663, and ANSI/AAMI RD47.

This TIR does not address water treatment performed within medical washers, washer–disinfectors, or automated endoscope reprocessors (AERs); it covers only the water coming into such equipment. The internal filtering or other additional treatment performed within a medical washer, washer–disinfector, or AER is the responsibility of the equipment manufacturer. However, it is in the best interest of reprocessing personnel to be informed of the internal water treatment apparatus and of the equipment manufacturer to take into account the water quality recommendations of this document. See the ANSI/AAMI and ISO 15883 series of documents.

2. Definitions and abbreviations

For the purpose of this TIR, the following terms and definitions apply.

2.1 anion: Negatively charged atom or molecule.

2.2 ATP assessment: Method using adenosine triphosphate (ATP) to indirectly measure viable microbial load.

2.3 automated endoscope reprocessor (AER): Machine intended to disinfect or sterilize loads containing endoscopes.

NOTE—Some AERs have provision for reprocessing accessories.

