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AAMI TIR34: 2014
Water for the reprocessing of medical devices
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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
AAMI Technical Information Report

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Published by

Association for the Advancement of Medical Instrumentation

4301 N. Fairfax Dr., Ste. 301

Arlington, VA 22203-1633

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Printed in the United States of America

## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glossary of equivalent standards</td>
<td>v</td>
</tr>
<tr>
<td>Committee representation</td>
<td>vi</td>
</tr>
<tr>
<td>Foreword</td>
<td>viii</td>
</tr>
<tr>
<td>Introduction</td>
<td>1</td>
</tr>
<tr>
<td>1. Scope</td>
<td>2</td>
</tr>
<tr>
<td>1.1 General</td>
<td>2</td>
</tr>
<tr>
<td>1.2 Inclusions</td>
<td>2</td>
</tr>
<tr>
<td>1.3 Exclusions</td>
<td>2</td>
</tr>
<tr>
<td>2. Definitions and abbreviations</td>
<td>2</td>
</tr>
<tr>
<td>3. The importance of water quality and effective water treatment</td>
<td>8</td>
</tr>
<tr>
<td>3.1 Introduction</td>
<td>8</td>
</tr>
<tr>
<td>3.2 Major impacts of adverse water quality on medical device reprocessing</td>
<td>8</td>
</tr>
<tr>
<td>3.2.1 General considerations</td>
<td>8</td>
</tr>
<tr>
<td>3.2.2 Microbial level in water</td>
<td>8</td>
</tr>
<tr>
<td>3.2.3 Inorganic and organic components of water</td>
<td>9</td>
</tr>
<tr>
<td>3.2.4 Water temperature</td>
<td>10</td>
</tr>
<tr>
<td>3.3 Treatment of water</td>
<td>10</td>
</tr>
<tr>
<td>3.3.1 General considerations</td>
<td>10</td>
</tr>
<tr>
<td>3.3.2 Pretreatment</td>
<td>11</td>
</tr>
<tr>
<td>3.3.3 Principal water treatment processes</td>
<td>11</td>
</tr>
<tr>
<td>3.3.4 Distribution</td>
<td>11</td>
</tr>
<tr>
<td>3.4 Categories of medical devices</td>
<td>12</td>
</tr>
<tr>
<td>3.4.1 Categories of water quality for medical device reprocessing</td>
<td>15</td>
</tr>
<tr>
<td>4. Categories of water quality for medical device reprocessing</td>
<td>15</td>
</tr>
<tr>
<td>4.1 Introduction</td>
<td>15</td>
</tr>
<tr>
<td>4.2 Two categories of water quality</td>
<td>15</td>
</tr>
<tr>
<td>5. Selection of water quality</td>
<td>18</td>
</tr>
<tr>
<td>5.1 Introduction</td>
<td>18</td>
</tr>
<tr>
<td>5.2 Cleaning</td>
<td>18</td>
</tr>
<tr>
<td>5.2.1 Manual cleaning</td>
<td>18</td>
</tr>
<tr>
<td>5.2.2 Mechanical cleaning by medical washers and medical washer–disinfectors</td>
<td>18</td>
</tr>
<tr>
<td>5.2.3 Automated cleaning by ultrasonic cleaners</td>
<td>20</td>
</tr>
<tr>
<td>5.3 Disinfection and sterilization</td>
<td>20</td>
</tr>
<tr>
<td>5.3.1 General considerations</td>
<td>20</td>
</tr>
<tr>
<td>5.3.2 Medical devices that receive steam sterilization or low-temperature gas sterilization</td>
<td>21</td>
</tr>
<tr>
<td>5.3.3 Medical devices that receive liquid chemical high-level disinfection</td>
<td>23</td>
</tr>
<tr>
<td>5.3.4 Medical devices that receive liquid chemical sterilization</td>
<td>25</td>
</tr>
<tr>
<td>5.3.5 Medical devices that receive pasteurization or thermal disinfection</td>
<td>27</td>
</tr>
<tr>
<td>6. Water treatment systems</td>
<td>28</td>
</tr>
<tr>
<td>6.1 Introduction</td>
<td>28</td>
</tr>
<tr>
<td>6.2 General issues associated with water treatment</td>
<td>28</td>
</tr>
<tr>
<td>6.3 Design of water treatment systems</td>
<td>29</td>
</tr>
<tr>
<td>6.3.1 General considerations</td>
<td>29</td>
</tr>
<tr>
<td>6.3.2 Physical layout of the water purification, distribution, and storage system</td>
<td>29</td>
</tr>
<tr>
<td>7. Monitoring water quality</td>
<td>30</td>
</tr>
<tr>
<td>7.1 Introduction</td>
<td>30</td>
</tr>
<tr>
<td>7.2 Goals of water quality monitoring</td>
<td>30</td>
</tr>
<tr>
<td>7.3 Water characteristics that should be monitored</td>
<td>30</td>
</tr>
<tr>
<td>7.3.1 General considerations</td>
<td>30</td>
</tr>
<tr>
<td>7.3.2 Water temperature</td>
<td>30</td>
</tr>
</tbody>
</table>
8 Strategies for bacterial control .................................................................33
9 Personnel considerations ........................................................................33
  9.1 Introduction ..........................................................................................33
  9.2 Device reprocessing personnel ..........................................................33
  9.3 Water maintenance personnel ............................................................33
  9.4 Audits .................................................................................................33
10 Continuous quality improvement ..........................................................33
  10.1 Introduction ........................................................................................33
  10.2 Quality process .................................................................................33

Annexes
A Water treatment methods .......................................................................35
  Monitoring water treatment equipment and processes ............................45
B Water storage and distribution .................................................................51
C Strategies for bacterial control .................................................................53
D Thermal disinfection ................................................................................57
E Water treatment using filtration ...............................................................58
F Typical presentation of water quality issues during the reprocessing of medical devices ...........................................60
G Bibliography ..........................................................................................63

Tables
1 Categories and recommended levels of water quality for medical device reprocessing ........................................16
2 Water quality for reprocessing devices to be sterilized by steam or low-temperature gas ..................................22
3 Water quality for reprocessing devices to be high-level disinfected ..................................................................24
4 Water quality for reprocessing devices to receive liquid chemical sterilization .................................................26
5 Water quality for reprocessing devices to be pasteurized or thermally disinfected ..............................................27
6 Overview of water quality monitoring .....................................................32
7 Quality monitoring of cleaning, disinfection, and sterilization equipment ..........................................................34
  A.1 Summary of water treatment methods .................................................40
  A.2 Processes that can remove interfering compounds that might be found in water .............................................41
  B.1 Monitoring water treatment equipment ...............................................47
  E.1 Holding times in instrument washers ....................................................57
  G.1 Examples of observed problems during device reprocessing that can be caused by poor water quality ................60

Figures
1 Stages of medical device reprocessing in which water quality is a consideration .................................................14
2 Example of a recommended general water treatment process for incoming water to produce treated water that is appropriate for use in medical device reprocessing .........................................................28
  A.1 Examples of water treatment processes to produce critical and softened water ..............................................42
  A.2 Example of a water treatment process .................................................42
  A.3 Example of a water treatment process .................................................42
  A.4 Example of a water treatment process .................................................42
Glossary of equivalent standards

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:

<table>
<thead>
<tr>
<th>Step</th>
<th>Procedure</th>
<th>What to Do</th>
<th>Who is Responsible</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Assessment of water quality</td>
<td>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.</td>
<td>Water maintenance personnel</td>
</tr>
<tr>
<td>2</td>
<td>Implementation of water treatment process</td>
<td>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.</td>
<td>Water maintenance personnel in conjunction with device reprocessing personnel</td>
</tr>
<tr>
<td>3</td>
<td>Assurance of proper water quality for the various stages in medical device reprocessing</td>
<td>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.</td>
<td>Device reprocessing personnel in conjunction with health care technology management personnel</td>
</tr>
<tr>
<td>4</td>
<td>Ongoing monitoring of water quality</td>
<td>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.</td>
<td>Water maintenance personnel in conjunction with device reprocessing personnel</td>
</tr>
</tbody>
</table>

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).
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–disinfector, 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.