

# Technical Information Report

AAMI TIR34:2007

## Water for the reprocessing of medical devices



Association for the Advancement  
of Medical Instrumentation



# Water for the reprocessing of medical devices

Approved 15 October 2007 by  
**Association for the Advancement of Medical Instrumentation**

**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

A technical information report (TIR) is a publication of the Association for the Advancement of Medical Instrumentation (AAMI) Standards Board that addresses a particular aspect of medical technology.

Although the material presented in a TIR may need further evaluation by experts, releasing the information is valuable because the industry and the professions have an immediate need for it.

A TIR differs markedly from a standard or recommended practice, and readers should understand the differences between these documents.

Standards and recommended practices are subject to a formal process of committee approval, public review, and resolution of all comments. This process of consensus is supervised by the AAMI Standards Board and, in the case of American National Standards, by the American National Standards Institute.

A TIR is not subject to the same formal approval process as a standard. However, a TIR is approved for distribution by a technical committee and the AAMI Standards Board.

Another difference is that, although both standards and TIRs are periodically reviewed, a standard must be acted on—reaffirmed, revised, or withdrawn—and the action formally approved usually every 5 years but at least every 10 years. For a TIR, AAMI consults with a technical committee about 5 years after the publication date (and periodically thereafter) for guidance on whether the document is still useful—that is, to check that the information is relevant or of historical value. If the information is not useful, the TIR is removed from circulation.

A TIR may be developed because it is more responsive to underlying safety or performance issues than a standard or recommended practice, or because achieving consensus is extremely difficult or unlikely. Unlike a standard, a TIR permits the inclusion of differing viewpoints on technical issues.

**CAUTION NOTICE:** This AAMI TIR may be revised or withdrawn at any time. Because it addresses a rapidly evolving field or technology, readers are cautioned to ensure that they have also considered information that may be more recent than this document.

All standards, recommended practices, technical information reports, and other types of technical documents developed by AAMI are *voluntary*, and their application is solely within the discretion and professional judgment of the user of the document. Occasionally, voluntary technical documents are adopted by government regulatory agencies or procurement authorities, in which case the adopting agency is responsible for enforcement of its rules and regulations.

Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

*Published by*

Association for the Advancement of Medical Instrumentation  
1110 N Glebe Road, Suite 220  
Arlington, VA 22201-4795  
[www.aami.org](http://www.aami.org)

© 2008 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

Publication, reproduction, photocopying, storage, or transmission, electronically or otherwise, of all or any part of this document without the prior written permission of the Association for the Advancement of Medical Instrumentation is strictly prohibited by law. It is illegal under federal law (17 U.S.C. § 101, *et seq.*) to make copies of all or any part of this document (whether internally or externally) without the prior written permission of the Association for the Advancement of Medical Instrumentation. Violators risk legal action, including civil and criminal penalties, and damages of \$100,000 per offense. For permission regarding the use of all or any part of this document, contact AAMI at 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795. Phone: (703) 525-4890; Fax: (703) 525-1067.

Printed in the United States of America

**ISBN 1-57020-302-4**

# Contents

	Page
Glossary of equivalent standards .....	v
Committee representation .....	vii
Acknowledgments .....	ix
Foreword .....	ix
Introduction .....	xi
<b>1</b> Scope.....	<b>1</b>
<b>1.1</b> General .....	<b>1</b>
<b>1.2</b> Inclusions.....	<b>1</b>
<b>1.3</b> Exclusions.....	<b>1</b>
<b>2</b> Definitions and abbreviations .....	<b>1</b>
<b>3</b> The importance of water quality and effective water treatment .....	<b>6</b>
<b>3.1</b> Introduction .....	<b>6</b>
<b>3.2</b> Major impacts of adverse water quality on medical device reprocessing .....	<b>6</b>
<b>3.2.1</b> General considerations.....	<b>6</b>
<b>3.2.2</b> Microbial level in water .....	<b>7</b>
<b>3.2.3</b> Inorganic and organic components of water .....	<b>7</b>
<b>3.2.4</b> Water temperature.....	<b>9</b>
<b>3.3</b> Treatment of water.....	<b>9</b>
<b>3.3.1</b> General considerations.....	<b>9</b>
<b>3.3.2</b> Pretreatment.....	<b>10</b>
<b>3.3.3</b> Principal water treatment processes.....	<b>10</b>
<b>3.3.4</b> Distribution systems.....	<b>11</b>
<b>3.4</b> Categories of medical devices .....	<b>11</b>
<b>3.5</b> Stages of medical device reprocessing in which water quality is a consideration .....	<b>12</b>
<b>4</b> Categories of water quality for medical device reprocessing.....	<b>13</b>
<b>4.1</b> Introduction .....	<b>13</b>
<b>4.2</b> Four categories of water quality.....	<b>13</b>
<b>5</b> Selection of water quality .....	<b>17</b>
<b>5.1</b> Introduction .....	<b>17</b>
<b>5.2</b> Cleaning.....	<b>17</b>
<b>5.2.1</b> Manual cleaning .....	<b>17</b>
<b>5.2.2</b> Automated cleaning by medical washers and medical washer–disinfectors .....	<b>18</b>
<b>5.2.3</b> Automated cleaning by ultrasonic cleaners .....	<b>20</b>
<b>5.3</b> Disinfection and sterilization.....	<b>20</b>
<b>5.3.1</b> General considerations.....	<b>20</b>
<b>5.3.2</b> Medical devices that receive steam sterilization or low-temperature gas sterilization.....	<b>21</b>
<b>5.3.3</b> Medical devices that receive liquid chemical high-level disinfection .....	<b>23</b>
<b>5.3.4</b> Medical devices that receive liquid chemical sterilization .....	<b>25</b>
<b>5.3.5</b> Medical devices that receive pasteurization or thermal disinfection.....	<b>27</b>
<b>6</b> Water treatment systems .....	<b>28</b>
<b>6.1</b> Introduction .....	<b>28</b>
<b>6.2</b> General issues associated with water treatment.....	<b>28</b>
<b>6.3</b> Design of water treatment systems.....	<b>29</b>
<b>6.3.1</b> General considerations.....	<b>29</b>
<b>6.3.2</b> Physical layout of the water purification, distribution, and storage system.....	<b>29</b>

7	Monitoring water quality .....	30
7.1	Introduction .....	30
7.2	Goals of water quality monitoring .....	30
7.3	Water characteristics that should be monitored .....	30
7.3.1	General considerations .....	30
7.3.2	Water temperature .....	30
8	Strategies for bacterial control .....	34
9	Personnel considerations .....	34
9.1	Introduction .....	34
9.2	Device reprocessing personnel .....	34
9.3	Water maintenance personnel .....	34
9.4	Audits .....	34
10	Continuous quality improvement .....	34
10.1	Introduction .....	34
10.2	Quality process .....	34

**Annexes**

A	Water treatment methods .....	36
B	Monitoring water treatment equipment and processes .....	46
C	Water storage and distribution .....	52
D	Strategies for bacterial control .....	54
E	Thermal disinfection .....	58
F	Water treatment using filtration .....	59
G	Bibliography .....	61

**Tables**

1	Categories of water quality for medical device reprocessing .....	14
2	Water quality for processing devices to be sterilized by steam or low-temperature gas .....	22
3	Water quality for processing devices to be high-level disinfected .....	24
4	Water quality for processing devices to receive liquid chemical sterilization .....	26
5	Water quality for processing devices to be pasteurized or thermally disinfected .....	27
6	Overview of water quality monitoring .....	32
7	Quality monitoring of cleaning, disinfection, and sterilization equipment .....	35
A.1	Summary of water treatment methods .....	40
A.2	Processes that can remove interfering compounds that may be found in water .....	42
B.1	Monitoring water treatment equipment .....	47
E.1	Holding times in instrument washers .....	58

**Figures**

1	Stages of medical device reprocessing in which water quality is a consideration .....	12
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 high-purity and softened water .....	43
A.2	Example of a water treatment process .....	43
A.3	Example of a water treatment process .....	43
A.4	Example of a water treatment process .....	43