American National Standard

# ANSI/AAMI/ ST15883-2: 2013

**(ISO 15883-2:2006, MOD)**

Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

AAMI
Advancing Safety in Medical Technology

# Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

## INTERPRETATIONS OF AAMI STANDARDS AND RECOMMENDED PRACTICES

Requests for interpretations of AAMI standards and recommended practices must be made in writing, to the AAMI Vice President, Standards Policy and Programs. An official interpretation must be approved by letter ballot of the originating committee and subsequently reviewed and approved by the AAMI Standards Board. The interpretation will become official and representation of the Association only upon exhaustion of any appeals and upon publication of notice of interpretation in the "Standards Monitor" section of the *AAMI News*. The Association for the Advancement of Medical Instrumentation disclaims responsibility for any characterization or explanation of a standard or recommended practice which has not been developed and communicated in accordance with this procedure and which is not published, by appropriate notice, as an *official interpretation* in the *AAMI News*.

**American National Standard**

**ANSI/AAMI ST15883-2:2013**
(ISO 15883-2:2006, MOD)

# Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

Approved 3 December 2012 by
**Association for the Advancement of Medical Instrumentation**

Approved 9 January 2013 by
**American National Standards Institute, Inc.**

**Abstract:** This document specifies particular requirements for washer disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anesthetic equipment, bowls, dishes and receivers, utensils and glassware.

**Keywords:** ISO 15883-2

## AAMI Standard

This Association for the Advancement of Medical Instrumentation (AAMI) standard implies a consensus of those substantially concerned with its scope and provisions. The existence of an AAMI standard does not in any respect preclude anyone, whether they have approved the standard or not, from manufacturing, marketing, purchasing, or using products, processes, or procedures not conforming to the standard. AAMI standards are subject to periodic review, and users are cautioned to obtain the latest editions.

**CAUTION NOTICE:** This AAMI standard may be revised or withdrawn at any time. AAMI procedures require that action be taken to reaffirm, revise, or withdraw this standard no later than 5 years from the date of publication. Interested parties may obtain current information on all AAMI standards by calling or writing AAMI, or by visiting the AAMI website at www.aami.org.

All AAMI 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.

*Published by*

Association for the Advancement of Medical Instrumentation
4301 N. Fairfax Dr., Suite 301
Arlington, VA 22203-1633
www.aami.org

© 2013 by the Association for the Advancement of Medical Instrumentation

All Rights Reserved

This publication is subject to copyright claims of ISO, ANSI, and AAMI. No part of this publication may be reproduced or distributed in any form, including an electronic retrieval system, without the prior written permission of AAMI. All requests pertaining to this document should be submitted to AAMI. 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, complete the reprint request form at www.aami.org or contact AAMI, 4301 N. Fairfax Dr., Suite 301, Arlington, VA 22203-1633. Phone: +1-703-525-4890; Fax: +1-703-525-1067.

Printed in the United States of America

**ISBN 1-57020-481-0**

# Contents

Page

## 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

### Washer-disinfectors Working Group

The adoption of ISO 15883-2 as an American National Standard was initiated by the AAMI Washer-disinfectors Working Group of the AAMI Sterilization Standards Committee. The AAMI Washer-disinfectors Working Group also functions as a U.S. Technical Advisory Group to the relevant work in the International Organization for Sterilization (ISO). U.S. representatives from the AAMI Washer-disinfectors Working Group (U.S. Sub-TAG for ISO/TC 198/WG 13) played an active part in developing the ISO standard.

At the time this document was published, the **AAMI Washer-disinfectors Working Group** had the following members:

*Cochairs:*
Kevin Corrigan, Johnson & Johnson
Patrick J. McCormick, PhD, Bausch & Lomb Inc.

*Members:*
Kendall Ashe, CS Medical LLC
Ralph J. Basile, MBA, Healthmark Ind Co Inc.
Chris Bible, Belimed Inc.
Holger Biering, PhD, Holger Biering
Dorin Cioraca, SciCan Ltd
Kevin Corrigan, Johnson & Johnson
Jacqueline Daley, Sinai Hospital of Baltimore (Independent Expert)
Steven J. Elliott, NAMSA
Mrs. Rosanna Fardo, RN BSN CIC CHSP, Department of Veterans Affairs
Gloria H. Frost, PhD DABT, Cardinal Health (MP&S)
Russell E. Gilbert, RN CNOR CRCST, Cox Medical Centers (Independent Expert)
Steve N. Goldstine, PhD, Steve Goldstine Consultants (Independent Expert)
Shelley Green, WuXi AppTec Inc.
Rachel Hill, CareFusion
Victoria M. Hitchins, PhD, FDA/CDRH
Beth Jacques, RAC, Biotest Laboratories Inc.
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Colleen Patricia Landers, RN, Canadian Standards Association
Mary Kneece Lane, BS MHA CSPDS CSPDM, Sarasota Memorial Hospital (Independent Expert)
Jo Ann Barbara Maltais, PhD, Maltais Consulting (Independent Expert)
Gerald E. McDonnell, PhD, Steris Corporation
Terry Mistalski, Medivators Inc.
Emily Mitzel, MS, Nelson Laboratories Inc.
Priya Muralidharan, Case Medical Inc.
Michael J. Schoene, Bausch & Lomb Inc.
Kristen Singleton, Steritec Products Mfg Co Inc.
Donald Socha, Jr., Getinge USA
Donna Swenson, BS CSPDM, West Suburban Medical Center (Independent Expert)
Donna Ungvarsky, MSN MEd RN CNOR, Olympus America Inc.
Mary Velasco, Henry Ford Macomb Hospital - Clinton Township (Independent Expert)
Craig A. Wallace, 3M Healthcare
Jonathan A. Wilder, PhD, H&W Technology LLC

*Alternates:*
David E. Barlow, PhD, Olympus America Inc.
Mike Cain, Getinge USA
Harriet Chan-Myers, Johnson & Johnson

Gordon M. Ely, WuXi AppTec Inc.
Thomas Grobaski, Belimed Inc.
Danny Hutson, CareFusion
Nancy E. Kaiser, Steris Corporation
Roland C. Kippenhan, Medivators Inc.
Stephen M. Kovach, Healthmark Ind Co Inc.
Tania Lupu, Case Medical Inc.
Elaine S. Mayhall, PhD, FDA/CDRH
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Michael Neilson, Nelson Laboratories Inc.
Shaundrea L. Rechsteiner, NAMSA
Klaus Roth, H&W Technology LLC
Andy Sun, SciCan Ltd
Grace A. Thornhill, PhD, 3M Healthcare

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

At the time this document was published, the **AAMI Sterilization Standards Committee** had the following members:

*Cochairs:*
Victoria M. Hitchins, PhD, FDA/CDRH
Michael H. Scholla, Ph.D., Dupont Protection Technologies

*Members:*
Christopher Anderson, Boston Scientific Corporation
Trabue D. Bryans, WuXi AppTec Inc.
Peter A. Burke, PhD, Steris Corporation
Nancy Chobin, RN CSPDM, St Barnabas Healthcare System (Independent Expert)
Charles Cogdill, Covidien
Ramona Conner, RN MSN CNOR, Association of Perioperative Registered Nurses
Jacqueline Daley, Sinai Hospital of Baltimore (Independent Expert)
Kimbrell Darnell, CR Bard
Lisa Foster, Adiuvo QS & SA Consulting
Joel R. Gorski, PhD, NAMSA
Joyce M. Hansen, Johnson & Johnson
Deborah A. Havlik, Hospira Worldwide Inc.
Victoria M. Hitchins, PhD, FDA/CDRH
Susan G. Klacik, CCSMC FCS ACE, IAHCSMM
Byron J. Lambert, PhD, Abbott Laboratories
Colleen Patricia Landers, RN, Canadian Standards Association
Reynaldo Lopez, Cardinal Health (MP&S)
Lisa N. Macdonald, Becton Dickinson & Company
Jeff Martin, Alcon Laboratories Inc.
Patrick J. McCormick, PhD, Bausch & Lomb Inc.
Janet M. Prust, 3M Healthcare
Nancy Rakiewicz, Moog Medical Devices
Michael H. Scholla, Ph.D., Dupont Protection Technologies
Mark Seybold, Baxter Healthcare Corporation
Andrew Sharavara, PhD, Propper Manufacturing Co Inc.
Mark N. Smith, Getinge USA
Martell Kress Winters, BS SM, Nelson Laboratories Inc.
William E. Young, (Independent Expert)
William T. Young, Sterigenics International

*Alternates:* Lloyd Brown, Covidien
Glenn W. Calvert, Becton Dickinson & Company
Dave Dion, Cardinal Health (MP&S)
Gordon M. Ely, WuXi AppTec Inc.
Thomas J. Frazar, Johnson & Johnson
Martha M. Kadas, Sterigenics International
Jim Kaiser, Bausch & Lomb Inc.
Natalie Lind, IAHCSMM
Ralph Makinen, Boston Scientific Corporation
Mary S. Mayo, CR Bard
Gerald E. McDonnell, PhD, Steris Corporation
David Ford McGoldrick, BS, Abbott Laboratories
Jerry R. Nelson, PhD, Nelson Laboratories Inc.
Patrick Polito, Moog Medical Devices
Karen Polkinghorne, Dupont Protection Technologies
Shaundrea L. Rechsteiner, NAMSA
Mike Sadowski, Baxter Healthcare Corporation
Craig A. Wallace, 3M Healthcare

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

## Background of ANSI/AAMI adoption of ISO 15883-2:2006

As indicated in the foreword to the main body of this document (page xvii), the International Organization for Standardization (ISO) is a worldwide federation of national standards bodies. The United States is one of the ISO members that took an active role in the development of this standard, which was developed by ISO Technical Committee 198, *Sterilization of health care products*, to fill a need for guidance regarding performance requirements for cleaning and disinfection by washer-disinfectors (WD) as well as for the accessories which can be required to achieve the necessary performance.

U.S. participation in this ISO TC is organized through the AAMI Sterilization Standards Committee which serves as the U.S. Technical Advisory Group for ISO/TC 198. Association for the Advancement of Medical Instrumentation (AAMI) ST/WG 13, *Washer disinfectors*, serves as the U.S. sub-TAG for the relevant ISO working group and supports the adoption of ISO 15883-2:2006 with substantive national deviations provided in this document for washer disinfectors.

The major differences between ANSI/AAMI ST15883-2:2013 and ISO 15883-2:2006 are the removal of $A_0$ as a means of evaluating the cleaning efficacy of thermal disinfection and the removal of user requirements.

ANSI/AAMI ST15883-2:2013 was approved by the American National Standards Institute (ANSI) on 09 January 2013.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

AAMI (and ANSI) have adopted other ISO standards. See the Glossary of Equivalent Standards for a list of ISO standards adopted by AAMI, which gives the corresponding U.S. designation and the level of equivalency with the ISO standard.

As used within the context of this document, “shall” indicates requirements strictly to be followed to conform to the recommended practice. “Should” indicates that among several possibilities, one is recommended as particularly suitable, without mentioning or excluding others, or that a certain course of action is preferred but not necessarily required, or that (in the negative form) a certain possibility or course of action should be avoided but is not prohibited. “May” is used to indicate that a course of action is permissible within the limits of the recommended practice. “Can” is used as a statement of possibility and capability. Finally, “must” is used only to describe “unavoidable” situations, including those mandated by government regulation.

The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data come to light.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

 © 2013 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST15883-2:2013

# U.S Deviations to ISO 15883-2:2006

As part of an effort to harmonize sterilization standards throughout an increasing global industry, the AAMI Washer-disinfectors Work Group voted in 200x to adopt ISO 15883-2:2006, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.* The AAMI Washer-disinfector Working Group also agreed that a number of U.S. deviations to the ISO standard would improve the document.

Deviations are listed below. A rationale for each change has also been provided by the working group. Within the document, deletions are indicated by ~~strikethrough~~ and additions are indicated by underline.

**Introduction**

1. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

2. 2nd, 3rd, and 4th paragraph: ISO 15883 replaced by AAMI/ST15883.

*Rationale*: AAMI/ST15883 is the harmonized U.S. standard.

3. 5th paragraph, 1st sentence: Word “the” deleted.

*Rationale*: Modified for appropriate English.

4. 6th paragraph: User requirements deleted.

*Rationale:* Suggestions for purchasers/users are not appropriate for the U.S. version of this standard.

5. 6th paragraph: Reference to ANSI/AAMI ST81:2004 added.

Rationale: ANSI/AAMI ST81:2004 is an appropriate U.S. standard.

6. 7th paragraph: Reference updated to IEC 61010-2-040.

*Rationale*: IEC 61010-2-045 was superseded by IEC 61010-2-040.

7. 8th paragraph: New text referencing AAMI TIR34.

*Rationale*: AAMI TIR34 is the appropriate U.S. reference.

8. 8th paragraph deleted: Reference to European water quality deleted.

*Rationale:* Reference to European water quality issues or standards are not appropriate for the U.S. version of this standard.

**Scope**

9. 1st, 2nd, 3rd paragraph: ISO 15883 replaced by AAMI ST15883

*Rational*: AAMI ST15883-1 is the harmonized U.S. series.

10. 2nd paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**Normative references**

11. ANSI/AAMI ST15883-1:2009 added and ISO 15883-1:2006 deleted.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

12. ANSI/AAMI ST81:2004 added.
*Rationale*: ANSI/AAMI ST81 is an appropriate U.S. standard.

13. AAMI TIR12:2010 added.
*Rationale*: AAMI TIR12 is the appropriate U.S. guideline.

14. ANSI/AAMI ST15883-1:2009/Amendment 1 added.
*Rationale*: The amendment contains definitions that apply.

15. AAMI TIR30:2011 added.
*Rationale*: AAMI TIR30 is an appropriate U.S. guideline.

**Terms and definitions**

16. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

17. 1st paragraph: ANSI/AAMI ST15883-1:2009/Amendment 1 added
*Rationale*: The amendment contains definitions that apply.

18. 3.1 $A_0$ deleted.
*Rationale:* There is not sufficient peer-reviewed literature on $A_0$ for inclusion in this edition.

19. 3.2 / 3.3 Text regarding cleaning instruction deleted.
*Rationale*: Cleaning instructions are design specific and should not be included in the definition.

20. New definitions added for high-level, intermediate-level, and low-level disinfection.
Rationale: Definitions added to establish disinfection levels for U.S. version of this standard to replace $A_0$ values.

**4.1.1**

21. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**4.1.2**

22. Add additional reference to ANSI/AAMI ST81.

*Rationale*: ANSI/AAMI ST81 is an appropriate U.S. standard.

23. Add additional reference to AAMI/TIR12.
*Rationale*: AAMI/TIR12 is the appropriate U.S. guideline.

**4.1.5**

24. 1st sentence: Change “lumen” to “lumened”.
*Rationale*: “Lumened” is the correct word to use.

**4.1.6**

25. Reference deleted.
*Rationale*: Reference deleted for clarity.

**4.1.7**.

26. Text regarding pass-through type WDs moved from section 5.2.3 and reference added to ANSI/AAMI ST15883-1 section on control of doors.

*Rationale*: This is a more appropriate section for the text to appear in.

**4.2.1**

27. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

28. 1st paragraph: AAMI TIR30 added as an additional reference.

*Rationale*: AAMI TIR30 is an appropriate U.S. reference.

**4.2.2**

29. 2nd bullet point: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**4.3.1**

30. Reference to $A_0$ deleted and intermediate-level disinfection substituted.

*Rationale*: There is not sufficient peer-reviewed literature on $A_0$ for inclusion in this edition.

**4.3.2**

31. Reference to $A_0$ deleted and intermediate-level disinfection substituted.

*Rationale*: There is not sufficient peer-reviewed literature on $A_0$ for inclusion in this edition.

**4.3.3**

32. Reference to $A_0$ deleted and claimed level of disinfection substituted.

*Rationale*: There is not sufficient peer-reviewed literature on $A_0$ for inclusion in this edition.

**4.3.3 NOTE**

33. Delete reference to $A_0$ in note as well as last bullet point and sentence. Substitute "the level of disinfection" where "$A_0$ and the disinfection temperature" appears.

*Rationale*: There is not sufficient peer-reviewed literature on $A_0$ for inclusion in this edition.

**4.3.4**

34. 2nd paragraph: ISO 15883 replaced by AAMI/ST15883.

*Rationale*: AAMI/ST15883 is the harmonized U.S. standard.

**5.1.1**

35. New note added.

*Rationale*: Note raises the issue of the potential impacts of the cleaning process.

**5.1.2.1 a) 1)**

36. Last sentence of 1) deleted.

*Rationale:* Suggestions for users/purchasers are not appropriate for the U.S. edition of this standard.

**5.2.2**

37. Note added.

*Rationale*: Added text clarifies that temperatures may need to be adjusted for specific operating conditions.

**5.2.3**

38. 2nd paragraph: Text moved to new 4.1.7.

*Rationale*: Text is more appropriate in new clause 4.1.7.

**5.3**

39. ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**6.1**

40. 1st paragraph and NOTE: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**6.2**

41. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

42. 1st paragraph: AAMI TIR30 added as an additional reference.

*Rationale*: AAMI TIR30 is the appropriate U.S. reference.

**6.2 NOTE 1 and NOTE 2**

43. Notes deleted.

*Rationale:* Suggestions for users/purchasers are not appropriate for the U.S. edition of this standard.

**6.3.1**

44. ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

**6.3.2.1**

45. ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

*Rationale:* ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

46. 'Testing' substituted by 'qualification'.

*Rationale*: Wording clarification.

**6.3.2.2**

47. 1st bullet point: text added.

*Rationale*: Enables users of the document to employ an equivalent standard to ISO 4017.

**Clause 7**

48. Reference to ANSI/AAMI ST15883-1:2009 Clause 8 deleted.

*Rationale:* Clause 8 was deleted in the U.S. edition.

**Clause 8**

49. Clause deleted.

*Rationale*: This was a list of recommendations which were not required and therefore do not belong in the standard. The standard should address the types of information that the manufacturer is required to provide, not that the user is recommended to provide.

**Bibliography**

50. Reference [1] updated to reflect current edition.

*Rationale*: IEC 61010-2-045 was superseded by IEC 61010-2-040.

# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-2 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

— *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical specification]

— *Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

# Introduction

It is recommended that this Introduction be read in conjunction with the introduction to ~~ISO~~ANSI/AAMI ST15883-1.

This part of ~~ISO~~ AAMI ST15883 is the second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for cleaning and thermal disinfection of medical devices intended for re-use such as:

— surgical instruments;

— powered devices;

— instrument trays;

— instruments for minimally invasive surgery;

— lumen devices and tubing;

— rigid endoscopes;

— anesthetic and respiratory equipment;

— bowls, dishes and receivers;

— glassware;

— containers for transit.

Fields of application within the scope of the ~~ISO~~ AAMI ST15883 series of standards include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for washer-disinfectors for other applications are specified in other parts of the ~~ISO~~ AAMI ST15883 series of standards.

When processed in the instrument washer-disinfector, ~~the~~ medical devices might be intended for immediate use or might be intended for packing and sterilization. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not unduly challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. ~~Users should be aware that s~~Some medical devices might require pre-treatment e.g. soaking, brushing, ultrasonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical manufacturer's instructions for reprocessing (see also ISO 17664 or ANSI/AAMI ST81).

Safety requirements for washer-disinfectors are given in IEC 61010-2-040~~5~~.

Requirements for the quality of water employed to process surgical instruments and related devices are found in AAMI TIR34.

~~In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:~~

~~a) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;~~

b) ~~the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.~~

 © 2013 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST15883-2:2013

# Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.

## 1 Scope

This part of ~~ISO 15883~~ AAMI ST15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anesthetic equipment, bowls, dishes and receivers, utensils and glassware.

NOTE 1 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The requirements specified in this part of ~~ISO 15883~~ AAMI ST15883 are applicable in conjunction with the general requirements specified in ~~ISO 15883-1~~ ANSI/AAMI ST15883-1.

The specified performance requirements of this part of ~~ISO 15883~~ AAMI ST15883 may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 2 If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4017, *Hexagon head screws — Product grades A and B*

ASTM F593, *Standard Specification for Stainless Steel Bolts, Hex Cap Screws, and Studs*

ISO 5356-2, *Anesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anesthetic reservoir bags*

ISO 5367, *Breathing tubes intended for use with anesthetic apparatus and ventilators*

ANSI/AAMI ST15883-1:2009, *Washer-disinfectors — Part 1: General requirements, definitions and tests*