American National Standard

ANSI/AAMI ST15883-2: 2013/(R)2023

(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 Health Technology

American National Standard **ANSI/AAMI ST15883-2:2013/(R)2023**
(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 and reaffirmed 23 November 2015 and 3 April 2023 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

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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:

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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.

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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, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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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*

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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.~~

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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*