American National Standard

ANSI/AAMI ST15883-3: 2012/(R)2023

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

AAMI
Advancing Safety in Health Technology

American National Standard **ANSI/AAMI ST15883-3:2012/(R)2023**
(ISO 15883-3:2006, MOD)

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

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Association for the Advancement of Medical Instrumentation

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Abstract: This document specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

Keywords: ISO 15883-3

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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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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 15883-3:2006

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 15883-3:2006 with substantive national deviations provided in this document for washer disinfectors.

The major differences between ANSI/AAMI ST15883-3:2012 and ISO 15883-3:2006 are the removal of A_0 as a means of evaluating the cleaning efficacy of thermal disinfection and the deletion of the clause that specifies information that a manufacturer must request from the purchaser.

ANSI/AAMI ST15883-3:2012 was approved by the American National Standards Institute (ANSI) on 10 December 2012.

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 15883-3:2006

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 15883-3:2006, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers.* 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 <u>underline</u>.

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. 6th paragraph: User requirements deleted.

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

4. 7th paragraph: Reference updated to IEC 61010-2-040.

Rationale: IEC 61010-2-045 was superseded by IEC 61010-2-040.

5. 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

6. 1st paragraph: ISO 15883 replaced by AAMI ST15883

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

7. 2nd paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

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

Normative references

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

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

9. ANSI/AAMI ST15883-1:2009/Amendment 1 added.

Rationale: The amendment contains definitions that apply.

10. AAMI TIR30:2011 added.

Rationale: AAMI TIR30 is an appropriate U.S. guideline.

Terms and definitions

11. 1st paragraph: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

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

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

4.1.1
13. 1st paragraph and 9th bullet point: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
Rationale: ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

4.2.1
14. The phrase "when specified by the purchaser" deleted.
Rationale: Requirements for purchasers/users are not appropriate for the U.S. edition of this standard.

4.3.1
15. First sentence deleted.
Rationale: Requirements for purchasers/users are not appropriate for the U.S. edition of this standard.

4.5.1
16. Reference to A_0 deleted and new text added regarding disinfection level claimed.
Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

4.5.2
17. ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
Rationale: ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

18. Reference to A_0 deleted in first and second paragraph. “disinfection levels” substituted in second paragraph.
Rationale: There is not sufficient peer-reviewed literature on A_0 for inclusion in this edition.

4.5.3
19. Sentence modified for clarity.
Rationale: The temperature range is stated more clearly.

4.5.4
20. Sentence modified for clarity.
Rationale: The temperature range is stated more clearly.

4.6
21. ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
Rationale: ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

22. NOTE converted to normative text.
Rationale: This is an important piece of information that should not be a note.

5.1.1
23. 1st and 2nd sentence: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.
Rationale: ANSI/AAMI ST15883-1 is the harmonized U.S. standard.

5.1.2
24. 1st sentence deleted and 2nd sentence modified.
Rationale: Requirements for purchasers/users are not appropriate for the U.S. edition of this standard.

5.2.2

25. NOTE 2 added.

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

5.2.3

26. Reference to A_0 deleted.

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

5.4

27. ISO 15883-1 replaced by ANSI/AAMI ST15883-1 twice.

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

6.1

28. 1st sentence and NOTE: ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

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

6.6

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

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

30. 1st paragraph: AAMI TIR30 added as an additional reference.

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

31. NOTE 1 and NOTE 2 deleted.

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

Clause 7

32. 1st sentence and f): ISO 15883-1 replaced by ANSI/AAMI ST15883-1.

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

Clause 8

33. 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.

Table A.1

34. User recommendations deleted.

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

Annex B

35. 'grammage' changed to 'weight'

Rationale: Editorial change to American English.

Bibliography

36. 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 15883-3 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 15883-1~~ ANSI/AAMI ST15883-1.

This part of ~~ISO~~ AAMI ST15883 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bedpan washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for emptying, flushing, cleaning and thermally disinfecting human waste containers intended for re-use such as:

— portable sanitary pans;

— supports for single-use bed pans;

— hospital bowls;

— urine bottles;

— suction bottles; and

— products similar to the above and used for similar purposes.

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 the ~~ISO~~ AAMI ST15883 series of standards.

Bedpan washer disinfectors are loaded manually. In order to reduce the risk of spillage and the generation of aerosols most machines incorporate means to empty human waste containers automatically e.g. by the action of closing the door.

Where equipment does not provide automatic emptying facilities, extra care is needed ~~by the user~~ to avoid exposure to human waste and contamination of the work environment including the generation of aerosols.

The reliability of a bedpan washer-disinfector may be adversely affected if the machine is connected to a poorly designed or constructed drainage system. ~~The purchaser is therefore recommended to ensure that the drainage system complies with the manufacturer's recommendations in all respects.~~

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

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

~~a) note 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) ~~this part of ISO 15883 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.~~

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

1 Scope

This part of ~~ISO~~ AAMI ST15883 specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

This part of ISO 15883 is to be applied in conjunction with ~~ISO 15883-1~~ ANSI/AAMI ST15883-1.

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.

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

ANSI/AAMI ST15883-1:2009/A1, *Washer-disinfectors — Part 1: General requirements, definitions and tests, Amendment 1*

~~ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, definitions and tests*~~

ISO/TS 15883-5, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

AAMI TIR30:2011, *A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ~~ISO 15883-1~~ ANSI/AAMI ST15883-1 and the following apply.

~~**3.1**~~
~~A_0~~
~~equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K~~

~~[ISO 15883-1:2006, definition 3.1]~~

~~NOTE See also ISO 15883-1:2006, Annex B.~~

3.2
emptying
discharging the contents of a container by gravity