American National Standard

ANSI/AAMI ST15883-3: 2012/(R)2015

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

AAMI
Advancing Safety in Healthcare 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:

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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.

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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 ST15883-3:2012/(R)2015**
(ISO 15883-3:2006, MOD)

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

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

Approved 10 December 2012 and reaffirmed 23 November 2015 by
American National Standards Institute, Inc.

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

AAMI Standard

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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 15883-3:2006

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, 4301 N. Fairfax Drive, Suite 301, Arlington, VA 22203-1633.

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 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. 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*

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

3.3
human waste
excretions and body fluids including feces, urine, blood, pus, vomit and mucus

3.4
human waste container
re-usable vessel for holding and transporting human waste

4 Performance requirements

4.1 General

4.1.1 The requirements of ~~ISO 15883-1~~ ANSI/AAMI ST15883-1 apply with the exception of its

— subclause 4.3.2 (which refers to chemical disinfection, see Scope of this part of ISO 15883);

— subclause 4.3.3 (which refers to the maximum range of temperatures permitted on the load items, see 4.1.4 of this part of ISO 15883);

— subclause 5.3.1.2 (which refers to the use of a machine purging and disinfection);

— subclause 5.7.4 (which refers to verification of the dose of process chemical admitted);

— subclause 5.7.5 (which specifies the accuracy and reproducibility of chemical dosing systems);

— subclause 5.8 (which refers to load temperature protection);

— subclause 5.9 (which refers to control of temperatures on the load and chamber walls, see 4.5.3 and 4.5.4 of this part of ISO 15883);

— subclause 6.8.5 (which refers to tests for load temperature protection);

— subclause 6.10.3.2 (which refers to protein residue tests, see also ~~ISO 15883-1~~ ANSI/AAMI ST15883-1, Table A.1 (load, 6.10.3) and Annex A of this part of ISO 15883).

4.1.2 The WD shall be designed to process either one type of human waste container or a variety of types of human waste container and the re-usable supports for single-use bedpans.

NOTE This can require the use of two or more types of load carrier.

4.1.3 The WD shall be designed to process either one human waste container per cycle, or several human waste containers per cycle.

4.1.4 The temperature attained on the surfaces of the load during the disinfection stage shall not be less than the disinfection temperature.

4.2 Chemical dosing systems

4.2.1 Provision shall be made for the installation of a chemical dosing system, ~~when specified by the purchaser,~~ to allow for the injection of a descalant, detergent and/or rinse aid.

4.2.2 The means to control the volume of additive(s) admitted shall be adjustable and shall deliver the set volume to an accuracy of ± 10 % or better.

4.2.3 The WD shall either be fitted with means to ensure that a fault is indicated when insufficient process chemical(s) has/have been admitted, or it shall be possible for the operator to visually verify that the required amount of process chemical(s) has/have been used.

4.3 Emptying

4.3.1 ~~The manufacturer shall require the purchaser to specify whether the containers are required to be emptied manually or automatically.~~

Manual emptying of containers should be avoided whenever possible.

4.3.2 When the container(s) are to be emptied automatically the emptying system shall ensure that there is no spillage of the container contents or discharge of aerosols of the contents of containers during automatic emptying.

Check for compliance in accordance with 6.5.1.

4.3.3 When the container(s) are to be emptied manually into the WD the door aperture and load support system shall be designed to enable the container to be emptied and then located in the load carrier without spillage or splashing.

Check for compliance in accordance with 6.5.2.

4.4 Cleaning

4.4.1 Flushing

The containers shall be flushed with sufficient water to remove the gross soiling.

NOTE The water used to flush the containers can be discharged without recirculation or be recirculated during a single flushing stage within one process cycle.

4.4.2 Washing

The containers shall be washed on both their inner and outer surfaces.

NOTE The water used to wash the containers can be discharged without recirculation or be recirculated during a single washing stage within one process cycle.

4.4.3 Test requirements

The cleaning process shall meet the requirements of the test specified in 6.6.

4.5 Disinfecting

4.5.1 Thermal disinfection shall be deemed to have been attained when all surfaces to be disinfected have been subjected to a process <u>that has been demonstrated to provide the disinfection level claimed by the manufacturer.</u> ~~providing an A_0 of at least 60.~~

4.5.2 When tested by the method specified in ~~ISO 15883-1~~ <u>ANSI/AAMI ST15883-1</u>, 6.8.2, 6.8.3 and 6.8.4, the surface temperatures and times shall provide ~~the specified A_0 values.~~ <u>the appropriate disinfection level.</u>

Different ~~A_0 values~~ disinfection levels may be specified for the inner surface of the human waste container, the outer surfaces of the human waste container and the walls of the WD chamber.

4.5.3 The temperature on the surface of the load shall be no less than the disinfection set temperature and no more than 15°C greater than the set temperature throughout the time specified for disinfection. ~~within 0 °C to 15 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time–temperature relationship.~~

4.5.4 The temperature recorded on the surface of the chamber wall shall be no less than the disinfection set temperature and no more than 15°C greater than the set temperature throughout the time specified for disinfection. ~~within 0 °C to 15 °C of the set temperature throughout the time specified for disinfection when this has been specified as a time–temperature relationship.~~

4.6 Rinsing

See ~~ISO 15883-1~~ ANSI/AAMI ST15883-1, 4.4.

~~NOTE~~ Rinsing can take place before, or simultaneously with, the disinfecting stage.

4.7 Drying

The provision of a separate drying stage within the operating cycle shall be optional.

5 Mechanical and control requirements

5.1 Instrumentation and control

5.1.1 The WD shall either be fitted with a display showing chamber temperature [see ~~ISO 15883-1~~ ANSI/AAMI ST15883-1, 5.11.4 a)] or an indicating light to show attainment of a pre-set disinfection temperature. The sensor shall be located as specified in ~~ISO 15883-1~~ ANSI/AAMI ST15883-1, 5.12.6.

5.1.2 ~~Provision shall be made for the installation of a temperature recorder when specified by the purchaser. When~~ If a temperature recorder is fitted this shall be deemed to meet the requirements of 5.1.1.

5.2 Process

5.2.1 The inner surfaces of the chamber shall be cleaned and disinfected during the process.

5.2.2 Means shall be provided to pre-set the disinfection temperature and time over a specified range. The range shall be either between 65 °C and 95 °C for 1 s to 1 h or over the range 75 °C to 95 C for 1 s to 5 min. Adjustment shall be by means of a code, key or tool.

NOTE 1 The facility to adjust the pre-set time and temperature over the ranges specified is to allow for disinfection for short time periods at high temperature or, to obtain equivalent effect, prolonged times at lower temperatures; this can be required for processing containers which will not withstand higher temperatures.

NOTE 2 The manufacturer might need to adjust the minimum temperature for the specific operating characteristics of the installation location (e.g., high altitude location).

5.2.3 The combination of disinfection time and disinfection temperature shall be set to achieve the specified ~~A_0 value~~ disinfection level.