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Washer-disinfectors —

Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment

Laveurs désinfecteurs —

Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant une désinfection thermique pour les dispositifs médicaux non invasifs, non critiques et pour l'équipement de soins de santé

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/ TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-6:2011), which has been technically revised.

The main changes are as follows:

— change of title to reflect application to non-critical medical devices;

— addition of new terms defining critical and semi-critical medical devices, and non-critical devices;

— alignment of other terms and definitions with ISO 11139:2018+Amd 1:2024;

— revision of cross-references to relevant clauses in ISO 15883-1 and ISO 15883-5;

— the temperatures recorded on the surface of the load, load carrier(s) and chamber walls follow the temperature profile specified for the disinfection stage and are within 0 °C and +10 °C as specified in 4.3.4;

— cleaning testing carried out in triplicate in accordance with ISO 15883-1 using the appropriate test method(s) and test soil(s) as specified in ISO 15883-5;

— addition of water quality specified in 4.4;

— updating of Bibliography.

A list of all parts in the ISO 15883 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document is the sixth part of the ISO 15883 series of standards specifying the general requirements and performance of washer-disinfectors (WD). The requirements given in this document apply to WD used for cleaning and thermal disinfection of non-critical medical devices (i.e. not penetrating skin or contacting mucosal membranes) and for other items for use without further treatment in healthcare settings. Such reusable equipment is cleaned and disinfected, but processing in a WD for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3), for endoscopes (see ISO 15883-4), or for non-critical thermolabile medical devices and health care equipment (see ISO 15883-7) is inappropriate or impractical.

Some examples include

— non-critical medical devices (e.g. laryngoscope handles);

— washbowls;

— cleaning equipment (buckets);

— footwear;

— container systems used to transport medical devices, including trolleys and transport carts;

— bed frames, wheelchairs, aids for the disabled.

Fields of application within the scope of the ISO 15883 series can include laboratory, veterinary and dental use, and other specific applications such as washer-disinfectors for 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 ISO 15883.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection stage. It is desirable that manufacturers of washer-disinfectors be very clear about the items that can be processed in the washer-disinfector, and that reference be made to the instructions for reprocessing provided in the instructions for use of the items to be processed.

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

Guidance for the quality of water for use in a WD is given in ISO /TS 5111.

NOTE Local or national regulations can apply in respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the WD and its intended use.

Washer-disinfectors —

Part 6:
Requirements and tests for washer-disinfectors employing thermal disinfection for noncritical medical devices and health care equipment

WARNING — Devices identified within the scope of ISO 15883-2, ISO 15883-3, ISO 15883-4 and ISO 15883-7 shall not be processed in washer-disinfectors specified in this part of ISO 15883. Examples of medical devices that are not to be processed in these washer-disinfectors include powered devices, lumened devices and other semi-critical and critical medical devices.

1 Scope

This document specifies particular requirements for washer-disinfectors (WD) intended for use when the level of assurance of disinfection that is necessary can be achieved by cleaning and thermal disinfection (A_0 not less than 60) and does not require an independent automated record of critical processes to be kept. It is intended to be used in conjunction with ISO 15883-1, which specifies general requirements for WD.

The range of products on which WD of this particular type can be used is restricted to devices and equipment which are non-invasive and non-critical (i.e. not penetrating skin or contacting mucosal surfaces).

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 15883-1:2024, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 15883-5, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
critical medical device
<washer-disinfector> item processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical medical devices will usually require sterilization before use.

Note 2 to entry: National regulations can use alternative wording for this term.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.333]

3.2
non-invasive device
device that does not penetrate inside the body, either through a body orifice or through the surface of the body

[SOURCE: ISO 11139:2018, 3.184]

3.3
non-critical device
<washer-disinfector> item processed in a washer-disinfector, whose surface(s) are intended to contact intact skin of a body but do not penetrate it, or device not intended for direct patient contact

EXAMPLE Blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, containers for transit.

Note 1 to entry: National regulations can use alternative wording for the definition for this term when applied to medical devices.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.357]

3.4
semi-critical medical device
<washer-disinfector> item processed in a washer-disinfector, that, during use, contacts mucous membranes or non-intact skin of a body

EXAMPLE Some probes, some respiratory therapy equipment.

Note 1 to entry: National regulations can use alternative wording for this term.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.369]

3.5
washing temperature
minimum temperature of the washing temperature band

[SOURCE: ISO 11139:2018, 3.322]

3.6
washing time
period for which the cycle variables are maintained within the values specified for washing.

EXAMPLE Temperature of the load, detergent concentration in the chamber.

[SOURCE: ISO 11139:2018, 3.323, modified – Example has been added]

3.7
worst-case
set of conditions, as compared with ideal conditions, justified to pose the highest probability of process or product failure.

Note 1 to entry: The set of conditions do not necessarily induce product or process failure.

Note 2 to entry: The set of conditions should be specified within the limitations of the intended use.

Note 3 to entry: The set of conditions should encompass upper and lower processing limits and circumstances.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.376]

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1 apply, with the exception of the following subclauses of ISO 15883-1:2024:

— ISO 15883-1:2024, 4.3.2 (which refers to chemical disinfection; see Clause 1 of this document);

— ISO 15883-1:2024, 5.7.4 (which refers to verification of the dose admitted);

— ISO 15883-1:2024, 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.5 of this document);

— ISO 15883-1:2024, 5.7.6 (which refers to indication of sufficient process chemical);

— ISO 15883-1:2024, 5.9 (which refers to control of temperatures on the load and chamber walls).

4.1.2 The WD shall be designed to clean and thermally disinfect the range of reusable items specified by the WD manufacturer.

4.1.3 The items shall be cleaned and disinfected on all surfaces which can, in normal use and handling, come into contact with patients or staff.

4.1.4 When necessary, the WD shall be provided with means to facilitate the correct alignment of the load in the washing chamber.

4.1.5 The means to control the volume of the process chemical(s) admitted shall be adjustable by means of an access device. The accuracy of the dosing system shall be ±10 % or better.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with ISO 15883-1:2024, using test soils and acceptance criteria in accordance with ISO 15883-5.

4.2.2 During the washing stage

a) the washing time shall start when the temperature at the control sensor of the WD is not less than the specified washing temperature and when the specified dosing of the relevant process chemicals has been achieved;

b) the temperatures recorded on the surface of the load and load carrier(s) for all the washing stages are within 0 °C to +10 °C of the relevant set temperature profile for this stage;

c) throughout the washing time, the temperatures on any surface of the load, chamber walls, chamber drain and the load carrier(s) shall

   1. be within the washing temperature band;

   2. not differ from one another by more than 5 °C.

NOTE A washing stage can include two or more washing temperatures and washing temperature bands.

4.3 Disinfecting

4.3.1 The operating cycle shall include a thermal disinfection stage for which the time at which the load is maintained at the disinfection temperature gives an A_0 of at least 60 on all surfaces of the load to be disinfected when tested in accordance with ISO 15883-1:2024, 6.8 (see also ISO 15883-1:2024, Table B.1).

NOTE For further information on the A_0 concept, see ISO 15883-1:2024, Annex B and Kremer et al[9].

4.3.2 The operating cycle shall include a thermal disinfection stage giving an A_0 of at least 60 on all the internal surfaces of the chamber and on the load carrier(s) when tested in accordance with ISO 15883-1:2024, 6.8 (see also ISO 15883-1:2024, Table B.1).

4.3.3 The WD shall provide for disinfection times and temperatures to achieve an A_0 value between 60 and 600.

NOTE 1 The choice of A_0 and disinfection temperature can depend upon:

a) the intended use of the load items;

b) the materials of which the load items are made;

c) the nature and extent of the bioburden on the load items with particular reference to heat resistant infective organisms.

NOTE 2 For further information on the A_0 concept, see ISO-15883-1:2024, Annex B and Kremer et al[9].

NOTE 3 Local personnel responsible for infection prevention and control can provide advice on the selection of appropriate A_0.

4.3.4 The temperatures recorded on the surface of the load, load carrier(s) and chamber walls follow the temperature profile specified for the disinfection stage and are within 0 °C and +10 °C of the set disinfection temperature for each specific disinfection temperature.

4.4 Water quality

The quality of water required for each processing stage shall be specified. The choice of water quality shall ensure appropriate processing of the devices suitable for their specified intended use.

NOTE 1 For specific application, or for optimizing the process, specific grades of purified water are recommended depending on the resulting risk.

NOTE 2 See ISO 15883-1:2024, ISO/TS 5111 and ANSI/AAMI ST108.

NOTE 3 Regional or national regulations or guidelines can apply.

5 Mechanical and control requirements

5.1 Control systems

5.1.1 Means shall be provided to pre-set the washing temperature over a range between room temperature and at least 60 °C. Adjustment shall be by means of an access device.

5.1.2 Either the WD shall be provided with a system to indicate when there is insufficient process chemical available for the next cycle or the supply shall be visible to the operator in order to permit manual verification that sufficient process chemical is present.

5.1.3 Either the WD shall be fitted with means to ensure that a fault is indicated when insufficient process chemical has been admitted or it shall be possible for the operator to visually verify that the required amount of process chemical has been used.

5.1.4 Means shall be provided to pre-set the disinfection temperature over a range between 70 °C (see ISO 15883-1:2024, Annex B) and an upper limit. The upper limit shall not be less than 90 C. Adjustment shall be by means of an access device.

5.1.5 Means shall be provided to pre-set the disinfection time over the range from 1 min to at least 60 min. Adjustment shall be by means of an access device.

5.2 Process verification

The WD shall be equipped with a means to visibly display the temperature attained in the chamber or the load or a means to visibly display that the required temperature has been attained. This means shall be independent from the controller in order to provide verification of achievement of the programmed cleaning and disinfection temperatures [see ISO-15883-1:2024, 5.11.4 a)].

NOTE A process verification system in accordance with ISO 15883-1:2024, 5.11.4 b) can also meet these requirements.

6 Testing for conformity

6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1:2024. See also Annex A of this document.

6.2 Tests for soil removal from chamber walls, load carrier(s) and load

The tests shall be carried out in triplicate in accordance with ISO 15883-1:2024, 6.10 using the appropriate test method(s), worst case conditions and test soil(s) as specified in ISO 15883-5 taking into consideration the corresponding category of the load.

NOTE 1 Local requirement can require the use of particular test soils and methods.

NOTE 2 The user's choice of test soil(s) and method(s) for operational testing can indicate a need to carry out similar testing before the WD is supplied.

The test soils used for the load, chamber wall and load carrier(s) could be different. If different test soils are used, then the rationale for the choice of test soil shall be documented.

6.3 Thermometric tests

These tests shall be performed in accordance with ISO-15883-1:2024, 6.8 with the reference load modified as follows.

a) The reference loads used shall be made up of a full load of items that the WD is intended to process.

b) The items chosen shall be those with the greatest mass, highest specific heat, and lowest thermal conductivity.

7 Information to be supplied

In addition to the information specified in ISO-15883-1:2024, Clause 8, the following information shall be provided to the purchaser:

a) range of load supports available and required;

b) the following, obtained by testing in accordance with 6.3:

1. the time for an operating cycle from a cold start;
2. the time for an operating cycle from a hot start;
3. the locations and temperatures of the coolest and hottest parts of the load during thermal disinfection.

8 Information to be requested from the purchaser by the supplier of the WD

In addition to the information specified in ISO-15883-1:2024, Clause 10, the following information shall be requested from the purchaser by the supplier of the WD:

a) the nature of the devices that it is intended to process;

b) the A_0 value, or the combination of time and temperature, to be attained for thermal disinfection.

If the A_0 value has not been specified by the purchaser, see 4.3.

Annex A
(informative)

Summary of test programmes

Table A.1 summarizes the recommended test programmes applicable to WD specified in document additional to those recommended in ISO-15883-1:2024, Table A.1. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational test	Performance test	Routine test
Load temperature test	4.3	6.3	X	X	X	X	O

X Recommended.

O Optional test which can be requested by the purchaser or user.

Annex ZA
(informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 and application of the edition of the normatively referenced standards as given in Table ZA.2 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be ‘reduced as far as possible’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ’removed or minimized as far as possible’, or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General

Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
5(a)	4.1.3, 4.1.4	Clauses 4.1.3, 4.1.4, only partly covered in respect of reducing the risks related to use error by reducing the risks related to the ergonomic features of the washer-disinfectors (WDs). Aspects related to the environment in which the WD is intended to be used are not covered. Aspects related to manufacturing are not covered.
14.2 (a)	4.1.5, 5.1, 5.2	All selected clauses only partly cover the requirement. Covered in respect of reducing the risks of injury, in connection with WD physical and ergonomic features. Aspects related to the WD manufacturing processes are not covered.
23.4 (k)	7a), 8 a) – 8 b)	Covered in respect of documentation provided for installation and safe operation of the WD.

Table ZA.2 — Applicable Standards to confer presumption of conformity as described in this Annex ZA

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding Europe- an Standard Edition
ISO 15883-1:2024	ISO 15883-1:2024	Washer-disinfectors — Part 1: General requirements, terms and definitions and tests	Not yet available
ISO 15883-5	ISO 15883-5:2021	Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy	EN ISO 15883-5:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 1(12) of Regulation (EU) 2017/745, the following Table ZA.3 details the relevant Essential Health and Safety Requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than the General Safety and Performance Requirements set out in Chapter II of Annex I of Regulation (EU) 2017/745 along with the corresponding clauses of this European Standard.

Table ZA.3, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.3 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 1, item 12, of Regulation (EU) 2017/745)

Essential Health and Safety Requirements of Directive 2006/42/EC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
1.2.1	4.1.4, 4.1.5	The selected clauses 4.1.4 and 4.1.5 are partly covered in respect of reliability of process control systems (here chemical dosing).
1.3.6	4.3.3, 5.1.4, 5.1.5	The selected clauses are covered to pre-set the disinfection temperature and time/A0 value to adapt to different conditions and clause.
1.6.4	5.1.4, 5.1.5	The selected clauses are covered with respect to authorized access for adjustment of parameters

Bibliography

[1] ISO/TS 5111, *Guidance on quality of water for sterilizers, sterilization and washer-disinfectors for health care products*

[2] ISO 11139:2018+Amd 1:2024, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

[3] ISO 15883-2, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices*

[4] ISO 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

[5] ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

[6] ISO 15883-7, *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection of non-critical thermolabile medical devices and healthcare equipment*

[7] IEC 61010-2-040, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

[8] ANSI/AAMI ST108, *Water for the processing of medical devices*

[9] Kremer T., McDonnell G., Mitzel E., Jain N., Hubert H., Roth K., Labrie P., Villela A., Thermal disinfection validation: The relationship between A_0 and microbial reduction. *BI&T.* 2021, **55** (3) pp. 85–90