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Washer-disinfectors —

Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment

Laveurs désinfecteurs —

Partie 7: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des dispositifs médicaux thermosensibles non critiques et des équipements 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 document 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 15883-7:2016), which has been technically revised.

The main changes are as follows:

— deletion of 'non-invasive' from the document title and within clauses;

— incorporation of requirements of and reference to ISO 15883-1:2024 and ISO 15883-5:2021;

— revision of cross-references to relevant clauses in ISO 15883-1:2024 and ISO 15883-5:2021;

— alignment with terms and definitions in ISO 11139:2018 and ISO 11139:2018/Amd1:2024;

— update of Introduction and addition of reference to ISO/TS 5111 on water quality;

— clarification on requirement for reused process chemicals (see 4.2.4 and 6.6.2);

— Annex A changed from normative to informative;

— updated Annex C method description to align with ISO 15883-1:2024 and ISO 15883-4:2018;

— revision of normative references and bibliographic references.

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 seventh part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and the general requirements for performance applicable to instrument WD. The requirements given in this document apply to WD used for cleaning and chemical disinfection of non-critical thermolabile medical devices and health care equipment without further treatment in health care 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 thermal disinfection of non-critical medical devices and health care equipment (see ISO 15883-6), is inappropriate and/or impractical. Examples of the equipment to which this document applies are beds and bedside furniture, trolleys and transport carts, operating tables, footwear, wheelchairs, or aids for people with disabilities.

Requirements for WD for other applications are specified in other parts of ISO 15883.

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

The quality of water to be used in a WD is covered 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 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-critical thermolabile medical devices and health care equipment

1 Scope

This document specifies the requirements for washer-disinfectors (WD) intended to be used for the cleaning and chemical disinfection, in a single operating cycle, of reusable items such as:

a) bed frames;

b) bedside tables;

c) transport carts;

d) containers;

e) surgical tables;

f) sterilization containers;

g) surgical clogs;

h) wheelchairs;

i) aids for persons with disabilities.

This document also specifies the performance requirements for the cleaning and disinfection of the WD and its components and accessories.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO 15883-4, and ISO 15883-6 do not fall within the scope of this document.

In addition, this document specifies the methods for type testing, works testing, validation (installation, operation, and performance qualification on first installation), routine control, and monitoring, as well as requalifications to be carried out periodically and after essential repairs.

NOTE 1 WD covered by this document can also be used for cleaning and chemical disinfection of other thermolabile and reusable devices as recommended in the instructions for use (IFU) for those devices.

NOTE 2 The performance requirements specified in this document cannot ensure the inactivation or removal of the causative agent(s) (prion proteins) of transmissible spongiform encephalopathies.

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 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

ISO 11139:2018/Amd1:2024, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards — Amendment 1: Amended and additional terms and definitions*

ISO 15883-1:2024, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

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

ISO 15883-5:2021, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

ISO 15883-6[1)], *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and health care equipment*

IEC 61010-2-040:2020, *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*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 10088-2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

EN 12353:2021, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 13727:2012+A2:2015, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11139:2018, ISO 11139:2018/Amd1:2024, ISO 15883-1, ISO 15883-4, ISO 15883-5, ISO 15883-6 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
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 of this term when applied to medical devices.

[SOURCE: ISO 11139:2018/Amd1:2024, 3.357]

1) Under revision with a modified title, *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-critical medical devices and health care equipment*. Stage at the time of publication: ISO/DIS 15883-6:2024.

4 Performance requirements

4.1 General

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

— ISO 15883-1:2024, 4.3.1 (which refers to thermal disinfection);

— ISO 15883-1:2024, 5.9 [process temperature control limits, however, ISO 15883-1:2024 5.9 d) and f) do apply];

— ISO 15883-1:2024, 5.11 [process verification, however ISO 15883-1:2024 5.11.4 b) does apply].

4.1.2 The WD shall be designed to clean and chemically disinfect non-critical thermolabile medical devices and health care equipment.

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

4.1.4 The means to control the volume of the process chemical(s) admitted (see ISO 15883-1:2024, 5.7.4 and 5.7.5) shall be adjustable by means of an access device. The accuracy of the dosing system shall be at least ±10 % or as specified and tested for conformity (see 6.6).

4.1.5 The automatic controller shall verify that the final concentration of disinfectant(s) is within specified limits.

NOTE Confirmation of the concentration of disinfectant can include the measurement of the volume of disinfectant and water admitted together with a certificate of conformity from the disinfectant supplier for the concentration of the disinfectant, together with data to support the shelf life, expiry date, etc.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1 using the methods described in ISO 15883-5:2021, Clause 5 that are relevant to the loads to be processed.

4.2.2 During the washing stage:

a) the washing stage starts when the temperature at the control sensor of the WD is not less than the minimum specified washing temperature;

b) the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit not greater than that defined in ISO 15883-1:2024, 4.2.3.

4.2.3 Cleaning efficacy shall be determined in accordance with 6.7.

4.2.4 If the WD is designed to allow the reuse of the cleaning agent on two (2) or more consecutive operating cycles, then care shall be taken to ensure that the efficacy and safety (e.g. accumulation of foreign material, device compatibility) of the cleaning solution is not impaired. This shall include testing in accordance with 6.6.2 and at least the following considerations.

a) Specified methods shall be used to ensure that the cleaning agent has retained the required cleaning efficacy. These methods shall be based on validation studies relevant to the cleaning agent, to determine suitable parameter(s) or indicator(s)/marker(s) that can be monitored. Suitable parameters may include the concentration of the active ingredient and other ingredients that can also affect performance (e.g. pH).

   NOTE Minor changes in formulation of the cleaning agent can have a significant effect on its stability, cleaning efficacy, and other aspects of performance.

b) Recommendations to the user for the maximum period or number of operating cycles for which the cleaning agent may be used. This shall be based on validated experimental data.

c) Where validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall

   — operate an audible and visible alarm and prevent the use of the operating cycle until the cleaning agent is changed, or

   — effect an automatic change of the cleaning agent in the WD.

d) If final rinse water including processing chemicals is to be reused (recycled) for a cleaning stage, absence of negative effects using the defined reuse instructions shall be demonstrated as defined in ISO 15883-1:2024, 4.2 and 4.4.

4.3 Disinfection

4.3.1 The operating cycle shall include a chemical disinfection stage, which may be combined with the cleaning and shall be deemed to have been achieved when testing requirements in 6.8 are met.

4.3.2 The requirements and tests in this document are based on the use of aqueous disinfectant solutions.

NOTE 1 Other systems based on gaseous disinfectants are not excluded. There are equivalent tests for these systems.

The requirements and tests shall include the following considerations.

a) Disinfectant(s) to be used, for which in vitro efficacy has been demonstrated based on relevant published standards. For the purpose of efficacy testing, a validated disinfectant neutralization method shall be used at the end of the disinfection stage of the operating cycle.

   NOTE 2 Demonstration that the disinfectant meets the above requirements can be made employing methods based on relevant published standards or other relevant publications, e.g. EN 13624,[5] EN 13727, EN 14476,[6] EN 14561,[7] EN 14562,[8] EN 14885,[9] AOAC Use dilution test,[10] ASTM E2197 virucidal test,[11] OECD Guideline.[12]

   NOTE 3 The method(s) can be provided with the disinfectant.

b) When tested on surfaces for the minimum exposure time at the minimum concentration and the minimum temperature to be used in the WD, the disinfectant demonstrates the following:

   1) at least a 5 $\log_{10}$ inactivation of vegetative bacteria;

   2) at least a 4 $\log_{10}$ inactivation of yeast-like fungi;

   3) at least a 4 $\log_{10}$ inactivation of enveloped viruses.

   NOTE 4 National regulatory authorities can require higher inactivation values or efficacy against a wider range of microorganisms. In this case, the tests listed in Note 2 can be modified to demonstrate efficacy.

   NOTE 5 Efficacy tests against vegetative bacteria can exclude mycobacteria. See also 8 g).

c) The compatibility of the cleaning and disinfection agents is indicated, including any effect on disinfection efficacy from carryover of cleaning agent.

d) The experimental conditions of tests intended to demonstrate the microbicidal efficacy of the disinfectant in vitro shall reflect the conditions of use of the disinfectant. Thus, when cleaning and disinfection are combined, the disinfectant shall be tested in the presence of applicable interfering substances that shall include soiling typically found in the loads to be processed.

4.3.3 The temperature of the process throughout the disinfection stage shall be monitored to verify that it remains within the specified limits of the disinfectant, and it shall be compatible with the temperature limits for the non-critical device(s) to be processed.

This shall be achieved either by controlling the temperature of the process, or, if the temperature in the WD is not controlled, then operation of the WD is prevented outside the specified disinfectant temperature range.

4.3.4 If the WD is designed to allow the reuse of the disinfectant on two or more consecutive operating cycles, then care shall be taken to ensure that the efficacy and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution is not impaired. This shall include testing in accordance with 6.6.2 and at least the following considerations.

a) The means that shall be used to ensure that the disinfectant has retained the required antimicrobial disinfection efficacy. These means shall be based on validation studies, which are normally available for the disinfectant, to determine suitable parameter(s) or indicator(s)/marker(s) that may be monitored to indicate the antimicrobial efficacy of the disinfectant. Suitable parameters include the concentration of the active ingredient and other ingredients that can also affect performance (e.g. pH, stability).

   NOTE 1 Minor changes in formulation of the disinfectant can have a significant effect on storage life, antimicrobial efficacy, and other aspects of performance.

b) Recommendations to the user for the maximum period or number of operating cycles for which the disinfectant may be used [see also Clause 8 f)]. This shall be based on validated experimental data.

c) When validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall provide an audible indication, or visible indication, or both, and prevent the use of the operating cycle until the disinfectant solution is changed (manually or automatically).

d) Provide a method for the user to monitor the disinfectant using a chemical indicator or other method specific for the disinfectant to show that the disinfectant is at or above the minimum recommended concentration [see also Clause 8 h)].

NOTE 2 The minimum recommended concentration is the lowest concentration of active and other ingredients to meet the label claim of a reusable disinfectant.

4.4 Final rinsing

The water quality used for rinsing after the disinfection stage shall not impair the result of cleaning/disinfection when tested in accordance with 6.3 and ISO 15883-1:2024, 6.10.5.

NOTE 1 WHO definition for potable water, ISO/TS 5111[4] definition of potable water, or national regulatory authorities can be considered.

NOTE 2 A contamination level higher than 100 CFU/ml under the test requirements of ISO 15883-1 can represent a risk.

4.5 Self-disinfection

4.5.1 If ISO 15883-1:2024, 4.7.2 does not apply, a self-disinfection cycle shall be provided so that the WD does not become a focus for contamination of the load, and to provide a means of disinfecting the WD after interventions for maintenance, repairs, or testing (see ISO 15883-1:2024, 4.7.6).

NOTE 1 The self-disinfection process also deals with the situation where the WD has become contaminated. Biofilm can easily develop in the piping used to convey rinse water to the load and can contain microorganisms in a state in which they are highly resistant to disinfection.

Thermal disinfection shall attain a minimum A_0 of 60 and shall be capable to be set to give an A_0 value of 600.