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Washer-disinfectors —

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

Laveurs-désinfecteurs —

Partie 6: Exigences et essais pour les laveurs-désinfecteurs utilisant la désinfection thermique pour les dispositifs médicaux non critiques et les équipements de soins de santé

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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.

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, non-critical devices and worst-case conditions;

— 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;

— revision of the temperature recorded on the surfaces, as specified in 4.3.4;

— addition of reference to ISO 15883-1 and ISO 15883-5 for the cleaning efficacy testing;

— addition of water quality specified in 4.4;

— update 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.

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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 devices or equipment for use without further treatment in health care settings. Such reusable equipment is cleaned and disinfected, but it is inappropriate or impractical to process it in a WD intended 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).

Examples of non-critical medical devices and health care equipment include:

— laryngoscope handles;

— washbowls and bowls;

— cleaning equipment (buckets);

— footwear;

— transport carriers, 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. Manufacturers of washer-disinfectors should be very clear about the devices or equipment 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 devices or equipment 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.

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Washer-disinfectors —

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

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 non-invasive and non-critical devices and equipment (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.

This document does not cover powered devices, lumened devices, and other semi-critical and critical medical devices.

Devices identified within the scopes of ISO 15883-2, ISO 15883-3, ISO 15883-4, and ISO 15883-7 do not fall within the scope of this document.

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/

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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 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 surfaces 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

Note 1 to entry: Typical examples of variables can be the temperature or detergent concentration.

[SOURCE: ISO 11139:2018, 3.323, modified — Note 1 to entry 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.

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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 shall 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; see 5.1.3 of this document);

— 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; see 5.1.2 of this document);

— 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 devices or equipment specified in the instructions for use of the WD.

4.1.3 The devices or equipment 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 chemicals 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, 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 carriers for all the washing stages shall be within 0 °C to +10 °C of the relevant temperature profile for this stage;

c) throughout the washing time, the temperatures on any surface of the load, chamber walls, and the load carriers 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.

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