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Washer-disinfectors —

Part 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

Laveurs désinfecteurs —

Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques

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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 15883-2:2006), which has been technically revised.

The main changes are as follows:

— change of title to reflect application to critical and semi-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 15883-1:2024 and ISO 15883-5:2021;

— the upper limit of the washing temperature band reduced to +5 °C;

— addition of a clause on water quality (see 4.5);

— clarification of requirements for lumen and powered devices (see 5.1);

— addition of informative Annex B providing guidance on assigning a medical device to a product family for cleaning and thermal disinfection processes;

— revision of references in the 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 second part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WDs) and the general requirements for performance applicable to instrument WDs. The requirements given in this document apply to WDs used for cleaning and thermal disinfection of critical and semi-critical medical devices intended for reuse such as:

— surgical instruments, which are divided into instrument product families based on design features, e.g. instruments without hinges, cavities or lumens, with hinges, with sliding shafts, with lumens, microsurgical instruments, and complex instruments (e.g. robotic);

— powered instruments;

— anaesthetic and respiratory equipment;

— medical devices comprising glass components;

— any non-critical devices used in conjunction with critical and semi-critical medical devices.

Requirements for WDs for other applications, such as for processing non-critical devices and thermolabile endoscopes, are specified in other parts of the ISO 15883 series of standards.

When processed in the WD, the medical devices can be intended for immediate use or can be intended for further processing. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well-being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not unduly challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices can require pre-treatment, e.g. soaking, brushing, ultrasonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical device instructions for reprocessing (see also the ISO 17664 series).

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

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 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

1 Scope

This document specifies requirements for washer-disinfectors (WDs) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of reusable critical and semi-critical medical devices, such as surgical instruments, anaesthetic equipment, and any non-critical devices used in conjunction with critical and semi-critical medical devices, such as bowls, dishes and receivers, utensils and glassware.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-1:2024, except those specified in 4.1.1.

NOTE The specified performance requirements of this document cannot ensure the inactivation or removal of the causative agent(s) (prion protein) 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 4017, *Fasteners — Hexagon head screws — Product grades A and B*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic and respiratory equipment — Anaesthetic reservoir bags*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

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

ISO 17664-1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1:2024 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
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code or tool.

[SOURCE: ISO 11139:2018, 3.4]

3.2
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 items 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]

3.3
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 of this term when applied to medical devices.

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

3.4
powered device
<washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air.

EXAMPLE Dental hand pieces, orthopaedic saws, and drills.

[SOURCE: ISO 11139:2018, 3.199]

3.5
product family
group or subgroup of product characterized by similar attributes determined to be equivalent for evaluation and processing purposes

Note 1 to entry: Design characteristics present specific challenges during the washing stage of medical devices in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.218, modified — Note 1 to entry added.]

3.6
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]

3.7
washing temperature
minimum temperature of the washing temperature band

[SOURCE: ISO 11139:2018, 3.322]

3.8
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 added.]

3.9
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 15883-1:2024 apply with the exception of:

— ISO 15883-1:2024, 4.3.2 (which refers to chemical disinfection);

— ISO 15883-1:2024, 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.6).

4.1.2 The WD shall be designed to clean and thermally disinfect specified medical devices that are intended to be reused and are designated as compatible with the WD process cycle [see ISO 15883-1:2024, 8.1 b) 2)]. Processing of medical devices in the WD shall be in accordance with the intended use of the WD and the instructions for processing the device as specified in accordance with ISO 17664-1:2021, Clause 6.

NOTE Some process chemicals or heat can promote fixation of proteinaceous or other soils to the devices to be cleaned and can therefore interfere with the removal of soil.

4.1.3 The medical devices shall be cleaned and disinfected on the outer surfaces, including covered surfaces and crevices, and where necessary for their safe use, safe handling and correct functioning, the inner surfaces. Any necessary dismantling for processing the inner surfaces shall be conducted as specified in accordance with ISO 17664-1:2021, 6.5.

4.1.4 If necessary for the process success or safety of load items, the WD shall be provided with means to facilitate the correct alignment of the load and load carrier(s) in the WD chamber.

4.1.5 In order to process lumen devices or powered devices, the WD shall be provided with the load carrier(s) and necessary connectors that shall be designed to ensure adequate irrigation with process fluids through each device.

4.1.6 The volume of the process chemical(s) that is/are admitted (see ISO 15883-1:2024, 5.7.2, 5.7.4 and 5.7.6) shall be adjustable by means of an access device that shall deliver the set volume to an accuracy of ± 5 % or better.

NOTE The volume of water admitted to the WD chamber can affect the effective concentration of process chemicals.

4.1.7 During any stage of the operating cycle, the process conditions affecting irrigation inside the pipework system shall be maintained above a specified level that is required for an effective cleaning, disinfection and rinsing process for any load configurations [e.g. load, load carrier(s), and if applicable, inside the pipework for connectors].

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2024, 4.2 and the performance requirements and test method criteria specified in ISO 15883-5:2021, Clause 4.

The cleaning process shall also meet the requirements of the test specified in 6.2.

Where applicable, any treatment required prior to cleaning in the WD shall be performed in accordance with the instructions for use for the load in ISO 17664-1:2021, 6.4 and 6.5, or for WD in ISO 15883-1:2024, 8.1 a)].

4.2.2 During the washing stage the following applies:

— the washing time shall start when the temperature at the control sensor of the WD reaches the lower limit of the first specified washing temperature band;

— the temperatures recorded on the surface of the load and load carrier(s) for the washing stage follow the temperature profile defined for this stage and are within +5 °C of the relevant set temperature for each holding time of the stage.

NOTE A washing stage can include two or more washing temperatures.

4.3 Disinfecting

4.3.1 Each 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 600 on all surfaces of the load and load carrier(s) to be disinfected when tested in accordance with 6.3.

NOTE 1 See Kremer et al.[13].

NOTE 2 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The chosen locations of the sensors for thermometric testing shall be appropriate to the load and shall be justified.

4.3.2 The operating cycle shall include a thermal disinfection stage giving an A_0 of at least 600 on all the inner surface of the chamber when tested in accordance with 6.3 and ISO 15883-1:2024, 6.8.3.

4.3.3 The WD shall be capable of being set for disinfection stages that deliver an A_0 of at least 3 000.