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Washer-disinfectors —

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

Laveurs désinfecteurs —

Partie 3: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique de récipients à déjections humaines

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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 15883-3:2006), which has been technically revised.

The main changes are as follows:

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

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

— addition of 4.1.2 listing exemptions from the requirements of ISO 15883-1:2024;

— alignment of text in clauses on cleaning and disinfecting with revised clauses of ISO 15883-2;

— addition of rinsing from former 4.6 to 4.4 and 4.5;

— addition of 4.7;

— 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 third part in the ISO 15883 series of standards specifying the performance of washer-disinfectors (WDs) and the general requirements for performance applicable to WDs for human waste containers. The requirements given in this document apply to WDs used for emptying, flushing, washing, and thermally disinfecting human waste containers intended for reuse such as:

— portable sanitary pans;

— supports for single-use bedpans;

— hospital bowls for containment of human waste;

— urine collection containers;

— suction bottles;

— products similar to the above and used for similar purposes.

Fields of application within the scope of the ISO 15883 series of standards can include laboratory, veterinary, dental and pharmaceutical applications, and other specific applications, such as WDs for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for WDs for other applications are specified in other parts of the ISO 15883 series of standards.

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 WD 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 human waste container WD can 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 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 3:
Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers

1 Scope

This document specifies requirements for washer-disinfectors (WDs) that are intended to be used for emptying, flushing, washing and thermal disinfection of non-critical devices in the form of human waste containers by one operating cycle.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-1:2024, except for those specified in 4.1.1, and with the requirements of ISO 15883-5:2021, except for those specified in 4.1.2.

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

ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices*

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
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]

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, 4.1.13 (which refers to minimum pressure inside the pipework during the washing stage);

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

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

— ISO 15883-1:2024, 5.7.5 (which specifies the accuracy and reproducibility of chemical dosing systems);

— ISO 15883-1:2024, 5.8 (which refers to load temperature protection);

— ISO 15883-1:2024, 5.9 (which refers to control of temperatures on the load and chamber walls, see 4.5.3 and 4.5.4 of this document);

— ISO 15883-1:2024, 5.21 b) (which refers to microprocessor control systems);

— ISO 15883-1:2024, 6.8.5 (which refers to tests for load temperature protection);

— ISO 15883-1:2024, 6.10.3 (which refers to protein residue tests).

4.1.2 The requirements of ISO 15883-5:2021 apply with the exception of:

— ISO 15883-5:2021, 4.1.4 (requirement that verification and documentation of the full cleaning stage does not interfere with analyte detection is not applicable);

— ISO 15883-5:2021, 4.4.3 (which refers to assay criteria);

— ISO 15883-5:2021, 5.1.1 (which refers to validation of cleaning test methods);

— ISO 15883-5:2021, 5.1.3 (which refers to validation of detection methods);

— ISO 15883-5:2021, 5.1.4 (which refers to analyte assay methods);

— ISO 15883-5:2021, 5.3.4 and 5.4.4 (requirements for action levels specified in 4.4.3 for the load, and conformance of cleaning efficacy for the test load with the alert levels in 4.4.3, are not applicable).

4.1.3 The WD shall be designed to process one or more human waste containers in an operating cycle.

NOTE This can require the use of a variety of types of load carrier(s).

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

4.2 Chemical dosing systems

4.2.1 Provision shall be made for the installation of specific chemical dosing system(s), when specified by the purchaser, to allow for the dosing of process chemical(s).

4.2.2 The volume of process chemical(s) admitted shall be adjustable by a means that 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 human waste containers are required to be emptied manually or automatically.

Manual emptying of human waste containers should be avoided whenever possible.

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

Check for conformance in accordance with 6.5.1.

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

Check for conformance in accordance with 6.5.2.

4.4 Cleaning

4.4.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2024, 4.2 and 6.10 and the performance requirements and test method criteria specified in ISO 15883-5:2021, Clauses 4 and 5, and Annex B.

NOTE 1 Some suitable test soils for human waste containers are described in Reference [7] and Reference [8].

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

Where applicable, any treatment required prior to cleaning in the WD shall be performed in accordance with the instructions for use for the load specified in ISO 17664-2:2021, 6.4, or for the WD specified in ISO 15883-1:2024, 8.1 a).

NOTE 2 ISO 17664-1 can be applicable if the human waste container is intended to contact broken skin.

4.4.2 Pre-wash (flushing)

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

4.4.3 Washing

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

NOTE 1 The water used to wash the human waste containers can be discharged without recirculation or be recirculated during a single washing stage within one operating cycle.

During the washing stage:

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

— 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 (see ISO 15883-1:2024, 4.2.3).

NOTE 2 A washing stage can include two or more washing temperatures and washing temperature bands.

4.5 Disinfecting

4.5.1 When tested in accordance with the method specified in ISO 15883-1:2024, 6.8.2, 6.8.3 and 6.8.4, each operating cycle shall include a thermal disinfection stage during which the specified minimum temperature for the specified minimum (holding) time, or the equivalent lethality of an A_0 of at least 60, is achieved on all surfaces which are required to be disinfected.

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

4.5.2 Higher A_0 values than 60 may be specified for the inner surface of the human waste container, the outer surfaces of the human waste container or the walls of the WD chamber.

4.5.3 The temperature on the surface of the load shall be 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 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.

4.5.5 If rinsing between cleaning and disinfection is omitted, then the requirements of ISO 15883-1:2024, 4.2.4 apply.

4.5.6 If there is a final rinsing after the disinfection stage, then ISO 15883-1:2024, 4.4 applies.

4.6 Drying

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

Hot air or compressed air used for drying shall be of a quality which shall not impair the cleanliness of, nor introduce microbial contamination to, the load.

NOTE ISO 8573-1, ISO 29463-1 and EN 1822-1 provide guidance and specifications on air quality.

4.7 Cooling

The provision of a separate cooling stage within the operating cycle is optional. Means used to cool the load shall not impair the cleanliness of, nor introduce microbial contamination to, the load.

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 15883-1:2024, 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 15883-1:2024, 5.12.6.

5.1.2 Provision shall be made for the installation of a temperature recorder when specified by the purchaser. When a 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.