International Standard

ISO 15883-3

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 pour déjections humaines

Second edition
2024-11

Reference number
ISO 15883-3:2024(en)

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Published in Switzerland

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Performance requirements ... **2**
4.1 General ... 2
4.2 Chemical dosing systems ... 2
4.3 Emptying ... 3
4.4 Cleaning ... 3
4.5 Disinfecting ... 4
4.6 Drying ... 4
4.7 Cooling ... 4

5 Mechanical and control requirements ... **4**
5.1 Instrumentation and control ... 4
5.2 Process ... 4
5.3 Venting, draining, and purging ... 5
5.4 Water quality ... 5

6 Testing for conformity ... **5**
6.1 General ... 5
6.2 Test for drain seal integrity ... 6
6.3 Test for flushing of non-absorbent material ... 6
6.4 Test for flushing of absorbent material (toilet tissue) ... 6
6.5 Test for loading/emptying of human waste containers ... 6
6.5.1 Automatic emptying ... 6
6.5.2 Manual emptying ... 6
6.6 Tests for soil removal from load, load carrier(s) and chamber walls ... 6

7 Information to be provided ... **7**

8 Information to be requested from the purchaser by the supplier of the WD ... **7**

Annex A (informative) **Summary of test programmes** ... **8**

Annex B (normative) **Specification for toilet tissue for use in tests on washer-disinfectors (WD) for human waste containers** ... **9**

Annex C (informative) **Measurement of water absorbency of toilet tissue by the basket method** ... **10**

Bibliography ... **11**

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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 15883-3:2006), 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 15883-5:2024;

— 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.

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Introduction

This document is the third part in the ISO 15883 series of standards specifying the performance of washer-disinfectors (WD) and the general requirements for performance applicable to WD for human waste containers. The requirements given in this document apply to WD 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 WD for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

Requirements for WD 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 WD 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.

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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 (WD) 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]

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