
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

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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-3 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

- *Part 1: General requirements, terms and definitions and tests*
- *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*
- *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*
- *Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*
- *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

Introduction

It is recommended that this Introduction be read in conjunction with the introduction to ISO 15883-1.

This part of ISO 15883 is the third of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bedpan washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for emptying, flushing, cleaning and thermally disinfecting human waste containers intended for re-use such as:

- portable sanitary pans;
- supports for single-use bed pans;
- hospital bowls;
- urine bottles;
- suction bottles; and
- products similar to the above and used for similar purposes.

Fields of application within the scope of the ISO 15883 series of standards include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as washer-disinfectors for bedsteads and transport carts and 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 the ISO 15883 series of standards.

Bedpan washer disinfectors are loaded manually. 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 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 bedpan washer-disinfector may 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 washer-disinfectors are given in IEC 61010-2-045.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

- a) note that until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;
- b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.

Washer-disinfectors —

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

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended to be used for emptying, flushing, cleaning and thermal disinfection of containers used to hold human waste for disposal by one operating cycle.

This part of ISO 15883 is to be applied in conjunction with ISO 15883-1.

2 Normative references

The following referenced documents are indispensable for the application 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 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, definitions and tests*

ISO/TS 15883-5, *Washer-disinfectors — Part 5: Test soils and methods 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.

3.1

t_0

equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

[ISO 15883-1:2006, definition 3.1]

NOTE See also ISO 15883-1:2006, Annex B.

3.2

emptying

discharging the contents of a container by gravity

3.3

human waste

excretions and body fluids including faeces, urine, blood, pus, vomit and mucus

3.4

human waste container

re-usable vessel for holding and transporting human waste

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1:2006 apply with the exception of its

- subclause 4.3.2 (which refers to chemical disinfection, see Scope of this part of ISO 15883);
- subclause 4.3.3 (which refers to the maximum range of temperatures permitted on the load items, see 4.1.4 of this part of ISO 15883);
- subclause 5.3.1.2 (which refers to the use of a machine purging and disinfection);
- subclause 5.7.4 (which refers to verification of the dose of process chemical admitted);
- subclause 5.7.5 (which specifies the accuracy and reproducibility of chemical dosing systems);
- subclause 5.8 (which refers to load temperature protection);
- subclause 5.9 (which refers to control of temperatures on the load and chamber walls, see 4.5.3 and 4.5.4 of this part of ISO 15883);
- subclause 6.8.5 (which refers to tests for load temperature protection);
- subclause 6.10.3.2 (which refers to protein residue tests, see also ISO 15883-1:2006, Table A.1 (load, 6.10.3) and Annex A of this part of ISO 15883).

4.1.2 The WD shall be designed to process either one type of human waste container or a variety of types of human waste container and the re-usable supports for single-use bedpans.

NOTE This can require the use of two or more types of load carrier.

4.1.3 The WD shall be designed to process either one human waste container per cycle, or several human waste containers per cycle.

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

4.2 Chemical dosing systems

4.2.1 Provision shall be made for the installation of a chemical dosing system, when specified by the purchaser, to allow for the injection of a descalant, detergent and/or rinse aid.

4.2.2 The means to control the volume of additive(s) admitted shall be adjustable and shall deliver the set volume to an accuracy of $\pm 10\%$ 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 containers are required to be emptied manually or automatically.

Manual emptying of containers should be avoided whenever possible.

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

Check for compliance in accordance with 6.5.1.

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

Check for compliance in accordance with 6.5.2.

4.4 Cleaning

4.4.1 Flushing

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

NOTE The water used to flush the containers can be discharged without recirculation or be recirculated during a single flushing stage within one process cycle.

4.4.2 Washing

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

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

4.4.3 Test requirements

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

4.5 Disinfecting

4.5.1 Thermal disinfection shall be deemed to have been attained when all surfaces to be disinfected have been subjected to a process providing an A_0 of at least 60.

4.5.2 When tested by the method specified in ISO 15883-1:2006, 6.8.2, 6.8.3 and 6.8.4, the surface temperatures and times shall provide the specified A_0 values.

Different A_0 values may be specified for the inner surface of the human waste container, the outer surfaces of the human waste container and 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.

4.6 Rinsing

See ISO 15883-1:2006, 4.4.

NOTE Rinsing can take place before, or simultaneously with, the disinfecting stage.

4.7 Drying

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

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 15883-1:2006, 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 15883-1:2006, 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.

5.2.2 Means shall be provided to pre-set the disinfection temperature and time over a specified range. The range shall be either between 65 °C and 95 °C for 1 s to 1 h or over the range 75 °C to 95 °C for 1 s to 5 min. Adjustment shall be by means of a code, key or tool.

NOTE The facility to adjust the pre-set time and temperature over the ranges specified is to allow for disinfection for short time periods at high temperature or, to obtain equivalent effect, prolonged times at lower temperatures; this can be required for processing containers which will not withstand higher temperatures.

5.2.3 The combination of disinfection time and disinfection temperature shall be set to achieve the specified A_0 value.

5.3 Venting, draining and purging

5.3.1 For free standing and single door WDs the drainage outlet shall be placed towards the rear of the WD.

This should be done in such a manner that it is possible to make connection with a drainage outlet in any position within a horizontal angle of 180°.

5.3.2 When tested in accordance with 6.2, the water seal in the trap between the chamber and the drain shall not be broken during five consecutive operating cycles.

NOTE When it is not practicable to vent to the outside atmosphere, a condenser can be used for indirect venting. This can produce a backpressure which, if excessive, will break the water seal between the chamber and the drain. The test is intended to verify that this does not occur.

5.3.3 After the completion of the washing stage of the operating cycle, the trap shall be clear of soil and waste.

Compliance shall be tested in accordance with 6.3 and 6.4.

After each of five tests carried out in accordance with 6.3 there shall be no test spheres retained within the chamber or trap.

After each of five tests carried out in accordance with 6.4 there shall be no toilet tissues retained within the chamber and the trap shall be clear.

5.4 Water quality

The tests required by ISO 15883-1:2006, 5.23.3 (see also ISO 15883-1:2006, 6.4.2.2) shall be limited to determination of hardness (expressed as millimole per litre (mmol/l) of CaCO_3) when the water is from a potable supply.

6 Testing for conformity

6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1:2006, Clause 6.

NOTE Annex A includes a summary of test programmes for WDs for human waste containers in addition to those recommended in ISO 15883-1:2006, Annex A.

6.2 Test for drain seal integrity

Fit a transparent test trap of the same type and dimensions as that normally fitted to the WD in place of the normal trap and connect it to a suitable outlet.

Pour sufficient water into the chamber of the WD to charge the trap and ensure that there are no leaks.

Carry out five consecutive cycles with a full load of bedpans without opening the door between consecutive cycles. On completion of the five cycles, observe the trap and check that the water seal in the trap has not been broken.

6.3 Test for flushing of non-absorbent materials

One non-absorbent test sphere shall be used for each bedpan that the WD is intended to process in a single operating cycle. Drop the non-absorbent test spheres [relative density of 1,075 to 1,080, diameter ($43 \pm 0,5$) mm] into the otherwise empty chamber, close the door and start the cycle. At the end of the cleaning (washing) stage and before the disinfection stage, stop the machine and examine the chamber and the trap for retained spheres.

Repeat the test four more times.

6.4 Test for flushing of absorbent material (toilet tissue)

Twelve sheets of toilet tissue in accordance with Annex B shall be used for each bedpan that the WD is intended to process in a single operating cycle. Crumple the required number of sheets of toilet tissue and drop into the chamber of the WD containing the maximum intended load of bedpans. Close the door and start the cycle. At the end of the cleaning (washing) stage, interrupt the operating cycle and record the number of tissue sheets remaining in the chamber and load; inspect the trap and record the number of tissues retained in the trap.

Repeat the test a further four times.

6.5 Test for loading/emptying of containers

6.5.1 Automatic emptying

For WDs complying with 4.3.2, each type of container which the WD is designed to process shall be tested. Fill each container with water to no less than 75 % of its brimful capacity and locate it in the load carrier in

accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid has been spilled or splashed outside the WD.

6.5.2 Manual emptying

For WDs complying with 4.3.3, each type of container which the WD is designed to process shall be tested. Fill each container with water to not less than 75 % of its brimful capacity and empty it into the WD and locate it in the load carrier in accordance with the manufacturer's instructions. Load the chamber to the maximum recommended capacity. Close the door. Observe whether any liquid has been spilled or splashed outside the WD.

6.6 Tests for soil removal from chamber walls, load carrier and load

The tests shall be carried out in accordance with ISO 15883-1:2006, 6.10 using one or more of the nationally published test soils and methods specified in ISO/TS 15883-5 (For reference see also References [2] to [9]).

NOTE 1 The attention of users is drawn to local requirements that can require the use of particular test soils and methods.

NOTE 2 The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.

The test soils used for the load, chamber wall and load carriers may not be the same. Where different test soils are used, the rationale for the choice of test soil should be documented.

7 Information to be supplied by the manufacturer

In addition to the information listed in ISO 15883-1:2006, Clause 8 the manufacturer shall provide the supplier with the following information:

- a) the maximum load or capacity and acceptable loading combinations;
- b) the range of load supports available and required;
- c) the quantity of water required per cycle;
- d) any details of ventilation discharge requirements e.g. air volume, system pressure drop and maximum temperature;
- e) the energy required per operating cycle;
- f) the following information obtained by testing in accordance with ISO 15883-1:2006, 6.13:
 - 1) the time for an operating cycle from a cold start;
 - 2) the time for each of five consecutive cycles, all having a hot start;
 - 3) the location and temperatures of the coolest and hottest parts of the load and the chamber wall during thermal disinfection;
- g) the disinfection temperature band.

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

In addition to the information listed in ISO 15883-1:2006, Clause 10, the manufacturer shall request the following information from the purchaser:

- a) the number, type and capacity of containers to be processed;
- b) whether containers are required to be emptied automatically;
- c) whether a descalant or detergent injection system is required;
- d) the duct work connections available;
- e) the A_0 value, or the combination of time and temperature, to be attained for thermal disinfection (if the A_0 value has not been defined by the purchaser, see 4.5.1).

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Annex A (informative)

Summary of test programmes

The following table summarizes the recommended test programmes applicable to WDs for human waste containers in addition to those recommended in ISO 15883-1:2006. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes for WDs for human-waste containers

| Brief description of test | Requirements subclause | Test subclause | Type Test | Works Test | Operational qualification | Performance qualification | Routine test |
|--|------------------------|----------------------|-----------|------------|---------------------------|---------------------------|--------------|
| Drain seal integrity | 5.3.2 | 6.2 | X | X | O | B | B |
| Flushing of non-absorbent materials | 5.3.3 | 6.3 | X | B | B | B | B |
| Flushing of absorbent materials | 5.3.3 | 6.4 | X | B | X | B | B |
| Safety of loading and emptying of containers | 4.3.2 or 4.3.3 | 6.5.1 or 6.5.2 | X | B | B | X | B |

X = recommended
 B = not recommended
 O = optional test which may be requested by the purchaser or user
 Optional tests may be carried out at the discretion of the user or may be required by local regulation.