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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 les laveurs désinfecteurs destinés à la désinfection thermique de récipients à déjections humaines

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ICS

English version

**Washer-disinfectors - Part 3: Requirements and tests for
washer-disinfectors employing thermal disinfection for human
waste containers (ISO/DIS 15883-3:2003)**

Laveurs désinfecteurs - Partie 3: Exigences et essais pour
les laveurs désinfecteurs de récipients à déjections
humaines (ISO/DIS 15883-3:2003)

Reinigungs-/Desinfektionsgeräte - Teil 3: Anforderungen an
und Prüfungen von Reinigungs-/Desinfektionsgeräten mit
thermischer Desinfektion für Behälter für menschliche
Ausscheidungen (ISO/DIS 15883-3:2003)

This draft European Standard is submitted to CEN members for second parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Foreword

This document (prEN ISO 15883-3:2003) has been prepared by Technical Committee CEN/TC 102, "Sterilizers for medical purposes", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 198 "Sterilization of health care products".

This document is currently submitted to the second parallel Enquiry.

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

— *Part 1: General requirements, definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, hollowware, 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 thermo-labile endoscopes*

Fields of application within the scope of EN ISO 15883 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.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

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

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

Annexes A and B are normative. Annexes C and ZA are given for information only.

Introduction

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

This part of prEN ISO 15883 is the third of a series specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to bed pan 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 hollowware, e.g. bowls;
- urine bottles;
- suction bottles; and
- products similar to the above and used for similar purposes.

Requirements for washer-disinfectors for other applications are specified in other parts of this standard.

Bed-pan 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 eg 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 bed-pan washer-disinfector may be adversely affected if the machine is connected to a poorly designed or constructed drainage system, and 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.

1 Scope

This part of prEN 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.

The requirements of this part apply in addition to the general requirements specified in prEN ISO 15883-1.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

prEN ISO 15883-1:2002 *Washer-disinfectors — Part 1: General requirements, definitions and tests.*

3 Terms and definitions

For the purposes of this part of prEN ISO 15883, the terms and definitions given in prEN ISO 15883-1:2002 and the following apply.

3.1

human waste

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

3.2

human waste container

re-usable vessel for holding and transporting human waste

3.3

emptying

discharging the contents of a container by gravity

4 Performance requirements

4.1 General

4.1.1 The requirements of prEN ISO 15883-1:2002 apply with the exception of

- subclause 4.3.2 (which refer to chemical disinfection, see Scope);
- subclause 4.3.3 (which refers to the maximum range of temperatures permitted on the load items, see 4.1.4 below);
- subclause 5.3.1.2 (which refers to the use of a machine purging and disinfection);
- 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 4.6.3 and 4.6.4 below); and
- subclause 6.8.5 (which refers to tests for load temperature protection).

4.1.2 The washer-disinfector 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 may require the use of two or more types of load carrier.

4.1.3 The washer-disinfector 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 be not 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 or rinse aid.

4.2.2 The means to control the volume of additive(s) admitted (see prEN ISO 15883-1:2002, 5.7.5. and 5.7.6) shall be adjustable and shall deliver the set volume to an accuracy of $\pm 10\%$ or better.

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.

NOTE 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 nor discharge of aerosols of the contents of containers during automatic emptying.

Check for compliance in accordance with 6.4.1.

4.3.3 When the container(s) are to be emptied manually into the washer-disinfector 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 6.4.2.

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 may be discharged without recirculation or be recirculated during a single flushing stage within one process cycle.

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4.4.2 Washing

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

NOTE The water used to wash the containers may 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 described in 6.5.

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 described in prEN ISO 15883-1:2002, 6.8 the surface temperatures and times shall provide the specified A_0 values.

NOTE 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 washer-disinfector chamber.

4.5.3 The temperature on the surface of the load shall be within $-0\text{ }^{\circ}\text{C} / +15\text{ }^{\circ}\text{C}$ 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 $-0\text{ }^{\circ}\text{C} / +15\text{ }^{\circ}\text{C}$ of the set temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship.

4.6 Rinsing

See prEN ISO 15883-1:2002, 4.4.

NOTE Rinsing may 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 washer-disinfector shall either be fitted with a chamber temperature indicator (see prEN ISO 15883-1:2002, 5.11.4 a)) or a temperature attained indicating light of a pre-set disinfection temperature; The sensor shall be located as specified in prEN ISO 15883-1:2002, 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 above.

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 may 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 washer-disinfectors the drainage outlet shall be placed towards the rear of the washer-disinfector and in such a manner that it is possible to make connection with a drainage outlet in any horizontal position through an arc of 180°.

5.3.2 When tested in accordance with 6.1 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 may be used for indirect venting. This may produce a back pressure 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 6.2 and 6.3.

After each of five tests carried out in accordance with 6.2 there shall be no test spheres retained within the chamber or trap.

After each of five tests carried out in accordance with 6.3 there shall be no toilet tissues retained within the chamber and the trap shall be clear.

5.4 Water quality

The tests required by prEN ISO 15883-1:2002, 5.23.3 (see also prEN ISO 15883-1:2002, 6.4.2.2) shall be limited to determination of hardness (expressed as mmol/l of CaCO₃) when the water is from a potable supply.

6 Testing for conformity

6.1 Test for drain seal integrity

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

Pour sufficient water into the chamber of the washer-disinfector 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.

6.2 Test for flushing of non-absorbent materials

One non-absorbent test sphere shall be used for each bedpan that the washer-disinfector is intended to process in a single operating cycle. Drop the non-absorbent test spheres (relative density 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.

6.3 Test for flushing of absorbent material (toilet tissue)

Twelve sheets of toilet tissue in accordance with Annex A shall be used for each bed-pan that the washer-disinfector 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 washer-disinfector containing the maximum intended load of bed-pans. Close the door and start the cycle. At the end of the cleaning (wash) 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.

6.4 Test for loading/emptying of containers

6.4.1 Automatic emptying

For washer-disinfectors complying with 4.3.2, each type of container which the washer-disinfector is designed to process shall be tested. Fill each container with water to not less than 75% of its brim full 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 washer-disinfector.

6.4.2 Manual emptying

For washer-disinfectors complying with 4.3.3, each type of container which the washer-disinfector is designed to process shall be tested. Fill each container with water to not less than 75% of its brim full capacity and empty it into the washer-disinfector 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 washer-disinfector.