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Washer-disinfectors —

Part 7:
Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO/DIS 15883-7:2014)

Laveurs désinfecteurs —

Partie 7: Exigences et essais pour les laveurs désinfecteurs utilisant la désinfection chimique pour les dispositifs médicaux et les équipements de soins thermosensibles non invasifs et non critiques (ISO/DIS 15883-7)

ICS: 11.080.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the European Committee for Standardization (CEN), and processed under the **CEN lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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Contents

Foreword

This document (prEN ISO 15833-7:2013) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN, in cooperation with Technical Committee ISO/TC 198 “Sterilization of health care products”.

This document is currently submitted to the parallel Enquiry.

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.

Introduction

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

This part of ISO 15883 is the seventh of a series specifying the performance of washer-disinfectors. It specifies the particular requirements for performance applicable to washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment. Its requirements apply to washer-disinfectors used for cleaning and disinfection of thermolabile equipment for use without further treatment in healthcare settings. Such reusable equipment needs to be cleaned and disinfected, but processing in a washer-disinfector for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3), for endoscopes (see ISO 15883-4) or for non-invasive, non-critical medical devices and healthcare equipment (see ISO 15883-6) is inappropriate and/or impractical. Examples of such equipment are bedsteads and bedside furniture, trolleys and transport carts, operating tables, footwear, wheelchairs, or aids for the disabled.

Requirements for washer-disinfectors for other applications are specified in other parts of this series of international standards.

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

a) until verifiable international criteria are adopted, the existing national regulations concerning the use and/or characteristics of the washer-disinfectors remain in force, and

b) the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restriction in any of the ISO member states.

Washer-disinfectors —

Part 7:

Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment (ISO/DIS 15883-7:2014)

1 Scope

This part of ISO 15883 specifies the particular requirements for washer-disinfectors (WD) intended to be used for the cleaning and chemical disinfection, in a single operating cycle, of re-usable items such as:

a) bedframes;
b) bedside tables;
c) transport carts;
d) containers;
e) surgical tables;
f) sterilization containers;
g) surgical clogs;
h) wheelchairs, aids for the disabled.

This Part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be necessary in order to achieve the required performance.

Devices identified within the Scopes of ISO 15883-2, ISO 15883-3, ISO I5883-4, and ISO 15883-6 do not fall within the scope of this part of ISO 15883.

In addition, the methods are specified as well as instrumentation and instructions required for type testing, works testing, validation (installation, operation, and performance qualification on first installation), routine control and monitoring as well as re-validations required to be carried out periodically and after essential repairs.

NOTE WDs corresponding to this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile and re-usable devices as recommended by the device manufacturer.

The performance requirements specified in this part of ISO 15883 may not ensure the inactivation or removal of the causative agent(s) (prion proteins) of Transmissible Spongiform Encephalopathies.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 11731-2, *Water quality — Detection and enumeration of Legionella — Part 2: Direct membrane filtration method for waters with low bacterial counts*

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 15883-2, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

ISO 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer disinfectors employing chemical disinfection for thermolabile endoscopes*

ISO 15883-6, *Washer-disinfectors — Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

ISO TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

IEC 61010-2-40:2005, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1, ISO 15883-4 and ISO 15883-6 apply.

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006 except for the following sub-clauses:

— 4.3.1 (which refers to thermal disinfection; see Clause 1 of this part of ISO 15883)

— 5.9 (process temperature control limits; without 5.9 d and e);

— 5.11 (process verification);

— 5.27.1°c) (force required to remove the load).

4.1.2 The WD shall be designed to clean and chemically disinfect the range of re-usable items specified by the WD manufacturer.

4.1.3 When necessary the WD shall be provided with means to facilitate the correct alignment of the load in the washing chamber.

4.1.4 The means to control the volume of the process chemical(s) admitted (see ISO 15883-1:2006, 5.7.4 and 5.7.5) shall be adjustable by means of a key, code or tool. The accuracy of the dosing system shall be at least ±10 % or as specified and tested for conformity by the manufacturer (see 6.7).

4.1.5 The automatic controller shall ensure that the final concentration of disinfectant and the volume of disinfectant solution (±10 %) are within the limits specified by the WD manufacturer.

NOTE Confirmation of the concentration of disinfectant can include the measurement of the volume of disinfectant and water admitted together with a certificate of conformity from the disinfectant supplier for the concentration of the disinfectant, together with data to support the shelf life, expiry date etc.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1 using the test soils and methods described in ISO/TS 15883-5 that are relevant to the loads to be processed.

4.2.2 During the washing stage:

a) the washing time starts when the temperature at the control sensor of the WD is not less than the specified washing temperature.

b) the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit of no greater than the specified washing temperature +10 °C (see ISO 15883-1:2006, 4.2.3);

4.2.3 Cleaning efficacy shall be determined in accordance with 6.8.

4.2.4 If the WD is designed to allow the reuse of the cleaning solution on two or more consecutive operating cycles then care shall be taken to ensure that the activity and safety (e.g. accumulation of foreign material, device compatibility) of the cleaning solution is not impaired during its working life. This shall include at least the following:

a) The WD manufacturer shall specify the means which shall be used to ensure that the cleaning solution has retained the required cleaning activity. These means shall be based on validation studies, which would normally be carried out by the cleaning solution manufacturer, to determine a suitable parameter or parameters that may be monitored. Suitable parameters may include the concentration of the active ingredient and excipients (that may also affect performance), pH, stability etc.

NOTE Minor changes in formulation of the cleaning solution can have a significant effect on storage life, cleaning activity etc.

b) The WD manufacturer shall recommend to the user the maximum period or number of operating cycles for which the cleaning solution may be used. This shall be based on validated experimental data.

c) When validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall:

— operate an audible and visible alarm and prevent the use of the operating cycle until the cleaning solution is changed; or

— effect an automatic change of the cleaning solution in the WD.

4.3 Disinfection

4.3.1 The cycle shall include a chemical disinfection stage, which may be combined with the cleaning and shall be deemed to have been achieved when testing requirements in 6.9 are met.

4.3.2 The requirements and tests in this standard are based on the use of aqueous solutions of a disinfectant. Other systems based on gaseous disinfectants are not excluded; equivalent tests are required.

4.3.2.1 The *in vitro* efficacy of the disinfectant shall be demonstrated based on relevant published standards.

4.3.2.2 A specific neutralization method for the disinfectant shall be validated.

NOTE These data can be provided by the disinfectant manufacturer.

4.3.2.3 When tested on surfaces for the minimum exposure time at the minimum concentration and the minimum temperature to be used in the WD the disinfectant shall demonstrate:

a) at least a $\log_{10}^5$ inactivation of vegetative bacteria and yeast-like fungi;

b) at least a $\log_{10}^4$ inactivation of enveloped viruses.

NOTE 1 National Regulatory Authorities can require higher inactivation values and/or activity against a wider range of microorganisms.

NOTE 2 Efficacy against vegetative bacteria can exclude mycobacteria. See also Clause 8.

4.3.2.4 The WD manufacturer shall ensure the compatibility of the cleaning and disinfection solutions, including an impact on disinfection efficacy from carryover of cleaning solution.

4.3.2.5 The experimental conditions of tests intended to demonstrate the microbicidal activity of the disinfectant in vitro shall reflect the conditions of use of the disinfectant. Thus, when cleaning and disinfection

is combined the disinfectant shall be tested in the presence of applicable interfering substances that shall include soiling typically found in the loads to be processed.

4.3.3 The temperature of the disinfectant solution throughout the disinfection stage shall be monitored to ensure that it remains within the limits specified by the manufacturer of the disinfectant and be compatible with the temperature limits for the device(s) to be processed.

This shall be achieved either by controlling the temperature of the disinfectant solution or, where appropriate, by operating the WD at ambient temperature with means to prevent operation of the WD when the disinfectant temperature is outside the specified temperature range.

4.3.4 If the WD is designed to allow the reuse of the disinfectant solution on two or more consecutive operating cycles then care shall be taken to ensure that the activity and safety (e.g. accumulation of foreign material, device compatibility) of the disinfectant solution is not impaired during its working life. This shall include at least the following:

a) The WD manufacturer shall specify the means which shall be used to ensure that the disinfectant solution has retained the required anti-microbial activity. These means shall be based on validation studies, which would normally be carried out by the disinfectant manufacturer, to determine a suitable parameter or parameters that may be monitored to indicate the anti-microbial activity of the disinfectant. Suitable parameters may include the concentration of the active ingredient and excipients/adjuvants (that may also affect performance), pH, stability etc.

NOTE 1 Minor changes in formulation of the disinfectant can have a significant effect on storage life, anti-microbial activity etc.

b) The WD manufacturer shall recommend to the user the maximum period or number of operating cycles for which the disinfectant may be used. This shall be based on validated experimental data.

c) When validated use conditions (maximum period or number of operating cycles) are exceeded, the automatic controller shall:

   — operate an audible and visible alarm and prevent the use of the operating cycle until the disinfectant solution is changed; or

   — effect an automatic change of the disinfectant solution in the WD.

d) The WD manufacturer shall provide a method for the user to monitor the disinfectant using a chemical indicator or other method specific for the disinfectant to show that the disinfectant is at or above the minimum effective concentration.

NOTE 2 The minimum effective concentration is the lowest concentration of active ingredient and excipients/adjuvant necessary to meet the label claim of a reusable disinfectant.

4.4 Final rinsing

The quality of the final rinse water used after the disinfection stage shall not impair the result of cleaning/disinfection and conform to WHO definition for potable water, when tested in accordance with 6.3.

NOTE National Regulatory Authorities can require specific standards for final rinse water quality.

4.5 Self-disinfection

4.5.1 A self-disinfection cycle shall be provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs or testing (see also ISO 15883-1:2006, 5.3.1.2).

NOTE 1 The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. Biofilm can easily develop on the piping used to convey rinse water to the load, and can contain microorganisms in a state in which they are highly resistant to disinfection.

Thermal disinfection shall attain a minimum A_0 of 60 and shall be capable to be set to give an A_0-value of 600.

If the use of thermal disinfection is not possible, a chemical disinfectant different from that used for disinfecting the loads shall be used.

NOTE 2 The use of the same disinfectant carries the risk of allowing organisms resistant to that particular disinfectant to proliferate.

4.5.2 The manufacturer shall provide details of the parts of the WD subjected to the self-disinfection cycle and whether this cycle includes other components such as the water treatment equipment.

4.5.3 When different from the normal operating cycle the WD self-disinfection cycle shall:

a) be operated under the control of the automatic controller;

b) be a user selectable cycle;

c) provide for disinfection of the chamber and all liquid transport systems;

d) include means to warn the user that the WD shall be operated without any load in the chamber and, so far as may be practicable, include means to verify that no device is present before the cycle will operate;

e) in the case of thermal self-disinfection of the WD, ensure that all the parts of the heating system and the associated pipework, via which the water or the steam reach the WD tank, attain an A_0-value of at least 60.

4.5.4 The self-disinfection cycle shall ensure that a WD that has become contaminated through failure of the water treatment equipment can be effectively disinfected. Compliance shall be verified by testing in accordance with 6.3.

4.5.5 Thermal disinfection systems shall be evaluated by thermometric monitoring of the system with sensors placed at those parts of the system specified by the WD manufacturer as representative of the lowest temperatures in the system. The entire system subjected to thermal disinfection shall attain the required disinfection temperature.

4.5.6 For chemical self-disinfection cycles a microbiological test shall be required. The capability of the WD to provide self-disinfection shall be deemed to have been established when tested in accordance with Annex B.

4.6 Drying

4.6.1 The WD shall, unless otherwise specified, be provided with equipment to allow drying of the load.

4.6.2 Drying of the load in the WD shall be deemed to have been achieved when plain surfaces of the items are visually dry (see 6.5).

4.7 Water treatment equipment

4.7.4 General

Means shall be provided to ensure that water treatment equipment that is part of the WD (softeners, de-ionizers, filters etc.) is operated within the limits (e.g. flow rates, supply pressures) specified by the manufacturer of the water treatment equipment.

4.7.5 Disinfection of water treatment equipment

4.7.2.1 When the water treatment equipment is a part of the WD, the former shall be designed and constructed so that it can be periodically submitted to a disinfection procedure. Guidance on the minimum frequency with which the equipment shall be disinfected shall be stated by the WD manufacturer in accordance with the information supplied by the purchaser for the quality of the water supply and the manufacturer of the water treatment equipment [see 8 h)].

NOTE The disinfection of the water treatment equipment can be carried out during a self-disinfection cycle.

The actual frequency should be decided by the user based upon known, e.g. seasonal, variations in the quality of water supplied to the WD and the operational history of the water treatment equipment.

The disinfection method shall not cause any damage to, nor impair the efficacy of, the treatment equipment.

The efficacy of the water equipment disinfection procedure to provide self-disinfection shall be deemed to have been established if, when tested in accordance with 6.3 there shall be less than 10 cfu recovered from each of two 100 ml samples and other controlling parameters have been achieved.

4.7.2.2 If the water treatment equipment is not part of the WD, the WD manufacturer shall specify the requirements for water supplied to the WD. This shall include specification of the permissible microbial contamination of the water supply [see 8 h)].

NOTE 1 To meet the specification of the permissible microbial contamination of the water supply, it can be necessary for the user to make provision for disinfection of the external water treatment equipment.

Means shall be provided to disinfect incoming water used for the final rinse. The disinfection process shall ensure that

a) there are fewer than 10 cfu/100 ml sample of final rinse water;

b) the water is free from legionellae, *Pseudomonas* and mycobacteria (see 6.3).

NOTE 2 The following methods can be suitable for control of the microbial contamination of rinse water:

— maintained in a dedicated reservoir at a temperature not less than 65 °C for the time demonstrated to achieve disinfection of the incoming supply; or

— disinfected immediately prior to use; or

— filtered to remove suspended particles of a size greater than 0,2 µm; or

— sterile, in a closed container, with a connection to the WD designed and constructed to provide aseptic transfer.

4.7.2.3 The connection between the water supply, which has been treated to remove microbial contamination and the circulation system for rinsing the endoscope shall be designed and constructed to provide aseptic transfer.

Provision shall be made for disinfection of this connection to be made periodically. The frequency and method of carrying out this disinfection shall be specified by the WD manufacturer.