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Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

ICS: 11.080.10

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CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 15883-1:2006), which has been technically revised.

The main changes compared to the previous edition are as follows:

- incorporation of ISO 15883-1:2006/Amd1:2014;
- alignment with terms and definitions with ISO 11139:2018;
- addition of requirements for load carrier(s);
- clarification of water quality requirements;
- relocation of former [Annex C](#), *Test methods for the detection and assessment of residual proteinaceous contamination*, to ISO/FDIS 15883-5:2020¹⁾,
- redesignation of former Annex D, *Microbiological recovery medium for estimation of bacterial contamination of water*, as [Annex C](#);
- increase in the minimum temperature limit for thermal disinfection and calculation of A_0 values from 65 °C to 70 °C;
- revision of 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.

1) Under preparation.

Introduction

This document is the first part of the ISO 15883 series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this document are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they are modified or added to by a subsequent part, in which case the requirements of that particular part apply.

Fields of application within the scope of ISO 15883 series can 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.

Washer-disinfectors are used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, references are made both to this document and to the relevant parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

This document has been prepared on the basis that each individual washer-disinfector is subject to validation tests (e.g. installation qualification, operational qualification, and performance qualification on first installation) and that in use continued compliance is established by periodic tests.

In respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the washer-disinfector and its intended use, it is noteworthy that the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restrictions in any of the ISO member states.

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Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

1 Scope

This document specifies general performance requirements for washer-disinfectors and their accessories that are intended to be used for cleaning and disinfection of reusable medical devices. It specifies performance requirements for cleaning and disinfection as well as for the accessories that can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and requalification, periodically and after essential repairs, are also specified.

NOTE 1 The requirements can be applied to washer-disinfectors intended for use with other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

The requirements for washer-disinfectors intended to process specific loads are specified in other parts of the ISO 15883 series. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of the ISO 15883 series apply.

This document does not specify requirements intended for machines for use for laundry or general catering purposes.

This document does not include requirements for machines which are intended to sterilize the load, or which are designated as "sterilizers", these are specified in other standards, e.g. EN 285^[21].

The specified performance requirements of this standard do not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 2 If it is considered that prion protein can be present, particular care is needed in the choice of cleaning agents and disinfectants to ensure that the chemicals used do not react with the prion protein in a manner that can inhibit its removal or inactivation.

This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a washer-disinfector. The test methods for demonstration of conformity with the requirements of this document can also be employed by users to demonstrate continued conformity of the installed washer-disinfector throughout its service life. Guidance on a routine test programme is given in [Annex A](#).

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 7000, *Symboles graphiques utilisables sur le matériel — Symboles enregistrés*

ISO 10012, *Systèmes de management de la mesure — Exigences pour les processus et les équipements de mesure*

ISO 14644-3, *Salles propres et environnements maîtrisés apparentés — Partie 3: Méthodes d'essai*

ISO 14971, *Dispositifs médicaux — Application de la gestion des risques aux dispositifs médicaux*

ISO/DIS 15883-1:2020(E)

ISO/FDIS 15883-5:2020¹, *Washer-disinfectors – Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

IEC 60417-DB, *Graphical symbols for use on equipment*

IEC 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances*

IEC 60751:2008, *Industrial platinum resistance thermometer sensors*

IEC 61010-2-040:2015, *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*

IEC 61326-1:2012, *Electrical equipment for measurement, control and laboratory use. EMC requirements – Part 1: General requirements*

IEC 80416-1, *Principes de base pour les symboles graphiques utilisables sur le matériel — Partie 1: Création des symboles graphiques pour enregistrement*

European Pharmacopoeia Assays – 2.5.30 Oxidising substances; Biological tests - 2.6.14 Bacterial endotoxins

United States Pharmacopeia Chemical tests <541> Titrimetry, Oxidation-Reduction (Redox) titrations; Biological tests <85> Bacterial endotoxins test

3 Terms and definitions

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For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

NOTE Terms and definitions relevant to ISO/TC 198 *Sterilization of health care products* are listed in ISO 11139.

3.1

A_0
measure of microbiological lethality delivered by a moist heat disinfection process expressed in terms of the equivalent time in seconds at 80 °C with reference to a microorganism with a z value of 10 K

Note 1 to entry: See [Annex B](#).

[SOURCE: ISO 11139:2018, 3.1, modified – Note 1 to entry has been added]

3.2

automatic controller

device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

[SOURCE: ISO 11139:2018, 3.18]

3.3

bedpan washer-disinfector

washer-disinfector for human waste containers that additionally empties and flushes

[SOURCE: ISO 11139:2018, 3.22]

3.4**bioburden**

population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]

3.5**calibration**

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

3.6**calorifier**

closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated fluid through a heat exchanger

[SOURCE: ISO 11139:2018, 3.32]

3.7**chamber**

part of equipment in which a load is processed

Note 1 to entry: The chamber does not include steam generators, pipework, e.g. drain and fittings from which it can be isolated.

[SOURCE: ISO 11139:2018, 3.36, modified – Note 1 to entry has been added]

3.8**chemical disinfection**

disinfection achieved by the action of one or more chemicals

[SOURCE: ISO 11139:2018, 3.42]

3.9**cleaning**

removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.10**continuous process machine**

equipment that moves one work unit at a time between each step of the process with the product generally remaining in motion

Note 1 to entry: This is contrasted with batch process equipment, which would expose the entire batch to each step of the process, one step at a time.

[SOURCE: ISO 11139:2018, 3.62]

3.11**cycle complete**

message from the automatic controller that the operating cycle has ended successfully

[SOURCE: ISO 11139:2018, 3.71]

3.12

D value

***D*₁₀ value**

time or dose required under stated conditions to achieve inactivation of 90% of a population of the test microorganisms

[SOURCE: ISO 11139:2018, 3.75]

3.13

dead volume

<washer-disinfector> enclosed space of pipework which is not purged by the usual flow of liquids during the operating cycle

[SOURCE: ISO 11139:2018, 3.318.2]

3.14

disinfection

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.15

disinfection temperature

minimum temperature on which the evaluation of the disinfection efficacy is based

Note 1 to entry: Several disinfection temperatures can prevail during the disinfection stage.

[SOURCE: ISO 11139:2018, 3.85, modified (Note 1 to entry has been added)]

3.16

disinfection time

period for which the process variable(s) is/are maintained at or above that/those specified

Note 1 to entry: Examples of process variables include temperature of the load, disinfectant concentration in the chamber.

[SOURCE: ISO 11139:2018, 3.86]

3.17

double-ended

having separate doors for loading and unloading in separate areas

[SOURCE: ISO 11139:2018, 3.92]

3.18

endoscope washer-disinfector

washer-disinfector intended to clean and disinfect loads comprising flexible endoscopes

[SOURCE: ISO 11139:2018, 3.100]

3.19

fail safe

attribute of equipment, or its associated services, that ensures that a malfunction will not give rise to a hazardous situation

[SOURCE: ISO 11139:2018, 3.115]

3.20**fault**

situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

3.21**fluid**

substance that continually deforms (flows) under applied shear stress

EXAMPLE Liquid, gas, vapour, plasma.

[SOURCE: ISO 11139:2018, 3.120]

3.22**flushing****purging**

removing by displacement with a fluid

[SOURCE: ISO 11139:2018, 3.121]

3.23**free draining**

allowing the unimpeded flow of liquids towards the discharge point under the influence of gravity

[SOURCE: ISO 11139:2018, 3.124]

3.24**holding time**

period during which process parameters are maintained, within their specified tolerances

[SOURCE: ISO 11139:2018, 3.133]

3.25**human waste**

body fluids and excretions

EXAMPLE Faeces, urine, blood, pus, vomit, mucus.

[SOURCE: ISO 11139:2018, 3.134]

3.26**human waste container**

vessel for holding and transporting human waste

[SOURCE: ISO 11139:2018, 3.135]

3.27**installation qualification****IQ**

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.28**load**

product, equipment, or materials to be processed together within an operating cycle

[SOURCE: ISO 11139:2018, 3.155]

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3.29

loading door

means of access through which a load is passed into the chamber before processing

[SOURCE: ISO 11139:2018, 3.157]

3.30

lumen device

item that consists of tube(s) or pipe(s)

[SOURCE: ISO 11139:2018, 3.158]

3.31

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception; iTeh STANDARD PREVIEW
- disinfection of medical devices; (standards.iteh.ai)
- providing information by means of *in vitro* examination of specimens derived from the human body, and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- items specifically intended for cleaning or sterilization of medical devices;
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 11139:2018, 3.166]

3.32

microbial reduction factor

extent to which the bioburden is reduced in tenfold increments

Note 1 to entry: It is expressed as log₁₀.

[SOURCE: ISO 11139:2018, 3.174]

3.33**microorganism**

entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: ISO 11139:2018, 3.176]

3.34**monitoring**

continual checking, supervising, critically observing, or determining the status in order to identify change from the performance level required or expected

[SOURCE: ISO 11139:2018, 3.180]

3.35**normal operation**

use of equipment in accordance with the manufacturer's instructions and with all process parameters within the specified tolerances

[SOURCE: ISO 11139:2018, 3.185]

3.36**operating cycle**

complete set of stages of a process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the operating cycle.

[SOURCE: ISO 11139:2018, 3.188]

3.37**operating pressure**

fluid pressure occurring during an operating cycle

[SOURCE: ISO 11139:2018, 3.189]

3.38**operational qualification****OQ**

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO 11139:2018, 3.220.3]

3.39**override**

system by which an operating cycle can be interrupted or modified as necessary

[SOURCE: ISO 11139:2018, 3.191]

3.40**performance qualification****PQ**

process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

Note 1 to entry: The performance qualification for washer-disinfectors relates to the number of items cleaned and disinfected to the required standard.

[SOURCE: ISO 11139:2018, 3.220.4, modified – Note 1 to entry has been added]