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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

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Foreword

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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 for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-1:2006), which has been technically revised. It also incorporates ISO 15883-1:2006/Amd 1:2014.

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

~~— incorporation of ISO 15883-1:2006/Amd1:2014;~~

— alignment of 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 15883-5:2021~~;~~

— 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 (see Reference [48]);

— 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.

Introduction

This document is the first part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (WDs) and specifies the general requirements for performance applicable to all ~~washer-disinfectors.~~ WDs. The requirements given in this document are applicable to all ~~washer-disinfectors~~WDs 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 ~~the~~ ISO 15883 series can include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as ~~washer-disinfectors~~WDs for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

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

In selecting the appropriate ~~washer-disinfector~~WD, references are made both to this document and to the relevant parts of ~~the~~ ISO 15883 series. It is the user's responsibility to ensure that the choice of type of ~~washer-disinfector~~WD, 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~~WD is subject to validation tests (e.g. installation qualification, operational qualification, and performance qualification on first installation) and that in use continued ~~compliance~~conformance 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~~WD and its intended use, it is noteworthy that the ISO 15883 series of standards provides no information as to whether the ~~washer-disinfectors~~WD may be used without restrictions in any of the ISO member states.

Washer-disinfectors — Part 1: General requirements, terms and definitions and tests

1 Scope

This document specifies general performance requirements for washer-disinfectors (WD) and ~~washer-disinfector~~WD 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 ~~WD~~WDs intended for use with other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

The requirements for ~~WD~~WDs intended to process specific loads are specified in ~~other parts of the~~ ISO 15883~~ series~~~~[1]~~-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7. For ~~WD~~WDs intended to process loads of two or more different types, the requirements of ~~all relevant parts of the~~ ISO 15883 ~~series~~-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7 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~~" and addressed in other standards.

The specified performance requirements of this ~~standard~~document 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~~Chemicals in ~~the choice of~~some cleaning agents and disinfectants ~~to ensure that the chemicals used do not~~ can react with ~~the~~ prion protein in a manner that can inhibit its removal or inactivation. If the presence of prion protein is considered a possibility, then this can influence the choice of cleaning agent and disinfectant.

NOTE 3 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. 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 WD 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, *Graphical symbols for use on equipment — ~~Index and synopsis~~Registered symbols*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15883-2:—[1], *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices*

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 15883-5:2021, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

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 15883-7:—[2], *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile non-critical medical devices and healthcare equipment*

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 and platinum temperature sensors*

IEC 61010-2-040:2020, *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 61326-1:2021, *Electrical equipment for measurement, control and laboratory use. EMC requirements – Part 1: General requirements*

IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

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*

[1] Under preparation. Stage at time of publication: ISO/DIS 15883-2:2023.
[2] Under preparation. Stage at time of publication: ISO/DIS 15883-7:2023.

3 Terms and definitions

For the purposes of this document, the following terms and definitions ~~given in ISO 11139 and the following~~ apply.

ISO and IEC maintain ~~terminological~~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 ~~http://www.electropedia.org/~~https://www.electropedia.org/

3.1
A_0
measure of microbiological lethality delivered by a moist heat *disinfection* (3.14) process expressed in terms of the equivalent time in seconds at 80 °C with reference to a *microorganism* (3.33) 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 (3.58) for human waste containers that additionally empties and flushes

[SOURCE: ISO 11139:2018, 3.22]

3.4
bioburden
population of viable *microorganisms* (3.33) 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

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calorifier
closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated *fluid* (3.21) through a heat exchanger

[SOURCE: ISO 11139:2018, 3.32]

3.7
chamber
part of equipment in which a *load* (3.28) 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 (3.14) 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* (3.33)

[SOURCE: ISO 11139:2018, 3.75]

3.13

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dead volume
<washer-disinfector> enclosed space of pipework which is not purged by the usual flow of liquids during the *operating cycle* (3.36)

[SOURCE: ISO 11139:2018, 3.318.2]

3.14
disinfection
process to inactivate viable *microorganisms* (3.33) 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* (3.14) efficacy is based

Note 1 to entry: Several *disinfection* (3.14) temperatures can prevail during the *disinfection* (3.14) 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)* (3.42) is/are maintained at or above that/those specified

Note 1 to entry: Examples of *process variables* (3.42) include temperature of the *load* (3.28), 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 (3.58) intended to clean and disinfect *loads* (3.28) 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

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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* (3.21)

[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* (3.21) 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* (3.25)

[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* (3.36)

[SOURCE: ISO 11139:2018, 3.155]

3.29
loading door
means of access through which a *load* (3.28) 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;

— disinfection of medical devices;

— 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;

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— 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* (3.4) is reduced in tenfold increments

Note 1 to entry: It is expressed as $\log_{10}$.

[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 (3.21) pressure occurring during an *operating cycle* (3.36)

[SOURCE: ISO 11139:2018, 3.189]

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