INTERNATIONAL STANDARD

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Second edition
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Washer-disinfectors —

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

Laveurs désinfecteurs —

Partie 4: Exigences et essais pour les laveurs désinfecteurs destinés à la désinfection chimique des endoscopes thermolabiles

Reference number
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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 15883-4:2008), which has been technically revised. The main changes compared to the previous edition are as follows:

— additional annexes for establishing endoscope type test groups and endoscope product families have been included.

A list of all the 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 introduction is intended to be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this document are intended to process devices that can be immersed in water or aqueous solutions. For some devices this will require that, prior to processing, relevant parts of the device are protected from immersion in accordance with the device manufacturer's operating instructions.

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

Safety requirements for washer-disinfectors are given in IEC 61010-2-040.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfector and its intended use, 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 provides no information as to whether the washer-disinfectors can be used without restriction in any of the ISO member states.

Washer-disinfectors —

Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes

1 Scope

This document specifies the particular requirements, including performance criteria for washer-disinfectors (WD) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This document also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which can be required to achieve the necessary performance criteria.

The methods, instrumentation and instructions required for type testing, works testing, validation (installation, operational and performance qualification on first installation), routine control and monitoring, and requalification of WD periodically and after essential repairs, are also specified.

NOTE 1 In addition, Annex A gives guidance on an appropriate division of responsibility for the range of activities covered by this document.

NOTE 2 WD complying with this document can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended and validated this method of disinfection.

WD complying with the requirements of this document are not intended for cleaning and disinfection of medical devices, including endoscopic accessories, which are heat stable and can be disinfected or sterilized by thermal methods (see ISO 15883-1:2006+Amd 1:2014, 4.1.5).

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

NOTE 3 If it is considered that prion protein might 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 and/or other protein in a manner that can inhibit its removal or inactivation from the load or washer-disinfector.

NOTE 4 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of the WD, manufacturers of endoscopes, cleaning products, and disinfecting products.

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

ISO 15883-1:2006+Amd 1:2014, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

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

IEC 61010-2-040, *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*

EN 12353, *Chemical disinfectants and antiseptics — Preservation of test organisms used for the determination of bactericidal (including Legionella), mycobactericidal, sporicidal, fungicidal and virucidal (including bacteriophages) activity*

EN 13727, *Chemical disinfectants and antiseptics — Quantitative suspension test for the evaluation of bactericidal activity in the medical area — Test method and requirements (phase 2, step 1)*

3 Terms and definitions

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

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

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
air break
physical separation in water supply pipes to prevent back flow from equipment

[SOURCE: ISO 11139:2018, 3.8]

3.2
analyte
chemical substance that is the subject of chemical analysis

[SOURCE: ISO 11139:2018, 3.12]

3.3
block
<endoscope> group of channels comprising part of an endoscope with specified lengths, diameters and interconnections

[SOURCE: ISO 11139:2018, 3.30]

3.4
channel separator
<endoscope> device used to keep apart interconnected fluid pathways

EXAMPLE A device inserted in a trumpet valve cylinder where multiple channels meet in order to separate the air and water pathways in the air/water valve assembly.

[SOURCE: ISO 11139:2018, 3.40]

3.5
colony forming unit
CFU
visible aggregation of microorganisms arising from a single cell or multiple cells

[SOURCE: ISO 11139:2018, 3.53]

3.6
disinfecting agent
physical or chemical agent used for disinfection

[SOURCE: ISO 11139:2018, 3.83]

3.7
disinfection
process to inactivate viable microorganisms to a level previously specified as appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.8
endoscope connector
device to interface with the fluid entry port of a channel of an endoscope that, where applicable, includes the tubing connected to the channel irrigation system of the washer-disinfector

[SOURCE: ISO 11139:2018, 3.94]

3.9
endoscope leak test
set of actions to identify a loss of integrity

Note 1 to entry: The test is intended to establish that the surface covering the device and/or lining a device channel is intact to the extent necessary to maintain a slightly positive pressure.

[SOURCE: ISO 11139:2018, 3.95, modified — Note 1 to entry has been added.]

3.10
endoscope port
part of an endoscope to which the irrigation system of the washer-disinfector is connected to irrigate all or part of a channel

[SOURCE: ISO 11139:2018, 3.96]

3.11
endoscope product family
group of endoscopes with comparable design, including the number, construction and purpose of the different endoscope channels

[SOURCE: ISO 11139:2018, 3.97]

3.12
endoscope surrogate device
item designed to represent construction elements of endoscope specific characteristics affecting the flow conditions in endoscope channels

Note 1 to entry: Elements can include channel length and diameter, connectors, channel separators, port closures, return valves, etc.

[SOURCE: ISO 11139:2018, 3.98]

3.13
endoscope type test group
endoscopes for which the general channel design and specific characteristics affecting the flow conditions in the endoscope are similar

Note 1 to entry: The general channel design includes lengths and diameters. Characteristics affecting the flow conditions in the endoscope are, for example, connectors, channel separators, port closures, return valves.

Note 2 to entry: Similar implies that small variations can be possible. Endoscopes that show small variations in channel specifications that do not lead to a significant variation in the flow and pressure characteristic through the channels could be in the same endoscope type test group.

[SOURCE: ISO 11139:2018, 3.99]

3.14
inoculated carrier
supporting material on or in which a specified number of viable test microorganisms has been deposited

[SOURCE: ISO 11139:2018, 3.144]

3.15
irrigation plan
<endoscope washer-disinfector> stipulated direction of flow of process fluids through the specified channels of an endoscope

[SOURCE: ISO 11139:2018, 3.148]

3.16
liquid transport systems
<washer-disinfector> components of equipment used to store, pump or transport water and/or solutions, excluding pipework before the air break

[SOURCE: ISO 11139:2018, 3.154]

3.17
microbial inactivation factor
measured change in microbial population caused by the lethal effect of the disinfection or sterilization process

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

[SOURCE: ISO 11139:2018, 3.173]

3.18
microbial reduction factor
extent to which the bioburden is reduced in tenfold increments

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

Note 2 to entry: This can be caused by the combination of the microbial inactivation factor and the physical removal of microorganisms.

[SOURCE: ISO 11139:2018, 3.174, modified — Note 2 to entry has been added.]

3.19
microbial resistance
ability of a microorganism or population of microorganisms to withstand a microbial reduction process

Note 1 to entry: This refers to resistance of microorganisms to disinfectants used in a WD.

[SOURCE: ISO 11139:2018, 3.175, modified — Note 1 to entry has been added.]

3.20
minimum effective concentration
MEC
lowest concentration of a chemical or product, used in a specified process, that achieves a claimed activity

[SOURCE: ISO 11139:2018, 3.177]

3.21
minimum recommended concentration
MRC
lowest concentration of a chemical or product specified for use in a process

[SOURCE: ISO 11139:2018, 3.178]

3.22
obstruction
<endoscope channel> partial or complete blockage

[SOURCE: ISO 11139:2018, 3.187]

3.23
port closure
<endoscope> device to close an endoscope port during processing in order to maintain the flow of process fluids throughout the length of the endoscope

EXAMPLE To close the suction valve port.

[SOURCE: ISO 11139:2018, 3.198]

3.24
self-disinfection cycle
operating cycle intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting and rinsing the load

Note 1 to entry: The self-disinfection cycle is used without a load in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.249]

3.25
thermolabile
readily damaged by heat

[SOURCE: ISO 11139:2018, 3.302]

3.26
washer-disinfector accessory
items or attachments, including connectors, required to process a medical device in a washer-disinfector

[SOURCE: ISO 11139:2018, 3.320]

4 Performance requirements

4.1 General

4.1.1 The WD shall conform to ISO 15883-1:2006+Amd 1:2014 with the exception of the following subclauses:

a) 4.2.3 (washing stage, modified by 4.3.3 of this document);

b) 4.3.1 (specification for thermal disinfection of the load carrier and chamber walls during a standard cleaning and disinfection cycle is not applicable to this document);

c) 4.3.3 (chemical and thermal disinfection, modified by 5.4 of this document);

d) 5.3.2.5 (microbial quality of final rinse water, modified by 4.5 of this document);

e) 5.11.4 (process verification, modified by 5.6 of this document);

f) 6.4.2.1 (test for quality of final rinse water – sampling, modified by 6.3 and Annex E of this document);

g) 6.5.6 (test for chamber venting to prevent pressurization by steam is not applicable to this document);

h) 6.8.2 (load temperature test, modified by 6.9.1 of this document);

i) 6.8.3 (chamber wall temperature test, replaced by 6.9.1 of this document);

j) 6.10.2 (cleaning efficacy test 1; modified by 6.11 of this document).

Means shall be provided to position temperature sensors for test purposes. Depending on the type of washer design the manufacturer can decide to follow ISO 15883-1:2006+Amd 1:2014, 5.1.11 or provide an alternative solution better fit to the purpose.

4.1.2 Each device, including any device channels and/or cavities, shall be processed by the WD as follows:

a) leak testing (where appropriate) in accordance with 4.2;

b) cleaning (which may include several stages) in accordance with 4.3;

c) disinfecting in accordance with 4.4;

d) final rinsing in accordance with 4.5;

e) purging of rinse water in accordance with 4.6;

f) drying (when appropriate) in accordance with 4.7.

4.1.3 After the complete process in the WD the endoscope shall be safe for its intended use. The combination of the cleaning, disinfection and rinsing process shall be designed to achieve this condition, recognizing the high level of microbial and other contamination that might exist, see References [33], [34] and [35]. It shall be necessary to take into account other factors such as the design of connectors. This capability shall be demonstrated during type testing for endoscopes that the WD is designed to process [see also 8 a), 8 b) and 8 c)].

Where the disinfection of the water supplied to the WD is performed by adding a low dosage of a disinfectant to the water, compliance with this document shall be demonstrated with and without the water disinfectant. Any variation in water disinfectant concentration due to local environmental conditions that might change the result of the test shall be taken into account.

Demonstration of the capability of the complete cycle efficacy shall be provided during additional type testing by employing a modification of the methods described in Annex B with added test soil and/or ISO/TS 15883-5:2005, Annex I, using the organism(s) previously established during *in vitro* tests as most resistant to the disinfectant under in-use conditions and on endoscopes that are representative for each relevant endoscope type test group [see 8 a) and Annex H].

According to the nature of the most resistant microorganism selected the minimum $\log_{10}$ reduction obtained after a complete standard cycle for that microorganism(s) shall be:

— 9 $\log_{10}$ for vegetative bacteria;

— 6 $\log_{10}$ for fungal spores;

— 6 $\log_{10}$ for mycobacteria; or

— 4 $\log_{10}$ for bacterial endospores.

NOTE 1 In order to limit the work load the type tests can be performed on representative endoscopes from endoscope type test groups (see Annex H to establish relevant endoscope type test groups).

NOTE 2 The efficacy of the process (including cleaning and disinfection) depends on a number of factors which include:

a) the nature (characteristics) of the device being processed;

b) the extent and nature of the soiling to be removed;

