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Washer-disinfectors —

Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy

Laveurs désinfecteurs —

Partie 5: Exigences de performance et critères des méthodes d'essai pour démontrer l'efficacité du nettoyage

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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).

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This first edition of ISO 15883-5 cancels and replaces ISO/TS 15883-5:2005, which has been technically revised. The main changes compared to the previous edition are as follows:

— new and previous terms and definitions were harmonized with ISO 11139:2018;

— considerations for selection of an appropriate test soil and test load have been included;

— performance requirements to demonstrate cleaning efficacy of a washer-disinfector were consolidated and specified;

— cleaning efficacy test and acceptance criteria for the type test and performance qualification test have been specified for a variety of analytes;

— alert and action levels were introduced for analytes to facilitate interpretation of cleaning validation data;

— examples of test soils relevant to certain procedures, as referenced in published literature, and suitable assay methods for detection or quantification of certain soil residuals have been included in Annex A;

— the immersion test protocol resulting from interlaboratory tests to evaluate cleaning performance of a protein-based test is specified in Annex B, together with examples of worksheets to assist laboratories performing the test in an Annex E;

— examples of protein detection methods were revised and transferred across from ISO 15883-1:2006 to informative Annex C;

— examples of haemoglobin detection methods were added to informative Annex D;

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— extensive 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.

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Introduction

Testing of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector (WD). This testing includes type testing under simulated use conditions. In addition to type testing, performance qualification testing is performed under clinical use conditions.

The cleaning efficacy of washer-disinfectors has historically been demonstrated by referring to different test soils and methods that have been used in several different countries. This document gives requirements for standardized methods for demonstration of cleaning efficacy, including examples of test soils. The individual requirements for the various types of washer-disinfectors and processing procedures can vary, but this document provides the basis for the demonstration of cleaning efficacy.

Cleaning efficacy testing is performed in the WD and with associated accessories in two phases:

— type testing, under simulated use conditions, with defined test soils and their analytes, soiling methods and test surfaces/medical devices/product representative of design and intended applications;

— performance qualification testing under clinical conditions with load(s) that are soiled with the most challenging soil from clinical use.

This document excludes the verification of cleaning of product that could have been exposed to prions, the causative agent in transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD).

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Washer-disinfectors —

Part 5:
Performance requirements and test method criteria for demonstrating cleaning efficacy

1 Scope

This document specifies procedures and test methods used to demonstrate the cleaning efficacy of washer-disinfectors (WD) and their accessories intended to be used for cleaning of reusable medical devices.

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

NOTE 2 This document does not apply to the activities to be performed by the manufacturers of reusable medical devices.

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-5, *Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity*

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

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 https://www.iso.org/obp

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

3.1
action level
value from monitoring that necessitates immediate intervention

[SOURCE: ISO 11139:2018, 3.5]

1) Under preparation. Stage at the time of publication: ISO/DIS 15883-1:2020.

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3.2
alert level
value from monitoring providing early warning of deviation from specified conditions

[SOURCE: ISO 11139:2018, 3.11]

3.3
analyte
chemical substance that is the subject of chemical analysis

[SOURCE: ISO 11139:2018, 3.12]

3.4
clean
visually free of soil and below specified levels of *analytes* (3.3)

[SOURCE: ISO 11139:2018, 3.45]

3.5
clinical use
use of a health care product during a procedure on a patient

Note 1 to entry: This encompasses all steps prior to processing in a WD.

[SOURCE: ISO 11139:2018, 3.49, modified – Note 1 to entry has been added]

3.6
load
product, equipment, or materials to be processed together within an operating cycle

[SOURCE: ISO 11139:2018, 3.155]

3.7
product
tangible result of a process

EXAMPLE Raw material(s), intermediates(s), sub-assembly(ies), health care product(s)

[SOURCE: ISO 11139:2018, 3.217]

3.8
rinsing
removing process residues through displacement by, and dilution with, water

[SOURCE: ISO 11139:2018, 3.237]

3.9
simulated use
use that mimics the intended use of the medical device

3.10
soil
natural or artificial contamination on a device or surface following its use or simulated use

[SOURCE: ISO 11139:2018, 3.257]

3.11
surrogate product
item designed to represent product in process simulations and which is comparable with the actual product

[SOURCE: ISO 11139:2018, 3.291]

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3.12
test soil
formulation designed for use as a substitute for a contaminant or debris found on a device after use

[SOURCE: ISO 11139:2018, 3.300]

3.13
washing
removal of contaminants from surfaces by means of an aqueous fluid

[SOURCE: ISO 11139:2018, 3.321]

4 Performance requirements

4.1 General

4.1.1 In addition to the requirements below (see 4.1.3 to 4.1.5), the relevant cleaning performance requirements of the subsequent parts of ISO 15883 that apply to the washer-disinfector type shall apply.

4.1.2 In addition to the tests specified in 4.1.4 and 4.1.5), the relevant cleaning tests of the subsequent parts of ISO 15883 that apply to the washer-disinfector type shall apply.

NOTE See for example ISO 15883-7[5].

4.1.3 The process conditions for cleaning, e.g. stages, temperatures, pressure, flow, process chemicals, quality and quantity of water, used to confirm conformance of the WD with the requirements of this standard shall be defined in accordance with ISO 15883-1:—, 4.1.12 and 8.2 b).

NOTE Refer to ISO 15883-1:—, 5.23 and ISO 15883-4 [4] for water quality.

4.1.4 Tests of cleaning efficacy shall be performed on the defined cleaning stages, including, where appropriate, flushing, rinsing, etc. (see 5.2). Cleaning stages shall be specified according to ISO 15883-1:—, 4.1. It shall be verified and documented that the full cleaning stage does not interfere with analyte detection. During tests of cleaning efficacy, the WD shall be operated without any disinfection or drying stage and should not affect the efficacy and safety of the WD process.

4.1.5 Cleaning efficacy testing shall be performed in the WD and with accessories specified for the particular load in two phases:

a) type testing under simulated use conditions with defined test soil(s), including the analyte(s) and representative test load(s) (see 4.4.1),

b) performance qualification testing with worst-case load(s) soiled by clinical use (see 4.4.1), or if justified (5.4.2), with surrogate product.

4.2 Test soil considerations

4.2.1 The rationale for the choice of test soil(s) and soiling method(s) shall be justified and documented. Test soil formulations may be chosen or developed based on a review of the literature and demonstration of its relevance based on the use of the medical device/product in clinical practice (see Annex A and the Bibliography).

NOTE The test soils for the load, chamber walls and load carriers can be different.

4.2.2 The protein-based test soil shall conform to the performance criteria specified in B.2.

NOTE Sample result sheets for data entry are provided in Annex E.

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