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Washer disinfectors —

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

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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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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 *[for Project Committee]* ISO/TC 198, *Sterilization of health care products*.

This first edition cancels and replaces ISO/TS 15883-5:2005.

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

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 and can be confirmed by performance qualification testing under clinical conditions.

Cleaning efficacy of washer-disinfectors has traditionally been demonstrated by referring to different test soils and methods that had been used in several different countries. This part of ISO 15883 recommends the methods, including examples of test soils, to standardize these requirements. The individual requirements for the various types of washer-disinfectors and device reprocessing applications 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, soiling methods and test surfaces/devices representative of design and intended applications;

— performance qualification testing under clinical conditions with load(s) soiled by the most challenging load to be processed in normal practice.

NOTE This standard currently excludes the verification of cleaning of devices that might have been exposed to prions, the causative agent in transmissible spongiform encephalopathies such as Creutzfeldt-Jakob disease (CJD).

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 re-usable medical devices and other items used in medical, dental, pharmaceutical and veterinary practice.

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 15883-1:2006/Amd1:2014, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests (under review)*

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*

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

Note 1 to entry: This is the maximum value of analyte not to be exceeded.

[SOURCE: ISO 11139:2018, 3.5, modified — Note 1 to entry has been added.]

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

Note 1 to entry: This is the target value of analyte.

[SOURCE: ISO 11139:2018, 3.11, modified — Note 1 to entry has been added.]

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

[SOURCE: ISO 11139:2018, 3.45]

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

[SOURCE: ISO 11139:2018, 3.49]

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

[SOURCE: ISO 11139:2018, 3.155]

3.7
soil
natural or artificial contamination on a device or surface following its use or simulated use

[SOURCE: ISO 11139:2018, 3.257]

3.8
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]

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 below, (see 4.1.4 to 4.1.5), the relevant cleaning tests of the subsequent parts of ISO 15883 that apply to the washer-disinfector type shall apply.

4.1.3 The conditions for cleaning, e.g. stages, temperatures, pressure, flow, chemicals, quality and quantity of water, used to confirm conformance of the WD with the requirements of this standard shall be defined.

NOTE Refer to ISO 15883-1:2006/Amd1:2014, 5.23 for water quality.

4.1.4 For each specified cleaning stage, e.g. for different load(s), tests for cleaning efficacy shall be performed (see 5.2.1). During tests of cleaning efficacy, the WD shall be operated without any disinfection or drying stage.

If parts of the disinfection cycle are considered important for adequate cleaning (e.g. for rinsing), then it shall be verified that this does not interfere with analyte detection, and should not affect the efficacy or 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).

4.2 Test soil considerations

4.2.1 The rationale for the choice of test soil and soiling method 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 devices in clinical practice. (See Annex A and Bibliography.)

4.2.2 The test soil shall conform to the performance criteria specified in Annex B.

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

4.2.3 The choice of test soil, its method of application, and conditioning (e.g. drying) shall simulate worst-case clinical use conditions of the devices.

a) Composition of the test soil shall include at least the concentration of analyte(s) representative of tissues/fluids, and if applicable, any associated procedural material(s) used on the device(s) during its clinical use, that are intended to be cleaned (e.g. contrast media, lubricants, cements, etc.).

b) The method of test soil application shall simulate the conditions of use of the device(s), for example, cauterization or heating that present a greater challenge to cleaning, and/or pressure gradients that may facilitate the penetration of material into various parts of the device(s). Parts of the device identified as the most difficult to clean shall be soiled (see 4.3).

c) After soiling of the device(s), consideration shall be given to transport and dwell time conditions (e.g. temperature, time, humidity) for the device(s) from point of use to place of reprocessing, and if applicable, any pre-treatment.

4.2.4 The method of test soil extraction (recovery) from devices, extraction efficiency, and detection of analytes shall be validated.

NOTE An appropriate percent recovery is greater than 50%, unless otherwise justified (see 5.1.3.2).

4.3 Load considerations

Load(s), including their respective devices that represent typical and worst-case, clinical-use conditions, shall be defined and justified. Such load(s) shall be used for cleaning efficacy and process residual type testing and performance qualification tests [see also ISO 15883-1:2006/Amd1:2014, 8.1b)]. The load(s) shall be considered appropriate for the type of washer-disinfector being tested.

NOTE These devices can be surrogate devices, which could be used for some tests if they are shown to be representative of the prescribed load.

Consideration shall be given to any applicable physical characteristics of the device type(s) and patient contact area, including but not restricted to:

— lumens;

— valves;

— crevices;

— hinges and joints;

— rough and irregular surfaces;

— material composition, including porosity;

— junctions and dead ends;

— internal moveable parts (e.g. cables).

These design characteristics are at a greater risk of accumulation and retention of soil and shall be considered in the estimation of cleaning efficacy of the entire device.

Any necessary pre-treatment of the device(s), e.g. manual pre-cleaning or disassembly shall be included as part of the test procedure.

4.4 Cleaning efficacy test criteria

4.4.1 General

Cleaning efficacy shall be determined by visual examination (see 4.4.2) and by the quantitative detection of protein (see Note 1). If applicable, at least one other validated quantitative analytical test method shall be used to measure another analyte(s) in addition to protein.

NOTE 1 A validated qualitative method can be used for performance qualification and routine testing when the detection level of this method is below the alert or action level assay criteria given in 4.4.3.

NOTE 2 Non-invasive devices, such as those that do not penetrate inside the body, either through a body orifice or through the surface of the body, might only require visual examination. Some non-invasive devices can represent higher levels of risk e.g. infant formula bottles, contact tonometers.

NOTE 3 Typical analytes are given in 4.4.3.3 (also see Bibliography).

NOTE 4 Refer to ISO I4971:2007 [3] for approach to risk assessment to support justification.

4.4.2 Visual examination

Visual examination shall demonstrate the absence of visible soil on all observable surfaces of the load(s), including device(s) following cleaning stage(s). This requirement does not apply where visual inspection of the surfaces of the device is not possible due to its configuration.

NOTE Adequate visual inspection requirements can include:

— defined instructions for inspection;

— adequate illumination;

— inspection aids, if applicable (e.g. gross magnification, boroscope);

— viewing distance.

Refer to EN 13018 [7] for additional information on visual inspection.

4.4.3 Assay criteria

4.4.3.1 General

Acceptance criteria for analytes may be specified in terms of both an alert level and an action level.

The alert and action levels for protein and other analytes are specified in 4.4.3 and 4.4.4. Their action levels are the maximum criteria for acceptable cleaning efficacy during testing, but the desired criteria are given as the alert levels. If values are detected between the alert and action levels they shall be investigated and considered to pass cleaning requirements, if justified.

For the purpose of meeting the requirements of ISO 15883-1, the action level shall be used.

4.4.3.2 Protein assay criteria

The alert and action level criteria for the protein assay are:

— Alert level, ≥3 µg/cm^2.

— Action level, ≥6,4 µg/cm^2

The maximum acceptable level of protein on a cleaned device shall be lower than the action level (see references[14],[27],[48],[52],[59]) for each sample, as justified.

NOTE 1 Protein detection methods can include those specified in Annex C, or as otherwise validated.

NOTE 2 Alert and action levels relate to cleaning efficacy and performance and not necessarily clinical risk. Clinical actions in response to adverse performance will depend on the types of instruments, procedures and patient risk factors.

4.4.3.3 Assay criteria for other analytes

Other analytes and their acceptable levels, if used, on a cleaned device, include:

a) Total organic carbon (TOC)

1) Alert level ≥ 6 µg/cm^2 (see reference[59])

2) Action level ≥ 12 µg/cm2 (see reference[44])

NOTE TOC is the quantity of carbon present in organic matter and determined as non-purgeable organic carbon.

b) Carbohydrate

1) Alert level ≥ 0,9 µg/cm^2

2) Action level, ≥ 1,8 µg/cm2 (see references,[14],[15] and[27])

c) Haemoglobin

1) Alert level, ≥ 1,0 µg/cm2 (see reference[49])

2) Action level, ≥ 2,2 µg/cm2 (see references,[13],[14],[15] and[27])

d) ATP

1) Alert level, ≥ 10 femtomoles of ATP/cm2 (see references[17] and[62])

2) Action level, ≥ 22 femtomoles of ATP/cm2 (see references[16],[17] and[20])

NOTE Conversion of RLU to femtomoles can be obtained from the specific ATP monitoring equipment supplier.

e) Endotoxin

1) Alert level, ≥ 2,2 EU/cm2 (see reference[14])

2) Action level, ≤20 EU/device (see references[71] and[72])

NOTE The recommended endotoxin levels are ≤20 EU/device for implants and blood-contacting devices, and ≤2.15 EU/device for a product having intrathecal patient contact (see references[5] and[72]).

4.4.4 Process residuals

The cleaning stage(s), including any post-washing rinse(s) shall not leave any process residuals on the load that are potentially harmful during subsequent use or impair the following process stages (see 5.5).

NOTE Refer to process chemicals in ISO 15883-1:2006/Amd1:2014, 4.6.

5 Testing for conformity

5.1 Cleaning test method validation

5.1.1 General

The cleaning test methods employed for both type testing (see 5.3) and performance qualification testing (see 5.4) shall be validated.

NOTE 1 Cleaning test method includes the test soil, soiling method, recovery method, and endpoint analysis.

NOTE 2 ISO 17025 [6] requires test assay methods to be validated. Other references, such as ASTM E-2857,[8] pharmacopoeias,[67] -[70] ICH guidelines,[38] give guidance on requirements for the validation of various types of analytical test methods.

5.1.2 Load soiling method

5.1.2.1 The load soiling method, including its application and any treatment, shall simulate an equivalent challenge to the WD cleaning stage as that presented by worst-case clinically soiled load(s), including the specified load carrier (see 4.2.3 and 5.2.1).

5.1.2.2 The load soiling method shall specify any conditioning, to include drying of soiled devices for a defined time, temperature and humidity that will represent the use of the device(s) being processed in the WD.

NOTE Refer to Köhnlein et al. 2008 [41] as an example for conditioning.

5.1.3 Detection method(s)

5.1.3.1 The level of detection, either directly or by extraction shall be determined for each analyte and each method used for cleaning validation studies.

5.1.3.2 The test soil recovery efficiency shall be determined and an appropriate correction factor applied (see 4.2.4).

NOTE ISO 11737-1 [2] gives examples of methods of ascertaining bioburden recovery efficiencies and application of bioburden correction factors. These principles and general methods can also be applied regarding test soil recovery.

5.1.3.3 Negative and positive controls shall be conducted to exclude interference of process conditions with the detection method (see 5.2.2).

5.1.4 Analyte assay method

The chosen analyte assay method shall be validated for each analyte used for cleaning validation studies.

