ISO/FDIS 15883-2~~:2024(E)~~

ISO/TC 198~~/WG 13~~

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Washer-disinfectors~~—~~ —

Part 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

Laveurs désinfecteurs —

Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des dispositifs médicaux critiques et semi-critiques

FDIS stage

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Contents

Foreword

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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 and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-2:2006), which has been technically revised.

The main changes are as follows:

— change of title to reflect application to critical and semi-critical medical devices;

— addition of new terms defining critical and semi-critical medical devices, and non-critical devices;

— alignment of other terms and definitions with ISO 11139:2018+Amd 1:2024;

— revision of cross-references to relevant clauses in ISO 15883--1:—[1]:2024 and ISO 15883-5:2021;

— the upper limit of the washing temperature band reduced to +5 °C;

— addition of a clause on water quality (see 4.54.5););

[1] Under preparation. Stage at the time of publication: ISO/FDIS 15883-1.

— ~~—~~clarification of requirements for lumen and powered devices (see 5.1~~5.1);~~);

— ~~—~~addition of informative Annex B~~Annex B~~ providing guidance on assigning a medical device to a product family for cleaning and thermal disinfection processes;

— ~~—~~revision of references in 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 second part of the ISO 15883 series of standards specifying the performance of washer-disinfectors (~~WD~~WDs) and the general requirements for performance applicable to instrument ~~WD~~WDs. The requirements given in this document apply to ~~WD~~WDs used for cleaning and thermal disinfection of critical and semi-critical medical devices intended for reuse such as:

— ~~—~~surgical instruments, which are divided into instrument product families based on design features, e.g. instruments without hinges, cavities or lumens, with hinges, with sliding shafts, with lumens, microsurgical instruments, and complex instruments (e.g. robotic);

— ~~—~~powered instruments;

— ~~—~~anaesthetic and respiratory equipment;

— ~~—~~medical devices ~~comprised of~~comprising glass components;

— ~~—~~any non-critical devices used in conjunction with critical and semi-critical medical devices.

Requirements for ~~WD~~WDs for other applications, such as for processing non-critical devices and thermolabile endoscopes, are specified in other parts of the ISO 15883 series of standards.

When processed in the WD, the medical devices can be intended for immediate use or can be intended for further processing. In both cases, the efficacy of the cleaning and disinfection is of major importance. In either case, this is for the well-being of the patient. In the latter case, it is also for the safety of the staff who handles the instruments in the process of inspection, testing and packing as well as ensuring that the sterilization process is not unduly challenged by residual soil.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. Users should be aware that some medical devices can require pre-treatment, e.g. soaking, brushing, ultrasonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical device instructions for reprocessing (see also the ISO 17664 series).

Safety requirements for ~~WD~~WDs are given in IEC 61010-2-040.

NOTE Local or national regulations can apply in respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the WD and its intended use.

Washer-disinfectors—- —

Part 2:
Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices

1 Scope

This document specifies requirements for washer-disinfectors (~~WD~~WDs) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of reusable critical and semi-critical medical devices, such as surgical instruments, anaesthetic equipment, and any non-critical devices used in conjunction with critical and semi-critical medical devices, such as bowls, dishes and receivers, utensils and glassware.

This document is intended to be used in conjunction with the general requirements specified in ISO 15883-- 1:—[2]:2024, except those specified in 4.1.1~~4.1.1.~~

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

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 4017, *Fasteners — Hexagon head screws — Product grades A and B*

ISO 5356-- 2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5361, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors*

ISO 5362, *Anaesthetic and respiratory equipment — Anaesthetic reservoir bags*

ISO 5367, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 15883-- 1:—;:2024, *Washer-disinfectors — Part 1: General requirements, terms and definitions and tests*

ISO 17664-- 1:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices*

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

EN 10088-- 2, *Stainless steels — Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

[2] ~~Under preparation. Stage at the time of publication: ISO/FDIS 15883-1.~~

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15883-1:2024 and the following apply.

ISO and IEC maintain 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 https://www.electropedia.org/

3.1
access device
means by which entry to restricted parts of equipment is achieved.

Note 1 to entry: this This can be by dedicated key, code or tool.

[SOURCE: ISO 11139:2018, 3.4]

3.2
critical medical device
<washer-disinfector> item processed in a washer-disinfector, intended to be introduced directly into, or have contact with, the vascular system or normally sterile areas of the body

EXAMPLE Surgical instruments.

Note 1 to entry: Critical items usually require sterilization before use.

Note 2 to entry: National regulations can use alternative wording for this term.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.333]

3.3
non-critical device
<washer-disinfector> item processed in a washer-disinfector, whose surface(s) are intended to contact intact skin of a body but do not penetrate it, or device not intended for direct patient contact

EXAMPLESEXAMPLE Blood pressure cuffs, wheelchairs, trays, bowls, dishes, glassware, receivers, containers for transit.

Note 1 to entry: National regulations can use alternative wording for the definition of this term when applied to medical devices.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.357]

3.4
powered device
<washer-disinfector> surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

Note 1 to entry: The power applied to the driven instrument can be mechanical (from a motor, either through direct coupling, flexible axle, or belt) or by the flow of a pressurized fluid or compressed air.

EXAMPLESEXAMPLE Dental hand pieces, orthopaedic saws, and drills.

[SOURCE: ISO 11139:2018, 3.199]