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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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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.

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).