INTERNATIONAL STANDARD

ISO 15883-4

First edition
2008-05-01

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
ISO 15883-4:2008(E)

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15883-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

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

— *Part 5: Test soils and methods for demonstrating cleaning efficacy*

Introduction

It is recommended that this introduction be read in conjunction with the introduction to ISO 15883-1.

The washer-disinfectors specified in this part of ISO 15883 are intended to process devices which 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 15883 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.

With respect to the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors:

a) note that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force;

b) this part of ISO 15883 provides no information as to whether the washer-disinfectors may be used without restriction in any of the member states of the EU or EFTA.

Washer-disinfectors —

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

1 Scope

This part of ISO 15883 specifies the particular requirements, including performance, for washer-disinfectors (WDs) that are intended to be used for cleaning and chemical disinfection of thermolabile endoscopes.

This part of ISO 15883 also specifies the performance requirements for the cleaning and disinfection of the washer-disinfector and its components and accessories which may be required to achieve the necessary performance.

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 re-validation, 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 part of ISO 15883.

NOTE 2 WDs complying with this part of ISO 15883 can also be used for cleaning and chemical disinfection of other thermolabile re-usable medical devices for which the device manufacturer has recommended this method of disinfection.

WDs complying with the requirements of this part of ISO 15883 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, 4.1.5).

The specified performance requirements of this part of ISO 15883 may 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 disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation from the load or washer-disinfector.

This part of ISO 15883 can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of WD manufacturers of endoscopes, cleaning products, disinfecting products, and also by users.

2 Normative references

The following referenced documents are indispensable for the application 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 11731-2, *Water quality — Detection and enumeration of Legionella — Part 2: Direct membrane filtration method for waters with low bacterial counts*

ISO 15883-1:2006, *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*

3 Terms and definitions

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

3.1
air break
physical separation in water supply pipes to prevent back syphonage into the water supply from a device connected to it

NOTE See EN 1717.

3.2
inoculated carrier
supporting material on or in which a defined number of viable test organisms has been deposited

[ISO 11138-1:2006, definition 3.10]

3.3
leak test
test 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

3.4
liquid transport systems
those components of the washer-disinfector used to store, pump or transport water and/or solutions within the washer-disinfector, excluding pipework before the air break

3.5
microbial inactivation factor
measured change in microbial population, expressed as $\log_{10}$, caused by the lethal effect of the disinfectant

3.6
microbial reduction factor
measured change in microbial population expressed as $\log_{10}$ caused by the combination of the microbial inactivation factor and the physical removal of microorganisms

3.7
obstruction
partial or complete blockage