
Washer-disinfectors —

Part 6:

**Requirements and tests for
washer-disinfectors employing thermal
disinfection for non-invasive, non-critical
medical devices and healthcare
equipment**

Laveurs désinfecteurs —

*Partie 6: Exigences et essais pour les laveurs désinfecteurs utilisant
une désinfection thermique pour les dispositifs médicaux non invasifs,
non critiques et pour l'équipement de soins de santé*



Reference number
ISO 15883-6:2011(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 15883-6 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* [Technical specification]
- *Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment*

Introduction

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

This part of ISO 15883 is the sixth of a series specifying the performance of washer-disinfectors and specifies the particular requirements for performance applicable to general-purpose washer-disinfectors. Its requirements apply to washer-disinfectors used for the cleaning and disinfection of non-invasive and non-critical reusable medical devices (i.e. not penetrating skin or contacting mucosal surfaces) and for other items for use without further treatment in healthcare settings. Such reusable items need to be cleaned and disinfected, but their processing in a washer-disinfector for surgical instruments (see ISO 15883-2), for human waste containers (see ISO 15883-3) or for endoscopes (see ISO 15883-4) is inappropriate and/or impractical.

Some examples are

- non-invasive medical devices,
- washbowls,
- cleaning equipment (buckets),
- footwear,
- container systems used to transport medical devices, including trolleys and transport carts, and
- bedsteads, wheelchairs, aids for the disabled.

Fields of application within the scope of ISO 15883 include laboratory, veterinary and dental use, and other specific applications such as washer-disinfectors for 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.

The efficacy of disinfection can be impaired if soil removal is incomplete before the start of the disinfection process. It is desirable that manufacturers of washer-disinfectors be very clear about the items that can be processed in the washer-disinfector, and that reference be made to the instructions for reprocessing provided by the manufacturer of the items to be processed.

In respect of the potential adverse effects on the quality of water intended for human consumption caused by the washer-disinfectors, it is noteworthy that

- a) until verifiable international criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfectors remain in force, and
- b) the ISO 15883 series of standards provides no information as to whether the washer-disinfectors may be used without restriction in any of the ISO member states.