
Washer-disinfectors —

Part 2:

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

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Laveurs désinfecteurs —

*Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la
désinfection thermique des instruments chirurgicaux, du matériel
d'anesthésie, des récipients, des ustensiles et de la verrerie, etc.*



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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 15883-2 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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]

Introduction

It is recommended that this Introduction be read in conjunction with the introduction to ISO 15883-1:2006.

This part of ISO 15883 is the second of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to instrument washer-disinfectors. The requirements given in this part apply to washer-disinfectors used for cleaning and thermal disinfection of medical devices intended for re-use such as:

- surgical instruments;
- powered devices;
- instrument trays;
- instruments for minimally invasive surgery;
- lumen devices and tubing;
- rigid endoscopes;
- anaesthetic and respiratory equipment;
- bowls, dishes and receivers;
- glassware;
- containers for transit.

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Fields of application within the scope of the ISO 15883 series of standards 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 the ISO 15883 series of standards.

When processed in the instrument washer-disinfector, the medical devices might be intended for immediate use or might be intended for packing and sterilization. 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 might require pre-treatment e.g. soaking, brushing, ultra sonic pre-cleaning, lumen irrigation or any combination of these techniques. Reference should be made to the medical manufacturer's instructions for reprocessing (see also ISO 17664).

Safety requirements for washer-disinfectors are given in IEC 61010-2-045.

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

- a) it should be noted 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) the ISO 15883 series of standards 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.

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Washer-disinfectors —

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

1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WD) that are intended for use for the cleaning and thermal disinfection, in a single operating cycle, of re-usable medical devices such as surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils and glassware.

NOTE 1 Thermal disinfection can be achieved by rinsing the load with hot water, exposure to steam or combination of the two.

The requirements specified in this part of ISO 15883 are applicable in conjunction with the general requirements specified in ISO 15883-1.

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 2 If it is considered that prion protein can 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.

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 4017, *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 reservoir bags*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 15883-1:2006, *Washer-disinfectors — Part 1: General requirements, definitions and tests*

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of re-sterilizable medical devices*

ISO/TS 15883-5:2005, *Washer-disinfectors — Part 5: Test soils and methods for demonstrating cleaning efficacy*

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

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
 A_0
equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

[ISO 15883-1:2006, definition 3.1]

NOTE See also ISO 15883-1:2006, Annex B.

3.2
anaesthetic and respiratory accessories
respiratory tubes, anaesthetic reservoir bags and other anaesthetic products that will not be sufficiently flushed by rotating spray nozzles, but which require positioning over fixed spray/jet nozzles

3.3
lumen device
device that consists of tubes, pipes (either single or coaxial combined) which require connecting to the WD by means of dedicated connectors

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3.4
powered device
surgical instrument which gives a rotating and/or oscillating movement to other surgical instruments

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NOTE 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.

EXAMPLES Dental hand pieces, orthopaedic saws and drills.

3.5
washing temperature
minimum temperature of the washing temperature band

3.6
washing temperature band
range of temperatures, expressed as the washing temperature and the maximum allowable temperature which may prevail throughout the load during the washing time

3.7
washing time
period for which the cycle variables (e.g. temperature of the load, detergent concentration in the chamber) are maintained at or above the values specified for washing

4 Performance requirements

4.1 General

4.1.1 The requirements of ISO 15883-1:2006 apply with the exception of its

- subclause 4.3.2 (which refers to chemical disinfection, see Scope of this part of ISO 15883);
- subclause 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.6 of this part of ISO 15883).

4.1.2 The WD shall be designed to clean and thermally disinfect specified medical devices that are intended by the device manufacturer to be reused and are designated as compatible with the WD process cycle in accordance with the device manufacturer's instructions for reprocessing as specified in accordance with ISO 17664.

4.1.3 The medical devices shall be cleaned and disinfected on the outer surfaces and where necessary for their safe use, safe handling and/or correct functioning, the inner surfaces.

4.1.4 When necessary the WD shall be provided with means to facilitate the correct alignment of the load in the washing chamber.

4.1.5 In order to process lumen devices and/or powered devices, the WD shall be provided with the necessary connectors and load carriers which shall be designed to ensure an adequate flow of process fluids to each device.

4.1.6 The means to control the volume of the process chemical(s) that is/are admitted (see ISO 15883-1:2006, 5.7.2, 5.7.4 and 5.7.5) shall be adjustable by means of a key, code or tool and shall deliver the set volume to an accuracy of $\pm 5\%$ or better.

4.2 Cleaning

4.2.1 Cleaning shall be tested in accordance with the requirements of ISO 15883-1:2006 using the test soils and methods specified in ISO/TS 15883-5 that are pertinent to the loads to be processed.

The cleaning process shall meet the requirements of the test specified in 6.2.

4.2.2 During the washing stage:

- the washing time shall start when the temperature at the control sensor of the WD reaches the specified washing temperature;
- the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit of, the washing temperature $+10\text{ }^{\circ}\text{C}$ (see ISO 15883-1:2006, 4.2.3).

4.2.3 Throughout the washing time the temperatures on any surface of the load, chamber walls, chamber drain and the load carrier shall:

- be within the washing temperature band;
- not differ from one another by more than 5 K.

NOTE A washing stage can include two or more washing temperatures and washing temperature bands.

4.3 Disinfecting

4.3.1 Each operating cycle shall include a thermal disinfection stage for which the time at which the load is maintained at the disinfection temperature gives an A_0 of at least 600 on all surfaces of the load to be disinfected when tested in accordance with 6.3.

4.3.2 The cycle shall include a thermal disinfection stage giving an A_0 of at least 600 on all the internal surfaces of the chamber and on the load carrier when tested in accordance with 6.3.

4.3.3 The WD shall provide for disinfection times and temperatures to be set to give an A_0 value up to a maximum value of not less than 3 000.