INTERNATIONAL STANDARD

**ISO 15883-6**

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# 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*



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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.

# Washer-disinfectors —

## Part 6:
## Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment

**WARNING — Devices identified within the scope of ISO 15883-2, ISO 15883-3 and ISO 15883-4 shall not be processed in washer-disinfectors specified in this part of ISO 15883. Examples of medical devices that are not to be processed in these devices include powered devices, lumened devices and other invasive devices.**



## 1 Scope

This part of ISO 15883 specifies particular requirements for washer-disinfectors (WDs) intended for use when the level of assurance of disinfection that is necessary can be achieved by cleaning and thermal disinfection ($A_0$ not less than 60) and does not require an independent automated record of critical processes to be kept. It is intended to be used in conjunction with ISO 15883-1, which gives general requirements for WDs.

The range of products on which WDs of this particular type can be used is restricted to devices and equipment which are non-invasive and non-critical (i.e. not penetrating skin or contacting mucosal surfaces).

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

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

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

## 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**
**non-invasive device**
device which does not penetrate inside the body, either through a body orifice or through the surface of the body

**3.2**
**washing time**
period for which the cycle variables are maintained within the values specified for washing

NOTE Cycle variables are, for example, the temperature of the load and the detergent concentration.

**3.3**
**washing temperature**
minimum temperature of the washing temperature band

**3.4**
**washing temperature band**
range of temperatures, expressed as the washing temperature and the maximum allowable temperature, which can prevail throughout the load during the washing time

## 4 Performance requirements

### 4.1 General

**4.1.1** The requirements of ISO 15883-1 apply, with the exception of the following subclauses of ISO 15883-1:2006

— 4.3.2 (which refers to chemical disinfection; see Clause 1 of this part of ISO 15883);

— 5.7.4 (which refers to verification of the dose admitted);

— 5.7.5 (which refers to the accuracy of dosing systems; see 4.1.5 of this part of ISO 15883);

— 5.7.6 (which refers to indication of sufficient process chemical);

— 5.9 (which refers to control of temperatures on the load and chamber walls).

**4.1.2** The WD shall be designed to clean and thermally disinfect the range of reusable items specified by the WD manufacturer.

**4.1.3** The items shall be cleaned and disinfected on all surfaces which can, in normal use and handling, come into contact with patients or staff.

**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** The means to control the volume of the process chemical(s) admitted shall be adjustable by means of a key, code or tool. The accuracy of the dosing system shall be ±10 % or better.

## 4.2 Cleaning

**4.2.1** Cleaning shall be tested in accordance with ISO 15883-1, using the test soils and methods in accordance with ISO/TS 15883-5 that are relevant to the loads to be processed.

**4.2.2** During the washing stage:

a) the washing time shall start when the temperature at the control sensor of the WD is not less than the specified washing temperature;

b) the washing temperature band shall have the lower limit defined by the washing temperature and an upper limit no greater than the specified washing temperature +10 °C (see ISO 15883-1:2006, 4.2.3);

c) throughout the washing time, the temperatures on any surface of the load, chamber walls, chamber drain and the load carrier shall

   1) be within the washing temperature band,

   2) not differ from one another by more than 5 °C.

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

## 4.3 Disinfecting

**4.3.1** The 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 60 on all surfaces of the load to be disinfected when tested in accordance with 6.3 (see also ISO 15883-1:2006, Table B.1).

**4.3.2** The cycle shall include a thermal disinfection stage giving an $A_0$ of at least 60 on all the internal surfaces of the chamber and on the load carrier when tested in accordance with 6.3 (see also ISO 15883-1:2006, Table B.1).

**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 600.

NOTE 1 The choice of $A_0$ and disinfection temperature will depend upon:

a) the intended use of the load items;

b) the materials of which the load items are made;

c) the nature and extent of the bioburden on the load items with particular reference to heat resistant infective organisms.

NOTE 2 For further information on the $A_0$ concept, see ISO 15883-1:2006, Annex B.

Users should seek advice from those responsible for infection prevention and control.

**4.3.4** The temperature on the surface of the load shall be within 0 °C and +10 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship.

**4.3.5** The temperature on the surface of the chamber walls and load carrier shall be within 0 °C and +10 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship.

# 5 Mechanical and control requirements

## 5.1 Control systems

**5.1.1** Means shall be provided to pre-set the washing temperature over a range between room temperature and an upper limit. The upper limit shall not be less than 60 °C. Adjustment shall be by means of a code, key or tool.

**5.1.2** Either the WD shall be provided with a system to indicate when there is insufficient process chemical available for the next cycle or the supply shall be visible to the operator in order to permit manual verification that sufficient process chemical is present.

**5.1.3** Either the WD shall be fitted with means to ensure that a fault is indicated when insufficient process chemical has been admitted or it shall be possible for the operator to visually verify that the required amount of process chemical has been used.

**5.1.4** Means shall be provided to pre-set the disinfection temperature over a range between 65 °C and an upper limit. The upper limit shall not be less than 90 °C. Adjustment shall be by means of a code, key or tool.

**5.1.5** Means shall be provided to pre-set the disinfection time over the range from 1 min to at least 60 min. Adjustment shall be by means of a code, key or tool.

WDs of the pass-through type should be employed when practicable, to provide separation of cleaned and disinfected items from those awaiting processing.

## 5.2 Process verification

**5.2.1** The WD shall be equipped with a means to visibly display the temperature attained in the chamber or the load or a means to visibly display that the required temperature has been attained. This means shall be independent from the controller in order to provide verification of achievement of the programmed disinfection temperature [see ISO 15883-1:2006, 5.11.4 a)].

**5.2.2** Provision shall be made for the installation of a temperature recorder when specified by the purchaser. When a recorder is fitted in accordance with ISO 15883-1:2006, 5.11.4 b), this shall be deemed to meet the requirement of 5.2.1.

# 6 Testing for conformity

## 6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1. See also Annex A.

## 6.2 Tests for soil removal from chamber walls, load carrier and load

The tests shall be carried out in accordance with ISO 15883-1:2006, 6.10, using one or more of the nationally published test soils and methods specified in ISO/TS 15883-5.

NOTE 1 The attention of users is drawn to local requirements that can require the use of particular test soils and methods.

NOTE 2 The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.

The test soils used for the load, chamber wall and load carriers could be different. If different test soils are used then the rationale for the choice of test soil shall be documented.

### 6.3 Thermometric tests

These tests shall be performed in accordance with ISO 15883-1:2006, 6.8, except for the load temperature test, which shall be performed in accordance with ISO 15883-1:2006, 6.8.2, modified as follows.

The reference loads used shall be made up of a full load of items that the WD is intended to process. The items chosen shall be those with the greatest mass, highest specific heat and lowest thermal conductivity.

## 7 Information to be supplied by the manufacturer

In addition to the information specified in ISO 15883-1:2006, Clause 8, the manufacturer shall provide the purchaser with the following information:

a) range of load supports available and required;

b) the following, obtained by testing in accordance with 6.3:

   1) the time for an operating cycle from a cold start;

   2) the time for an operating cycle from a hot start;

   3) the locations and temperatures of the coolest and hottest parts of the load during thermal disinfection.

## 8 Information to be requested from the purchaser by the supplier of the WD

In addition to the information specified in ISO 15883-1:2006, Clause 10, the following information shall be requested from the purchaser by the supplier of the WD:

a) the nature of the devices that it is intended to process;

b) the $A_0$ value, or the combination of time and temperature, to be attained for thermal disinfection.

If the $A_0$ value has not been defined by the purchaser, see 4.3.