BS EN ISO 15883-6:2015

BSI Standards Publication

Washer-disinfectors

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

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National foreword

This British Standard is the UK implementation of EN ISO 15883-6:2015. It supersedes BS EN ISO 15883-6:2011 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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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 (ISO 15883-6:2011)

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 (ISO 15883-6:2011)

Reinigungs-Desinfektionsgeräte - Teil 6: Anforderungen und Prüfverfahren für Reinigungs-Desinfektionsgeräte mit thermischer Desinfektion für nicht invasive, nicht kritische Medizinprodukte und Zubehör im Gesundheitswesen (ISO 15883-6:2011)

This European Standard was approved by CEN on 4 August 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 15883-6:2015 E

European foreword

This document (EN ISO 15883-6:2015) has been prepared by Technical Committee ISO/TC 198 “Sterilization of healthcare products” in collaboration with CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2016, and conflicting national standards shall be withdrawn at the latest by February 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 15883-6:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 15883-1	EN ISO 15883-1:2009+A1:2014	ISO 15883-1:2006+Amd1:2014
ISO/TS 15883-5	CEN/ISO/TS 15883-5:2005	ISO/TS 15883-5:2005

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15883-6:2011 has been approved by CEN as EN ISO 15883-6:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to the Essential Requirements of the Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
9	7.2	In addition requirements of EN ISO 15883-1 apply.
4.1.1,8	7.2	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1, 4.1.5	7.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	7.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	7.6	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
		are covered
4.1.1	8.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.2, 4.1.3, 4.1.5, 4.2, 4.3, 5.1, 5.2, 6.2, 6.3, 8	8.1	
6.1	8.1	Testing for conformity according to EN ISO 15883-1
4.1.1	9.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.2, 4.1.3, 7	9.1	
4.1.1	9.2, 9.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.6	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.2	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	12.7.5	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered

Clauses/subclauses of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1	13.1	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	13.3	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	13.4	This part shall comply also with the requirements of EN ISO 15883-1 in which the essential requirements are covered
4.1.1	13.3 a)	This relevant Essential Requirement is partly addressed in EN ISO 15883-1
7	13.6	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.1.1	1	
4.1.1	1.1.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.1, 5.1.2, 5.2 and 5.3.2 a)
4.1.1	1.1.5	See in addition EN ISO 15883-1:2009+A1:2014, 9.2
4.1.1	1.1.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.12.3, 5.27.1 and 6.6.2
4.1.1	1.1.7	See in addition EN ISO 15883-1:2009+A1:2014, 5.2
4.1.1	1.2.1, 1st and 2nd dash	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.2, 5.2.4, 5.12.1, 5.20 and 5.22

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.1.1	1.2.2, 1st dash	See in addition EN ISO 15883-1:2009+A1:2014, 5.2, 5.12.3, 5.12.8 and 5.12.9
4.1.1	1.2.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.2.4	
4.1.1	1.2.5	See in addition EN ISO 15883-1:2009+A1:2014, 5.18 and 5.19
4.1.1	1.2.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.2 and 5.4.1.9
4.1.1	1.3.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, 7.3
4.1.1	1.3.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.1, 5.2.1 and 8.3 g)
4.1.1	1.3.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.3.4	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.6 and 5.2.1 Including reference to EN 61010-2-040:2005, clause 7
4.1.1	1.3.7	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.3.8	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.4	See in addition EN ISO 15883-1:2009+A1:2014,

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
		5.2.1 and 8.3
4.1.1	1.5.5	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.6	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 5.8
4.1.1	1.5.8	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1
4.1.1	1.5.13	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8.1 b) Including reference to EN 61010-2-040:2005, clause 11
4.1.1	1.5.14	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 Including reference to EN 61010-2-040:2005, clause 15
4.1.1	1.6.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.5 and 5.2.1
4.1.1	1.6.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.1.5 and 5.2.1
4.1.1	1.6.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8.2 a) and b)
4.1.1	1.6.4	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 5.4.1.6
4.1.1	1.6.5	See in addition EN ISO 15883-1:2009+A1:2014, 4.2.1.1 and 5.1.10
4.1.1	1.7.1	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1, 5.10.2, 5.10.3 and 5.20 h)
4.1.1	1.7.2	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 8 f)
4.1.1	1.7.3	See in addition EN ISO 15883-1:2009+A1:2014, 5.2.1 and 9.1
4.1.1	1.7.4	See in addition EN ISO 15883-1:2009+A1:2014,

Clause(s)/sub-clause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
		Clause 7 and Clause 8

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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.

INTERNATIONAL STANDARD **ISO 15883-6:2011(E)**

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.

Annex A
(informative)

Summary of test programmes

Table A.1 summarizes the recommended test programmes applicable to WDs specified in this part of ISO 15883 additional to those recommended in ISO 15883-1:2006, Table A.1. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational test	Performance test	Routine test
Load temperature test	4.3	6.3	X	X	X	X	B
X = recommended B = not recommended							

Bibliography

[1] ISO 15883-2, *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc*.

[2] ISO 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

[3] ISO 15883-4, *Washer-disinfectors — Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes*

[4] 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*

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