BRITISH STANDARD

BS EN ISO
15883-2:2009

Washer-disinfectors

Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)

ICS 11.080.10

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 15883-2:2009. It is identical to ISO 15883-2:2006. It supersedes BS EN ISO 15883-2:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

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.

Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)

Laveurs désinfecteurs - Partie 2: Exigences et essais pour laveurs désinfecteurs destinés à la désinfection thermique des instruments chirurgicaux, du matériel d'anesthésie, des bacs, plats, récipients, ustensiles, de la verrerie, etc. (ISO 15883-2:2006)

Reinigungs-Desinfektionsgeräte - Teil 2: Anforderungen und Prüfverfahren von Reinigungs-Desinfektionsgeräten mit thermischer Desinfektion für chirurgische Instrumente, Anästhesiegeräte, Gefäße, Utensilien, Glasgeräte usw. (ISO 15883-2:2006)

This European Standard was approved by CEN on 16 May 2009.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 15883-2:2009: E

Foreword

The text of ISO 15883-2:2006 has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15883-2:2009 by Technical Committee 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 December 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 15883-2:2006.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15883-2:2006 has been approved by CEN as a EN ISO 15883-2:2009 without any modification.

Annex ZA
(informative)

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

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 Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

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

Clauses/subclauses of this International Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1	1, 2, 3, 4, 5, 6, 7.1, 7.2, 7.3, 7.5, 7.6, 8.1, 9.1, 9.2, 9.3, 12.1, 12.5, 12.6, 12.7.1, 12.7.2, 12.7.3, 12.7.5, 13.1, 13.3, 13.4	The WD shall comply with the requirements of ISO 15883-1:—
4.1.2	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.3	1, 3, 4, 6, 7.1, 8.1, 9.1	
4.1.5	3, 7.1	
4.1.6	7.3, 8.1	
4.2	3, 8.1	
4.3	3, 8.1	
4.4	3, 8.1	
5.1	3, 8.1	
5.2	3, 8.1	
5.3	3, 8.1	
6.1	1, 2, 3, 4, 7.1, 8.1	Testing for conformity according to ISO 15883-1:—
6.2	3, 8.1	
6.3	3, 8.1	
7	9.1, 13.6	
8	1, 3, 7.1, 7.2, 8.1	

	7.4, 8.2, 8.3, 8.4, 8.5, 8.6, 8.7, 10.1, 10.2, 10.3, Clause 11, 12.2, 12.3, 12.4, 12.7.4, 12.8, 13.5, 14	not applicable
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
4.1.1	13.3 a)	This relevant Essential Requirement is partly addressed in this European Standard
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard

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 EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
4.1.1	1.1.7, 1.2.2, 1.2.3, 1.2.4, 1.2.5, 1.3.2, 1.3.3, 1.3.4, 1.5.1, 1.5.2, 1.5.3, 1.5.5, 1.5.6, 1.5.8, 1.5.13, 1.5.14, 1.6.2, 1.6.3, 1.6.4, 1.6.5	This relevant EHSR are addressed in this Standard
4.1.1	1.1.3, 1.1.5, 1.1.6, 1.2.1, 1.2.6, 1.3.1, 1.3.7, 1.3.8.1, 1.3.8.2, 1.5.4, 1.6.1, 1.7.1, 1.7.2, ,1.7.3, 1.7.4	This relevant EHSR are partly addressed in this Standard
	1.3.9, 1.4.1, 1.4.2, 1.4.3, 1.5.9, 4	This relevant EHSR are not addressed in 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 15883-2 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.

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.

INTERNATIONAL STANDARD **ISO 15883-2:2006(E)**

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 resterilizable 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

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

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 °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.

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

— the intended use of the load items;

— the materials of which the load items are made;

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

Advice will usually be sought from those with responsibility for advising on control of infection.

4.3.4 If the disinfection is done with steam, the temperature on the surfaces of the load, chamber walls, drain or the free chamber space shall remain below the boiling point of water corresponding to the pressure in the WD chamber in order that water remain on the surface of the device to be disinfected.

Conformity to this part of ISO 15883 shall be established by examination of the data obtained from thermometric testing (see 6.3).

4.4 Temperature of internal surfaces of processed devices

For anaesthetic and respiratory tubing, lumen devices and powered devices, the temperature requirements for the inner surfaces shall be deemed to have been achieved when:

— the temperature of the process fluids at the connection to, and the discharge from, the devices is within the limits specified by the manufacturer of the WD and conforms to 4.2 and 4.3;

— the flow of the process fluids at the connection to the instrument is within the limits specified by the manufacturer when tested in accordance with 5.1.2 and 6.3.3;

— the results from the cleaning tests as described in 6.2 are acceptable.

5 Mechanical and control requirements

5.1 Load connectors

5.1.1 Connectors for powered devices

For powered devices and lumen devices, in which the internal surfaces are to be flushed, the WD or load carrier shall be fitted with connectors, specified by the manufacturer of the medical device. For powered devices these connectors shall provide means to drive the instrument during the cycle. The speed of rotation shall be chosen to ensure that all the internal surfaces of axles, gears etc. come into contact with the process fluids for the specified times.

5.1.2 Verification of flow through lumen and powered devices

5.1.2.1 During the washing, disinfection and rinsing stages, it is necessary for the various process fluids to flow through each of the internal channels and/or cavities of the devices that are required to be cleaned and disinfected. Assurance that this has taken place shall be provided either:

a) by requiring in the instructions for use that the user:

   1) verifies that all channels allow the free passage of water before the device is loaded into the WD; (Some devices can include channels that require a particular method for verifying that the channel is patent. Careful attention should be paid to specific device manufacturer's instructions regarding these procedures.)

   2) confirms that all necessary connections were made before, and were still in place at the end of, the cycle;

b) by the automatic controller providing means to verify the flow of process fluids through each channel. Failure to achieve the required flow through each channel shall cause a fault to be indicated.

5.1.2.2 When there is a common connection for fluid at the same supply pressure to more than one channel or device, evidence shall be provided that the flow through each of the channels meets the minimum that is required for effective cleaning, disinfection and rinsing of each device to be processed.

5.2 Control systems

5.2.1 Means shall be provided to pre-set the washing temperature over a range between room temperature and to 60 °C or higher. Adjustment shall be by means of a code, key or tool.

5.2.2 Means shall be provided to pre-set the disinfection temperature over a range between 75 °C and not less than 95 °C. Adjustment shall be by means of a code key or tool.

5.2.3 Means shall be provided to pre-set the disinfection time over the range from one minute 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.

5.3 Process verification

The WD shall be equipped with a temperature recorder which has sensors and signal processing that are independent from the controller, to record the attainment of the programmed disinfection conditions [see ISO 15883-1:2006, 5.11.4 b)].

6 Testing for conformity

6.1 General

Testing for conformity shall be carried out in accordance with ISO 15883-1:2006, Clause 6.

NOTE Annex A includes a summary of test programmes for WDs for surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware etc. in addition to those recommended in ISO 15883-1:—, 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 (For reference, see also References [3] to [14]).

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 use of test soils for the load, chamber wall and load carriers may not be the same. Where different test soils are used the rationale for the choice of test soil should be documented.

6.3 Thermometric tests

6.3.1 General

The tests shall be performed in accordance with ISO 15883-1:2006, 6.8, with the modifications given in 6.3.2 to 6.3.3.

6.3.2 Load temperature test

6.3.2.1 General

The load temperature test shall be carried out in accordance with the requirements of ISO 15883-1:2006, 6.8.2. The test loads specified below are reference loads which shall be used for type tests and may be used for works test or operational qualification test. A full load of medical devices of the type to be processed, or surrogates for these devices, may be used for operational testing but recourse to the reference loads given below shall be made in case of dispute.

6.3.2.2 Solid devices (e.g. most surgical instruments)

For operational qualification testing, the load shall consist of a mass of stainless steel bolts evenly distributed throughout the loading space to the maximum mass of load specified by the WD manufacturer. The bolts shall:

— conform to ISO 4017;

— be austenitic stainless steel grade conforming to EN 10088-2;

— be M12 × 100 mm with hexagon heads;

— be cleaned, degreased and dried before use.

For performance qualification testing a full load of instruments of the type intended to be processed shall be used.

6.3.2.3 Bowls, dishes and receivers (including both polypropylene and metal)

The test load shall consist of a full load of bowls, dishes and receivers and shall include:

— one instrument tray 200 mm × 150 mm;

— one instrument tray 300 mm × 250 mm;

— one kidney dish 150 mm × 350 mm;

— one lotion bowl of 100 mm × 45 mm;

— one lotion bowl of 250 mm × 110 mm;

— one gallipot of 40 mm diameter (30 ml to 60 ml);

— one gallipot of 80 mm diameter (250 ml to 280 ml).

When the WD is to be used to process re-usable instrument containers (see EN 868-8) the load items specified above shall be replaced with a 300 mm × 600 mm × 150 mm container and internal basket and a 300 mm × 300 mm × 150 mm container and internal basket.

6.3.2.4 Glassware

The test load shall consist of a full load of glassware and shall include:

— 100 rimless test tubes with an outside diameter of 16 mm, a length of 100 mm and wall thickness of 1,2 mm;

— 24 low-form beakers, with spout, and a volume of 1 000 ml, diameter of 106 mm and a height of 145 mm.

6.3.2.5 Anaesthetic and respiratory accessories

The test load shall consist of a full load of anaesthetic/respiratory accessories and shall include:

— one breathing tube conforming to ISO 5367;

— one anaesthetic reservoir bag with 15 mm connector, 1,5 l capacity conforming to ISO 5362;

— one anaesthetic reservoir bag with 22 mm connector, 1,5 l capacity conforming to ISO 5362;

— two unassembled conical connectors for anaesthetic and respiratory equipment, of 15 mm, screw threaded, and with cone and socket joints conforming to ISO 5356-2;

— two unassembled conical connectors for anaesthetic and respiratory equipment, of 30 mm, screw-threaded, and with cone and socket joints conforming to ISO 5356-2;

— a tracheostomy tube and connector, conforming to ISO 5361 of 11 mm or of a larger size if the WD is intended to process a larger size;

— a endotracheal tube connector, conforming to ISO 5361 of 11 mm or of a larger size if the WD is intended to process a larger size;

— four face masks.

6.3.2.6 Lumen devices

The usable space shall be filled to the maximum capacity with the lumen devices which the WD is designed to process, as specified by the manufacturer of the WD. This test load shall be evenly distributed throughout the usable space with the specified load support system in place.

6.3.2.7 Powered devices

The usable space shall be filled to the maximum capacity with the powered devices instruments for which the WD is designed to process, as specified by the manufacturer of the WD.

6.3.3 Temperature of internal surfaces of devices

For internal surfaces of devices, the following additional test requirements apply.

a) Insert one temperature sensor in each connector or in the pipe to the connector, as close to the connector as possible. (It might be necessary to modify the connector or the pipe to the connector in order to position the temperature sensor.)

b) Install a flow meter in the pipe to each connector.

c) Insert a temperature sensor in the discharge of process fluid from the device. The temperature sensor shall be shielded from heating by contact with process fluids within the chamber.

The flow meter [see b)] should have a scale range from 0 to (the maximum flow specified by the manufacturer of the WD +20 %) and an accuracy of at least 5 % of the full scale over the temperature range 20 °C to 100 °C.

For operational qualification and performance qualification testing, the four points identified during type testing as representing the range of temperatures shall be used

7 Information to be supplied by the manufacturer

In addition to the information listed 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) range of connectors that are available and required for the processing of lumen devices, hollow instruments and/or powered devices;

c) the following information 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;

d) the temperature and flow rate of process fluids for devices connected so that the inner surface is flushed.

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

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

a) whether holders for bowls, dishes and receivers and connectors for hollow devices and/or powered devices need to be installed and in what numbers and locations;

b) the combination of time and temperature to be attained for thermal disinfection (see 4.3.2).

Annex A
(informative)

Summary of test programmes

Table A.1 summarizes the recommended test programmes applicable to WDs for surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware, etc., in addition to those recommended in ISO 15883-1:2006, Annex A. Other tests or schedules of tests providing equivalent assurance are equally acceptable.

Table A.1 — Summary of test programmes for WDs for surgical instruments, anaesthetic equipment, bowls, dishes and receivers, utensils, glassware, etc.

Brief description of test	Requirements clause	Test clause	Type test	Works test	Operational qualification	Performance qualification	Routine test
Temperature of internal surfaces of devices	4.4	6.3.3	X	X	X	X	B
X = recommended B = not recommended							

Bibliography

[1] IEC 61010-2-045, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-045: Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields*

[2] EN 868-8, *Packaging materials and systems for medical devices which are to be sterilized — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods*

[3] SIS - TR 3:2002, *Washer-disinfectors — Test for cleaning efficacy*

[4] BS 2745-3:1993, *Washer-disinfectors for medical purposes. Specification for washer-disinfectors except those used for processing human-waste containers and laundry*

[5] Health Technical Memorandum 2030, Washer-disinfectors — Validation and verification — The Stationery Office, London. 1997 ISBN 0-11-322071-5

[6] ASTM International. Standard test method for determination of effectiveness of cleaning processes for reusable medical instruments using a microbiologic method (simulated use test). ASTM E2314:03, Philadelphia: ASTM International, 2003

[7] *Richtlinie des Bundesgesundheitsamtes zur Prüfung von thermischen Desinfektionsverfahren in Reinigungsautomaten*. Bundesgesundheitsblatt, **23**, 1980, pp. 364-367

[8] Qualitätssicherung von Reinigungs- und Desinfektionsprozessen, Anforderungen, Prüfmethoden, Dokumentation, Bezugsquellen, Herausgeberinnen: C. Höller, S. Krüger, H. Martiny und R. Zschaler, Behr's Verlag Hamburg, 2003

[9] Prüfung und Bewertung der Reinigungs und Desinfektionswirkung von Endoskop-Dekontaminations- sowie Desinfektionsautomaten. *Hygiene und Medizin*, **20**, 1995, pp. 40-47

[10] KOLLER, W. *Cleaning and Disinfection of crockery and cutlery, instruments and containers for excreta in hospitals*. Verlag Dieter Göschl, Wien 1981

[11] ORZECHOWSKI, T.J.H. and DE BRUIN, A.C.P. *Test soil for use on stainless steel items including surgical instruments*. RIVM Bilthoven

[12] SCHRADER, G. and GÖRISCH, G. The Limitations of Instrument Cleaning Based on Data Collected on vCJD-Risks Posed by Medical Instrument. *Hyg. Med.*, **28**, 2003, pp. 306-309

[13] EDMUNDS, L.M. and RAWLINSON, A. The effect of cleaning on blood contamination in the dental surgery following periodontal procedures. *Australian Dental Journal*, **43**(5), 1998; pp. 349-353

[14] MICHELS, W. Evaluation of a quick test for examining cleaning efficiency of processed surgical and minimally invasive instruments. Hyg. Med., **22**, 1997; pp. 173-184

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