

Washer-disinfectors

Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)

ICS 11.080.10

National foreword

This British Standard is the UK implementation of EN ISO 15883-1:2009+A1:2014. It is identical to ISO 15883-1:2006, incorporating amendment 1:2014. It supersedes BS EN ISO 15883-1:2009 which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

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.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2009

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ISBN 978 0 580 76590 2

Amendments/corrigenda issued since publication

Date	Comments
30 September 2014	Implementation of ISO amendment 1:2014 with CEN endorsement A1:2014. Annex ZA updated

English Version

Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)

Laveurs désinfecteurs - Partie 1: Exigences générales, termes et définitions et essais (ISO 15883-1:2006)

Reinigungs-Desinfektionsgeräte - Teil 1: Allgemeine Anforderungen, Begriffe und Prüfverfahren (ISO 15883-1:2006)

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.

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Foreword

The text of ISO 15883-1:2006 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 15883-1:2009 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 15883-1:2006.

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 15883-1:2006 has been approved by CEN as a EN ISO 15883-1:2009 without any modification.

Foreword to amendment A1

This document (EN ISO 15883-1:2009/A1:2014) has been prepared by Technical Committee ISO/TC 198 “Sterilization of health care products” in collaboration with Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This Amendment to the European Standard EN ISO 15883:2009 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2015, and conflicting national standards shall be withdrawn at the latest by January 2015.

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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.

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Endorsement notice

The text of ISO 15883-1:2006/Amd 1:2014 has been approved by CEN as EN ISO 15883-1:2009/A1:2014 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 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 Union 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 European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
4.5.2.1, 5.4.1.2, 5.5.1, 5.7, 5.24, 5.25, 6.10, 6.11, 6.12, 9.2	7.2	Including reference to EN 61010–2-040:2005, 5.4.4 b), e), f), 5.4.5 and 5.4101
4.6, 5.1, 5.2, 5.7, 6.9	7.3	Including reference to EN 61010–2-040:2005, 5.4.3 k), m), 11.1 and 11.2
5.1.7, 5.1.8, 5.2, 5.4, 5.4.1.2, 5.4.5.3, 6.5.3, 5.24, 5.25, 8.2 g), and h), 10 c)	7.5	Including reference to EN 61010–2-040:2005, 5.2, 11.3 and 11.4
4.5.3, 4.5.4, 5.3.2, 5.26, 6.11	7.6	Including reference to EN 61010–2-040:2005, 5.3.4 and 11.101
4, 5.2, 5.3.1, 5.3.2, 5.4.3, 5.4.4, 5.5.1, 5.24, 5.26, 6.1, 6.2, 6.11	8.1	
3, 4, 5.1.11, 5.2, 8.1 b), 8.3	9.1	Including reference to EN 61010–2-040:2005, 5.4.3, Clause 14, ISO 14121:1999, EN ISO 14971:2013 and EN 61508–1:2010
4, 5.1, 5.1.5, 5.1.9, 5.2.1, 5.2.2, 5.2.3, 5.4.1.9, 5.4.2, 5.4.3.4, 5.10.2, 5.10.3, 5.27.1, 5.28, 5.29	9.2	Including reference to EN 61010–2-040:2005, Clause 7, ISO 14121:1999 and EN 61508–1:2010
5.2	9.3	
5.7	10.1	
5.2.1, 5.2.2, 8.2 c) and d)	11.1	Including reference to EN 61010–2-040:2005, Clause 12 and

		EN 61326-1:2006
5.2.1, 5.2.2	11.4.1	Including reference to EN 61010-2-040:2005, Clause 12 and EN 61326-1:2006
5.2.1, 5.2.4, 5.4, 5.7.4, 5.7.6, 5.8., 5.11, 5.12.7, 5.12.8, 5.12.9, 5.12.10, 5.13.2 g), 5.14 g), 5.17.2, 5.18, 5.20, 5.21	12.1	Including reference to EN 61010-2-040:2005, 4.4, 7.104, 14.103 and 14.104, and EN ISO 14971:2013 State of the art comprehends many standards; note refers to EN ISO 12100:2003, ISO 13489-2:2003, and EN 954-1:1997
5.2	12.5	Including reference to EN 61326-1:2006
5.2	12.6	Including reference to EN 61010-2-040:2005, 1.4, Clauses 4, 5 and 6, 11.6, Clause 14. Note refers to ISO 14121:1999 and EN 61508-1:2010
5.1, 5.2, 5.4, 5.27.1 b)	12.7.1	Including reference to EN 61010-2-040:2005, 7.2, 7.3 and 7.4.101
5.2	12.7.2	Including reference to EN 61010-2-040:2005, Clause 8
5.2	12.7.3	Including reference to EN 61010-2-040:2005, 12.5.1
5.2	12.7.4	Including reference to EN 61010-2-040:2005, Clause 6
5.2, 5.8	12.7.5	Including reference to EN 61010-2-040:2005, 10.1
5.10, 5.12	12.9	Including reference to IEC 60417:2004, ISO 7000:2012 and IEC 80416-1:2008
5.2, 5.4.1.3, 5.4.2, 5.23, 7, 8, 9.1	13.1	Including reference to EN 61010-2-040:2005, Clause 5
5.10.3	13.2	Including reference to IEC 60417:2004, ISO 7000:2012 and IEC 80416-1:2008
9.1 b) and c)	13.3 k)	
9.1 a)	13.3 l)	
8.1 b)	13.4	
8 k), 8 a), 8 j),	13.6 a)	
5.2.3, 7, 8, 9.1	13.6 a), b), c), d)	Including reference to EN 61010-2-040:2005, 5.1.2
8.1, 6.1.3	13.6 i)	
8.3 j)	13.6 q)	

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
5.2.3, 5.2.4	1	
5.1.1, 5.2, 5.3.2.1 a)	1.1.3	
9.2	1.1.5	
5.12.3, 6.6.2	1.1.6	
5.2	1.1.7	
5.12.1	1.2.1	
5.2, 5.18, 5.19	1.2.2	
5.2	1.2.3	
5.2, 5.18, 5.19	1.2.4	
5.18, 5.19	1.2.5	
5.2	1.2.6	
5.4.1.5, 5.18.4, 5.22, 6.3.5, 6.3.7	1.3.1	
5.1, 5.2, 8.3 g)	1.3.2	
5.2	1.3.3	
5.2, 5.6	1.3.4	
5.2	1.3.7	
5.2	1.5.1	
5.2, 6.3.1	1.5.2	
5.2	1.5.3	
5.2	1.5.4	
5.2	1.5.5	
5.2	1.5.6	
5.2	1.5.8	
5.2	1.5.13	
5.2, 5.4.1.7	1.5.14	
5.2, 8.3 g)	1.6.1	

5.1.5	1.6.2	
5.2	1.6.3	
5.1.5	1.6.5	
5.2, 5.10, 5.10.3, 5.12.3, 5.22, 8.3 a), 8.3 b)	1.7.1	
5.2	1.7.2	
5.2, 9.1	1.7.3	
5.2, 8.3, 9.1	1.7.4	

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 15883-1 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]
- A1 — *Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment* A1

Introduction

This part of ISO 15883 is the first of a series of standards specifying the performance of washer-disinfectors and specifies the general requirements for performance applicable to all washer-disinfectors. The requirements given in this part of ISO 15883 are applicable to all washer-disinfectors specified in subsequent parts of the ISO 15883 series, except insofar as they may be modified or added to by a subsequent part, in which case the requirements of that particular part will apply.

Fields of application within the scope of ISO 15883 series 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.

Washer-disinfectors should be used only for processing the type of loads specified by the manufacturer of the washer-disinfector.

In selecting the appropriate washer-disinfector, reference should be made both to this part of ISO 15883 and to the relevant subsequent parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of washer-disinfector, operating cycle or quality of services or process chemicals is appropriate for any particular load.

[A1] *Text deleted* **[A1]**

This part of ISO 15883 has been prepared on the basis that each individual washer-disinfector will be subject to validation tests (commissioning and performance qualification on first installation) and that in use continued compliance will be established by periodic tests carried out by, or on behalf of, the user.

Verification of cleaning efficacy is a key aspect of establishing satisfactory performance of a washer-disinfector. The current state of knowledge has not permitted development of a single test method. As an interim measure reference has been made to test methods which are currently being applied in a number of different countries. The specification for these test methods including their test soils can be found in ISO/TS 15883-5. It remains the intention of the Technical Committee of TC 198 to develop a single test method.

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

- 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-disinfector remain in force;
- b) the ISO 15883 series of standards provides no information as to whether the washer-disinfector may be used without restrictions in any of the member states of the EU or EFTA.

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

1 Scope

This part of ISO 15883 specifies general performance requirements for washer-disinfectors (WD) and their accessories that are intended to be used for cleaning and disinfection of re-usable medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice. It specifies performance requirements for cleaning and disinfection as well as for the accessories which can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and re-validation, periodically and after essential repairs, are also specified.

The requirements for washer-disinfectors intended to process specific loads are specified in subsequent parts of this standard. For washer-disinfectors intended to process loads of two or more different types the requirements of all relevant parts of this standard apply.

This part of ISO 15883 does not specify requirements intended for machines for use for laundry or general catering purposes.

This part of ISO 15883 does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers”, these are specified in other standards e.g. EN 285.

The specified performance requirements of this standard may not ensure the inactivation or removal of the causative agent(s) (prion protein) of transmissible spongiform encephalopathies.

NOTE 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.

This part of ISO 15883 may be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of compliance with the requirements of this part of ISO 15883 may also be employed by users to demonstrate continued compliance of the installed WD throughout its working life. Guidance on a routine test programme is given in Annex A.

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 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 10012, *Measurement management systems — Requirements for measurement processes and measuring equipment*

ISO 14644-3:2005, *Cleanrooms and associated controlled environments — Part 3: Test methods*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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

IEC 60417-DB, *Graphical symbols for use on equipment*

IEC 60584-1:1995, *Thermocouples — Part 1: Reference tables*

IEC 60751:1983, *Industrial platinum resistance thermometer sensors*

Ⓐ IEC 61010-2-040:2005, *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*

IEC 61326-1:2006, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements* Ⓐ

IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of symbol originals*

European Pharmacopeia, European Directorate for the Quality of Medicines, Council of Europe, Strasbourg, France

United States Pharmacopeia, USP Pharmacopeia, Rockville, USA

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

NOTE See Annex B.

3.2

automatic controller

device that, in response to pre-determined cycle variables, operates the apparatus sequentially through the required stages of the process or processes

3.3

bedpan washer-disinfector

washer-disinfector intended to be used for the emptying, flushing, cleaning and thermal disinfecting of human waste containers

3.4

bioburden

Ⓐ population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO/TS 11139:2006, 2.2] Ⓐ

3.5

calibration

[A1] set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system or values represented by a material measure or a reference material, and the corresponding values realized by standards

[SOURCE: EN 285:2006+A2:2009, 3.5] **[A1]**

3.6

calorifier

closed vessel, in which water is indirectly heated, by the flow of heated fluid through a heat exchanger, under a pressure greater than atmospheric

3.7

chamber

that part of the washer-disinfector in which the load is processed

NOTE The chamber does not include steam generators, pipework, e.g. drain and fittings from which it can be isolated.

3.8

chemical disinfection

disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbicidal

3.9

cleaning

removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use

3.10

continuous process machine

machine which automatically transports the load through each stage of the operating cycle

3.11

critical process variables

those process variables for which the values during an operating cycle have been identified by the manufacturer as sufficient to ensure that the cycle meets the performance defined during validation

3.12

cycle complete

indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber

3.13

cycle control recorder

a device which records the values of one or more control variables as seen by the automatic controller

3.14

[A1] D value

D₁₀ value

time or dose required to achieve inactivation of 90% of a population of the test microorganism under stated conditions

[SOURCE: ISO/TS 11139:2006, 2.11] **[A1]**

3.15

dead volume

volume of pipework which is not purged by the usual flow of liquids during the operating cycle

3.16

disinfection

reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use

3.17

disinfection temperature

minimum temperature of the disinfection temperature band

3.18

disinfection temperature band

range of temperatures, expressed as the disinfection temperature (3.17) and the maximum allowable temperature which may prevail throughout the load during the disinfection time

3.19

disinfection time

period for which the critical process variable(s) (e.g. temperature of the load, disinfectant concentration in the chamber) are maintained at or above that specified for disinfection

3.20

door

device provided as a means of closing and sealing the chamber

3.21

double-ended washer-disinfector

washer-disinfector with separate doors for loading and unloading

3.22

endoscope washer-disinfector

washer-disinfector intended to clean and disinfect loads containing flexible endoscopes

3.23

fail safe

attribute of washer-disinfector design, or its associated services, that ensures that a single fault condition will not give rise to a safety hazard

3.24

fault

recognition by the automatic controller that at least one of the pre-set process variables for the washer-disinfector cycle have not been attained

3.25

fluid

liquid, gas or vapour

3.26

flushing

removal of gross contamination and/or the contents of a load item, but not necessarily contamination adhering to the surface of the load item, by displacement with water

3.27

free draining

allowing the unimpeded flow of liquids under the influence of gravity towards the discharge point

3.28

holding time

period during which the critical process variables are maintained at or above the values specified

3.29

human waste

excretions and body fluids including faeces, urine, blood, pus, vomit and mucus

3.30

human waste container

re-usable vessel for holding and transporting human waste

3.31

installation qualification

IQ

process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

Ⓐ [SOURCE: ISO/TS 11139:2006, 2.22] Ⓐ

3.32

instrument washer-disinfector

washer-disinfector intended to clean and disinfect loads containing surgical instruments, anaesthetic accessories, bowls, dishes, receivers, utensils, glassware and similar items

3.33

load

collective term used to describe all the goods, equipment and materials that are put into a washer-disinfector at any one time for the purpose of cleaning and disinfecting it by an operating cycle

3.34

loading door

door in a double-ended washer-disinfector through which the load is put into the washer-disinfector prior to processing

3.35

medical device

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or relative article, intended by the manufacturer to be used, alone or in combination, for human beings for one more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment, or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[ISO 13485:2003, definition 3.7]

3.36

microbial reduction factor

extent to which the bioburden is reduced in tenfold increments expressed as logarithms (base 10)

3.37

monitoring

measurement of physical variables and comparison of the values obtained with the values specified for the process

3.38

normal operation

operation of the washer-disinfector in accordance with the manufacturer's instructions and with all process parameters within the limits specified by the manufacturer

3.39

operating cycle

complete set of stages that is carried out in the sequence as regulated by the automatic controller

3.40

operating pressure

gauge pressure at which a vessel is operated during normal use

3.41

operational qualification

OQ

process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

 [SOURCE: ISO/TS 11139:2006, 2.27] 

3.42

override

system by which the operating cycle can be interrupted or modified as necessary

3.43

performance qualification

PQ

process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

 [SOURCE: ISO/TS 11139:2006, 2.30] 

NOTE The performance qualification for washer-disinfectors would concern the number of items cleaned and disinfected to the required standard.

3.44

process chemical

formulation of chemical compounds intended for use in a washer-disinfector

NOTE Process chemicals include for example detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners.

3.45

process variable

physical and chemical properties that influence the efficacy of all stages of the process

EXAMPLE Times, temperatures, disinfectant concentration, pressures and flows.

3.46

process verification recorder

device that, independently of the automatic controller, records values obtained for some, or all, of the control variables

3.47

recorder

system fitted to the washer-disinfector, or connected to the washer-disinfector, producing a permanent record of information graphically, digitally or electronically

3.48

re-qualification

repeat of part or all of the validation test requirements for the purpose of confirming process reliability

3.49

rinsing

removal of process residues by displacement and dilution with water

3.50

routine test

periodic checking and testing carried out to establish that the operational performance of the washer-disinfector remains within the limits established during validation

3.51

steam generator

vessel designed to contain water and a heating system (e.g. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state

3.52

tank

process vessel, integral to the washer-disinfector, designed to hold fluids that are used during processing

3.53

test microorganism

microbial strain from a recognised culture collection used in microbiological testing of the performance of a washer-disinfector

NOTE A recognized culture collection is an international depository under the Budapest Treaty on "The International Recognition of the Deposit of Microorganisms for the Purpose of Patent and Regulation".

3.54

test soil

formulation used to test the efficacy of cleaning in a washer-disinfector

3.55

thermal disinfection

disinfection achieved by the action of moist heat

3.56

type test

test programme to verify conformity of a washer-disinfector type to this standard and establish data for reference in subsequent tests

3.57

unloading door

door in a double-ended (3.21) washer-disinfector through which the load is removed after an operating cycle

3.58

validation

documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

Ⓐ [SOURCE: ISO/TS 11139:2006, 2.55] Ⓐ

3.59

verification

confirmation through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2005, definition 3.8.4]

3.60

viable microorganism

microorganisms, including viruses, which are capable of multiplication under specified culture conditions

3.61

warning pipe

secondary overflow pipe so fitted that its outlet, whether inside or outside the machine, is in a conspicuous position to indicate an overflow condition

3.62

washer-disinfector

WD

machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice

3.63

washing

removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary

3.64

works test

series of tests performed prior to delivery to demonstrate compliance of each washer-disinfector with its specification

3.65

***z* value**

Ⓐ temperature change required to effect a ten fold change in *D* value

[SOURCE: ISO 17665-1:2006, 3.61] Ⓐ

4 Performance requirements

4.1 General

4.1.1 Compliance with the performance requirements shall be tested in accordance with the methods given in Clause 6.

NOTE Conformity of a WD to this part of ISO 15883 and subsequent relevant parts of ISO 15883 can be tested and documented as the condition of the WD as supplied by the manufacturer ("as supplied" is defined in 6.1.2) and as the condition of the WD as installed by the manufacturer, user, or third party ("as installed" is defined in 6.1.3).

4.1.2 Any item which has been processed in a WD conforming to the ISO 15883 series shall have been cleaned, disinfected, rinsed and, when appropriate, dried.

NOTE The performance requirements depend on a number of factors, which include the nature of the item(s) to be processed, the disinfection efficacy required (as determined by the level of risk associated with the use of the item), the nature of the contamination to be removed, the nature and extent of any pre-treatment, the temperature, the physical energy (type, power, duration), detergent system, permissible extent of process residues, etc.

4.1.3 The specified performance shall be achieved by an operating cycle under the control of an automatic controller and including, when appropriate, the stages for:

- a) cleaning, which may include several stages;
- b) disinfecting;
- c) rinsing;
- d) drying (when appropriate).

When appropriate, two or more stages specified above can be combined as a single stage.

4.1.4 Throughout the operating cycle the rate and extent of any change in temperature, pressure [see 8.1 b) 6)] or concentration of process chemicals [see 8.1 b) 5)] shall be within limits specified by the device manufacturer as those which are compatible with the item(s) which the WD is intended to process [see 8.1 b) 2)].

4.1.5 Disinfection is specified by reference to time and temperature for thermal disinfection or as time, temperature and concentration for chemical disinfection.

Whenever practicable, thermal disinfection is preferred. Thermal disinfection processes are more easily controlled and avoid the hazards to staff, patients and the environment that can occur through the use of chemical disinfectants.

The required disinfection conditions or the minimum microbial reduction factor necessary, i.e. the A_0 value, are specified in subsequent parts of ISO 15883.

Disinfection performances specified in subsequent parts of ISO 15883 are minimum requirements. Regulatory authorities can specify more stringent requirements within the territories for which they are responsible.

4.1.6 Within the WD each chamber which is used to contain the load shall be capable of being disinfected under the control of the automatic controller. For single chamber machines this shall be part of the normal operating cycle. For machines with two or more chambers the disinfection cycle may be separate from the normal operating cycle. For multi-chamber machines a disinfection cycle shall not be required for any chamber which is used only for drying.

4.1.7 Chambers in which process fluid may be present during the process cycle shall be free draining (see 6.5.2 and 6.5.4).

4.1.8 Continuous process WDs shall be designed in such a way that the WD, the load carriers and the load are not re-contaminated by the simultaneous processing of other loads.

4.1.9 The environment in contact with the load during the final rinse and drying stages shall be of at least the purity (chemical and microbial) specified by the device manufacturer as that which will not adversely affect the items that the WD is intended to process or impair the intended use of the items.

The environment includes, but is not necessarily limited to, all the fluids and materials in direct contact with the load.

4.1.10 The extent and frequency of testing, undertaken to verify the purity of the environment in contact with the load, shall be determined by risk analysis. The risk analysis shall take into account the intended use of the processed items and the nature of any control mechanisms and sub-systems e.g. water treatment systems.

4.2 Cleaning

4.2.1 General

4.2.1.1 Cleaning shall be deemed to have been achieved if the acceptance criteria for the test method in 6.10 and the relevant subsequent parts of ISO 15883 have been met.

The test method for type testing and operational testing (6.10.2) shall employ one of the nationally published tests soils and methods as described in ISO/TS 15883-5 (see also **A1** References [13], [14], [15], [22], [23], [24], [25], [35] to [44] **A1**).

NOTE 1 ISO/TS 15883-5 includes the description of test methods including their test soils which are currently being applied in different countries.

NOTE 2 Additional verification of attainment of the required cleaning efficacy during operational testing can be provided by the use of one of the methods for the detection and assessment of residual protein given in 6.10.3 and Annex C.

NOTE 3 A test for residual protein is performed for determining cleaning efficacy on used medical devices but can also be used with proteinaceous test soil.

The test method for performance qualification of cleaning efficacy is described in 6.10.3 and shall include the use of one of the methods for the detection and assessment of residual proteinaceous contamination given in Annex C.

NOTE 4 The three test methods for protein residue testing in Annex C are not equally sensitive. The ninhydrin method (C.1) and biuret method (C.3) have similar sensitivities but are regarded as a limit test and a semi-quantitative test respectively. The OPA method (C.2) is more sensitive but requires the use of laboratory facilities. Both the ninhydrin and OPA methods react with α - and ε -amino groups of proteins; other amino compounds can give false positives.

4.2.1.2 The manufacturer shall state (see Clause 8) the process chemicals and the quality of water (see 6.4) used during product compatibility studies and testing to confirm compliance of the WD with the requirements of this standard.

4.2.2 Flushing stage

The in-flowing water shall be maintained at a temperature low enough to preclude the occurrence of protein coagulation.

NOTE Temperatures higher than 45 °C can cause protein coagulation during the flushing stage and cause cleaning problems.

4.2.3 Washing stage

The temperature of water and aqueous solutions in contact with the load during the washing stage shall be controlled within limits stated by the WD manufacturer.

The temperature of the detergent solutions shall be controlled within the maximum and minimum temperatures stated by the detergent manufacturer.

4.3 Disinfection

4.3.1 Thermal disinfection

4.3.1.1 Thermal disinfection of the load and load carriers shall be deemed to have been achieved if, when tested in accordance with 6.8.2 and the relevant subsequent parts of ISO 15883, the specified minimum temperature for the specified minimum (holding) time, or the equivalent lethality (A_0 , see Annex B), is achieved on all surfaces which are required to be disinfected.

4.3.1.2 Thermal disinfection of the chamber walls shall be deemed to have been achieved if when tested in accordance with 6.8.3 and the relevant subsequent parts of ISO 15883, the specified minimum temperature is attained for the specified minimum time, or the equivalent lethality (A_0), is achieved on all chamber walls.

4.3.1.3 The temperature shall be continuously maintained within the specified disinfection temperature band for the specified disinfection time.

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

4.3.2 Chemical disinfection

4.3.2.1 Chemical disinfection of the load shall be deemed to have been achieved when all load surfaces have been exposed to the specified conditions of chemical disinfectant concentration and temperature for the required contact time.

4.3.2.2 Chemical disinfection of the chamber walls and load carriers shall be deemed to have been achieved when the specified conditions of chemical disinfectant concentration, temperature and contact time have been attained on all chamber walls and load carriers.

4.3.2.3 The conditions of time, temperature and chemical disinfectant concentration shall be those specified, under the conditions of use, by the disinfectant manufacturer.

Alternatively, a party other than the disinfectant manufacturer should determine the conditions of time, temperature and chemical disinfectant concentration that provide the required microbial reduction factor (see 4.1.5).

Appropriate additional testing (e.g. load compatibility, environmental safety, disinfectant stability) shall have been performed also.

4.3.2.4 Microbiological testing shall be performed (see ISO 15883-4).

4.3.3 Thermal and chemical disinfection

4.3.3.1 The temperature on all surfaces of the load and load carrier shall be within $-0\text{ }^{\circ}\text{C}$ and $+5\text{ }^{\circ}\text{C}$ of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2).

4.3.3.2 The temperatures recorded on the surface of the chamber wall shall be within $-0\text{ }^{\circ}\text{C}$ and $+5\text{ }^{\circ}\text{C}$ of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3).

4.4 Rinsing

4.4.1 The WD shall be provided with a rinsing stage which reduces the concentration of process chemicals on the load to a level not exceeding that specified by the manufacturer, or supplier, of the process chemical(s) as safe in the context of the intended use of the load.

4.4.2 Rinsing shall be deemed to have been achieved if, when tested in accordance with 6.10.4 and with the relevant subsequent parts of ISO 15883, the reduction of process chemicals has been determined and been shown to have been sufficient for the subsequent intended use of the load.

4.4.3 Means shall be provided, or specified, to ensure that the chemical and microbial quality of the final rinse water will not impair the standard of cleanliness and disinfection (see also 6.4.2).

4.5 Drying

4.5.1 The WD shall, unless otherwise specified, be provided with a drying stage which removes surface moisture from the load.

4.5.2 Drying of the load shall be deemed to have been achieved if, when tested in accordance with 6.12 and the relevant subsequent parts of ISO 15883, no residual water is detected at the end of the drying stage.

4.5.3 Hot air or compressed air used for drying shall be of a quality which shall not impair the cleanliness of, nor introduce microbial contamination to, the load.

When air free from bacterial or particulate contamination is necessary to fulfil this requirement, this can be achieved for example by the use of HEPA (high efficiency particulate air) filtered air.

4.5.4 When air filters are fitted, means shall be provided to enable the filtration system to be tested.

The filter used shall be tested for particulate arrest efficiency at the point of use (see 6.11).

Microbial sampling will not normally be required for the system unless otherwise specified in the purchase contract.

For applications where it is important that the air be free from microbial contamination, it might be necessary to carry out testing during the process or before and/or after each cycle.

Many WDs are fitted with air filters to remove particulate material from the air supplied to the drying stage. These filters are often HEPA filters (e.g. Class H 12 or Class H 13 as specified in EN 1822-1:1998) of the type used to remove bacterial contamination from an air supply. When they are used as general particulate filters, performance tests will not normally be required on the installed filter.

4.6 Process chemicals

The WD manufacturer shall obtain, from the manufacturer of each specified process chemical [see 8.2 g)], any requirements for safe handling, data on the maximum permitted residual level on devices and the method of detection to be used for determining process residuals. The sampling method and analytical method specified shall be capable of determining the presence of process chemical at concentrations below that specified as potentially harmful, i.e. as the maximum acceptable level.

NOTE 1 The residual level which can be tolerated will depend upon the nature of the chemical and the intended use of the product being processed.

NOTE 2 The specified performance cannot be achieved if other process chemicals than those which were tested during type testing are used.

When using process chemicals, the instructions from the manufacturer of the process chemical, e.g. regarding the concentration and temperature, should be followed.

5 Mechanical and process requirements

5.1 Materials, design and manufacture/construction

5.1.1 The materials used in the WD and its accessories, including load carriers, shall tolerate the chemical, mechanical and thermal strains encountered during normal use as specified by the manufacturer.

The parts of the WD which come into contact with the load should be manufactured from materials which have corrosion and abrasion resistance properties.

All parts of the machine which come into contact with the water, chemicals and/or steam should be able to withstand the possible corrosive actions of these substances or the classes of chemicals which are not to be used should be clearly stated in the instructions for use.

In the selection of the materials of construction, due attention should be paid to the effects of galvanic attack, vibration and differential expansion when dissimilar metals are used in contact.

The combination of materials used in the construction of the WD should be compatible with each other and with the parameters of the process.

5.1.2 The components of the system used to contain and dispense chemical additives shall be constructed from materials resistant to reaction with acid, alkaline, oxidizing and other chemical systems such that there is no adverse interaction with the load which the WD is intended to process.

5.1.3 Unless otherwise stated by the WD manufacturer, the chamber shall be designed to withstand no less than 10 000 operational cycles without suffering failure when operated and maintained in accordance with the WD manufacturer's instructions.

Compliance shall be established by review of the design verification data (see ISO 9001:2000, 7.3.5).

5.1.4 Floor mounted WDs shall be provided with means to compensate for irregular surfaces on floors. The WD manufacturer shall state the maximum deviation from a plane horizontal surface that can be accommodated.

5.1.5 The WD shall be constructed so as to enable access without the use of tools for routine tasks which are intended to be carried out by the operator.

Due regard should be given to the means of access for component maintenance and general cleaning. Panels should be easily removed and reinstalled. Information supplied by the purchaser should indicate if the machine's location restricts access to the machine, e.g. it is located against a wall [see 10 m)].

5.1.6 All accessible components and surfaces shall be free from sharp edges, burrs, etc.

External surfaces of the WD should be finished smooth and easy to clean.

5.1.7 During normal operation of the WD the chamber, pipework and associated components shall be free from leaks apparent to visual inspection.

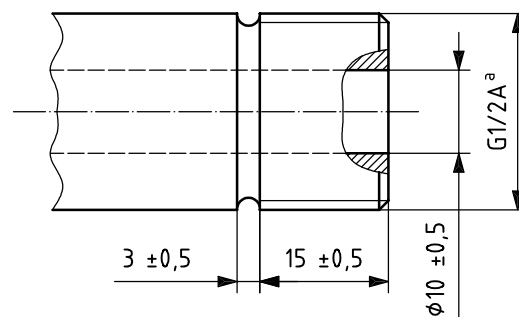
5.1.8 The chamber shall not leak when tested in accordance with 6.5.3.

5.1.9 Load carriers shall be provided to locate the load during the washing and disinfection processes. If interchangeable load carriers/baskets are provided, each carrier load shall be capable of being fitted and removed from the WD without the use of tools.

The type and quantity of load carriers (see 5.27) are items to be specified by the purchaser.

5.1.10 The construction of the load carriers shall be such that these are cleaned and disinfected during the normal operating cycle and do not obstruct the free flow of water to the drain [see 5.9.1 a), b) and e)]. Compliance shall be checked by testing in accordance with 6.5.2, 6.5.4, 6.8.2 and 6.10.2.

Dimensions in millimetres



^a Pipe thread ISO 228-G 1/2 A.

Figure 1 — Entry port for temperature sensor leads