INTERNATIONAL STANDARD

ISO 15883-1

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Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

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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]

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.

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

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 61010-2-045, *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*

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 a product and/or its container

3.5
calibration
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 standard

[EN 285:1996, definition 3.5]

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
***D* value**
exposure time required under a defined set of conditions to cause a 1-logarithm or 90 % reduction in the population of a particular microorganism

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

[ISO/TS 11139:2001, definition 2.20]

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

[ISO/TS 11139:2001, definition 2.24]

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

[ISO/TS 11139:2001, definition 2.26]

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

[ISO/TS 11139:2001, definition 2.50]

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**
change in temperature in kelvins (K) required to achieve a tenfold change in the rate of microbial inactivation by a moist heat disinfection process

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.