



International Standard

ISO 15883-1

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

**Second edition
2024-10**



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Published in Switzerland

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15883-1:2006), which has been technically revised. It also incorporates ISO 15883-1:2006/Amd 1:2014.

The main changes are as follows:

- alignment of terms and definitions with ISO 11139:2018 + Amd 1:2024;
- addition of requirements for load carrier(s);
- clarification of water quality requirements;
- elaboration of load dryness tests for external and internal surfaces of load items (see [6.12](#));
- relocation of former Annex C, *Test methods for the detection and assessment of residual proteinaceous contamination*, to ISO 15883-5:2021;
- redesignation of former Annex D, *Microbiological recovery medium for estimation of bacterial contamination of water*, as [Annex C](#);
- increase in the minimum temperature limit for thermal disinfection and calculation of A_0 values from 65 °C to 70 °C (see Reference [\[48\]](#));
- revision of the Bibliography.

A list of all parts in the ISO 15883 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

Fields of application within the scope of ISO 15883 series can include laboratory, veterinary, dental and pharmaceutical applications and other specific applications, such as WD for bedsteads and transport carts and the disinfection of crockery and cutlery intended for use with immunologically compromised patients.

WD are used only for processing the type of loads specified by the manufacturer of the WD.

In selecting the appropriate WD, references are made both to this document and to the relevant parts of ISO 15883 series. It is the user's responsibility to ensure that the choice of type of WD, operating cycle or quality of services or process chemicals is appropriate for any particular load.

This document has been prepared on the basis that each individual WD is subject to validation tests (e.g. installation qualification, operational qualification, and performance qualification on first installation) and that in use continued conformance is established by periodic tests.

NOTE Local or national regulations can apply in respect of the potential adverse effects on the quality of water intended for human consumption or environmental impacts caused by the WD and its intended use.

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

1 Scope

This document specifies general performance requirements for washer-disinfectors (WD) and washer-disinfectors accessories that are intended to be used for cleaning and disinfection of reusable medical devices. It specifies performance requirements for cleaning and disinfection as well as for the accessories that can be required to achieve the necessary performance. The methods and instrumentation required for validation, routine control and monitoring and requalification, periodically and after essential repairs, are also specified.

NOTE 1 The requirements can be applied to WD intended for use with other articles used in the context of medical, dental, pharmaceutical and veterinary practice.

The requirements for WD intended to process specific loads are specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7. For WD intended to process loads of two or more different types, the requirements of the applicable parts of ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7 apply.

This document does not specify requirements intended for machines for use for laundry or general catering purposes.

This document does not include requirements for machines which are intended to sterilize the load, or which are designated as “sterilizers” and addressed in other standards.

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

NOTE 2 Chemicals in some cleaning agents and disinfectants can react with prion protein in a manner that can inhibit its removal or inactivation. If the presence of prion protein is considered a possibility, then this can influence the choice of cleaning agent and disinfectant.

NOTE 3 This document can be used by prospective purchasers and manufacturers as the basis of agreement on the specification of a WD. The test methods for demonstration of conformity with the requirements of this document can also be employed by users to demonstrate continued conformity of the installed WD throughout its service life. Guidance on a routine test programme is given in [Annex A](#).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7000, *Graphical symbols for use on equipment — Registered symbols*

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

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

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

ISO 15883-2¹⁾, *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 15883-3, *Washer-disinfectors — Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

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

ISO 15883-5:2021, *Washer-disinfectors — Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy*

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

ISO 15883-7²⁾, *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment*

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

IEC 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances*

IEC 60751:2008, *Industrial platinum resistance thermometer and platinum temperature sensors*

IEC 61010-2-040:2020, *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 61326-1:2020, *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 graphical symbols for registration*

European Pharmacopoeia, *Assays – 2.5.30 Oxidising substances; Biological tests - 2.6.14 Bacterial endotoxins*

United States Pharmacopeia, *Chemical tests <541> Titrimetry, Oxidation-Reduction (Redox) titrations; Biological tests <85> Bacterial endotoxins test*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

3.1

A_0
measure of microbiological lethality delivered by a moist heat *disinfection* (3.14) process expressed in terms of the equivalent time in seconds at 80 °C with reference to a *microorganism* (3.33) with a z value of 10 K

Note 1 to entry: See [Annex B](#).

[SOURCE: ISO 11139:2018, 3.1, modified — Note 1 to entry has been added.]

1) 2006 version title (current version). The second edition title will be: *Washer-disinfectors — Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for critical and semi-critical medical devices*.

2) 2016 version title (current version). The second edition title will be: *Washer-disinfectors — Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile non-critical medical devices and healthcare equipment*.

3.2

automatic controller

device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

[SOURCE: ISO 11139:2018, 3.18]

3.3

bedpan washer disinfectant

washer-disinfectant ([3.58](#)) for human waste containers that additionally empties and flushes

[SOURCE: ISO 11139:2018, 3.22]

3.4

bioburden

population of viable *microorganisms* ([3.33](#)) on or in product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]

3.5

calibration

operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO 11139:2018, 3.31]

3.6

calorifier

closed vessel, at a pressure greater than atmospheric, in which water is indirectly heated by the flow of heated *fluid* ([3.21](#)) through a heat exchanger

[SOURCE: ISO 11139:2018, 3.32]

3.7

chamber

part of equipment in which a *load* ([3.28](#)) is processed

Note 1 to entry: The chamber does not include steam generators, pipework, e.g. drain and fittings from which it can be isolated.

[SOURCE: ISO 11139:2018, 3.36, modified — Note 1 to entry has been added.]

3.8

chemical disinfection

disinfection ([3.14](#)) achieved by the action of one or more chemicals

[SOURCE: ISO 11139:2018, 3.42]

3.9

cleaning

removal of contaminants to the extent necessary for further processing or for intended use

[SOURCE: ISO 11139:2018, 3.46]

3.10

continuous process machine

equipment that moves one work unit at a time between each step of the process with the product generally remaining in motion

Note 1 to entry: This is contrasted with batch process equipment, which would expose the entire batch to each step of the process, one step at a time.

[SOURCE: ISO 11139:2018, 3.62]

3.11

cycle complete

message from the automatic controller that the operating cycle has ended successfully

[SOURCE: ISO 11139:2018, 3.71]

3.12

D value

D₁₀ value

time or dose required under stated conditions to achieve inactivation of 90% of a population of the test *microorganisms* ([3.33](#))

[SOURCE: ISO 11139:2018, 3.75]

3.13

dead volume

<washer-disinfector> enclosed space of pipework which is not purged by the usual flow of liquids during the *operating cycle* ([3.36](#))

[SOURCE: ISO 11139:2018, 3.318.2]

3.14

disinfection

process to inactivate viable *microorganisms* ([3.33](#)) to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.15

disinfection temperature

minimum temperature on which the evaluation of the *disinfection* ([3.14](#)) efficacy is based

Note 1 to entry: Several *disinfection* ([3.14](#)) temperatures can prevail during the *disinfection* ([3.14](#)) stage.

[SOURCE: ISO 11139:2018, 3.85, modified — Note 1 to entry has been added.]

3.16

disinfection time

period for which the *process variable(s)* ([3.42](#)) is/are maintained at or above that/those specified

Note 1 to entry: Examples of *process variables* ([3.42](#)) include temperature of the *load* ([3.28](#)), disinfectant concentration in the chamber.

[SOURCE: ISO 11139:2018, 3.86]

3.17

double-ended

having separate doors for loading and unloading in separate areas

[SOURCE: ISO 11139:2018, 3.92]

3.18

endoscope washer-disinfector

washer-disinfector ([3.58](#)) intended to clean and disinfect *loads* ([3.28](#)) comprising flexible endoscopes

[SOURCE: ISO 11139:2018, 3.100]

3.19

fail safe

attribute of equipment, or its associated services, that ensures that a malfunction will not give rise to a hazardous situation

[SOURCE: ISO 11139:2018, 3.115]

3.20

fault

situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: ISO 11139:2018, 3.116]

3.21

fluid

substance that continually deforms (flows) under applied shear stress

EXAMPLE Liquid, gas, vapour, plasma.

[SOURCE: ISO 11139:2018, 3.120]

3.22

flushing

purging

removing by displacement with a *fluid* ([3.21](#))

[SOURCE: ISO 11139:2018, 3.121]

3.23

free draining

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

[SOURCE: ISO 11139:2018, 3.124]

3.24

holding time

period during which process parameters are maintained, within their specified tolerances

[SOURCE: ISO 11139:2018/Amd1:2024, 3.133]

3.25

human waste

body *fluids* ([3.21](#)) and excretions

EXAMPLE Faeces, urine, blood, pus, vomit, mucus.

[SOURCE: ISO 11139:2018, 3.134]

3.26

human waste container

vessel for holding and transporting *human waste* ([3.25](#))

[SOURCE: ISO 11139:2018, 3.135]

3.27

installation qualification

IQ

process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: ISO 11139:2018, 3.220.2]

3.28

load

product, equipment, or materials to be processed together within an *operating cycle* (3.36)

[SOURCE: ISO 11139:2018, 3.155]

3.29

loading door

means of access through which a *load* (3.28) is passed into the chamber before processing

[SOURCE: ISO 11139:2018, 3.157]

3.30

lumen device

item that consists of tube(s) or pipe(s)

[SOURCE: ISO 11139:2018, 3.158]

3.31

medical device

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, or software material, or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical 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 by means of in vitro examination of specimens derived from the human body,

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

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- items specifically intended for cleaning or sterilization of medical devices;
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.166]

3.32

microbial reduction factor

extent to which the *bioburden* (3.4) is reduced in tenfold increments

Note 1 to entry: It is expressed as $\log_{10}$.

[SOURCE: ISO 11139:2018, 3.174]

3.33

microorganism

entity of microscopic size, encompassing bacteria, fungi, protozoa, and viruses

[SOURCE: ISO 11139:2018, 3.176]

3.34

monitoring

continual checking, supervising, critically observing, or determining the status in order to identify change from the performance level required or expected

[SOURCE: ISO 11139:2018, 3.180]

3.35

normal operation

use of equipment in accordance with the manufacturer's instructions and with all process parameters within the specified tolerances

[SOURCE: ISO 11139:2018, 3.185]

3.36

operating cycle

complete set of stages of a process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the operating cycle.

[SOURCE: ISO 11139:2018, 3.188]

3.37

operating pressure

fluid (3.21) pressure occurring during an *operating cycle* (3.36)

[SOURCE: ISO 11139:2018, 3.189]

3.38

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 11139:2018, 3.220.3]

3.39

override

system by which an *operating cycle* (3.36) can be interrupted or modified as necessary

[SOURCE: ISO 11139:2018, 3.191]

3.40

performance qualification

PQ

process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

Note 1 to entry: The performance qualification for washer-disinfectors relates to the number of items cleaned and disinfected to the required standard.

[SOURCE: ISO 11139:2018, 3.220.4, modified — Note 1 to entry has been added.]

3.41

process chemical

formulation of substances intended for use in equipment

EXAMPLE Detergents, surfactants, rinse aids, disinfectants, enzymatic cleaners.

[SOURCE: ISO 11139:2018, 3.207, modified — EXAMPLE has been added.]

3.42

process variable

chemical or physical attribute within a cleaning, *disinfection* ([3.14](#)), packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: ISO 11139:2018, 3.213]

3.43

recognized culture collection

depository authority under The Budapest Treaty on *The International Recognition of the Deposit of Microorganisms for the Purposes of Patent and Regulation*

[SOURCE: ISO 11139:2018, 3.222]

3.44

recorder

equipment that records and produces a permanent record of information graphically, digitally, or electronically

[SOURCE: ISO 11139:2018, 3.224]

3.45

reference microorganism

microbial strain obtained from a recognized culture collection

[SOURCE: ISO 11139:2018, 3.228]

3.46

requalification

repetition of part or all of *validation* ([3.56](#)) for the purpose of confirming the continued acceptability of a specified process

[SOURCE: ISO 11139:2018, 3.220.5]

3.47

rinsing

removing process residues through displacement by, and dilution with, water

[SOURCE: ISO 11139:2018, 3.237]

3.48

routine test

technical operation conducted periodically to establish that the operational performance of the equipment or process remains within the limits established during *validation* ([3.56](#))

[SOURCE: ISO 11139:2018, 3.238]

3.49

self-disinfection cycle

operating cycle (3.36) intended to disinfect all liquid transport systems' piping, chamber(s), tanks and other components which come into contact with the water and/or solutions used for cleaning, disinfecting, and rinsing the *load* (3.28)

[SOURCE: ISO 11139:2018, 3.249, modified — Note 1 to entry has been deleted.]

3.50

stage

<operating cycle> part of an *operating cycle* (3.36) with a specified function

[SOURCE: ISO 11139:2018, 3.262, modified — EXAMPLE deleted.]

3.51

temperature band

range of temperatures expressed as the minimum and the maximum temperatures which prevail during the specified period of a cycle

[SOURCE: ISO 11139:2018, 3.293, modified — Note 1 to entry has been deleted.]

3.52

test soil

formulation designed for use as a substitute for a contaminant or debris found on a device after use

[SOURCE: ISO 11139:2018, 3.300]

3.53

thermal disinfection

disinfection (3.14) achieved by the action of moist heat

[SOURCE: ISO 11139:2018, 3.301]

3.54

type test

technical operation to verify conformity of an equipment type to a standard or specification, and to establish data for reference in subsequent tests

[SOURCE: ISO 11139:2018, 3.306]

3.55

unloading door

means through which a *load* (3.28) is removed from the chamber after processing

[SOURCE: ISO 11139:2018, 3.310]

3.56

validation

confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

Note 4 to entry: Surrogate product or clinically used product can be used for validation performed in a washer-disinfector.

[SOURCE: ISO 11139:2018, 3.313, modified — Note 4 to entry has been added.]

3.57

verification

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

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “verified” is used to designate the corresponding status.

[SOURCE: ISO 11139:2018, 3.314]

3.58

washer-disinfector

WD

equipment designed to clean and disinfect product

[SOURCE: ISO 11139:2018, 3.319]

3.59

washer-disinfector accessory

items or attachments, including connectors, required to process a medical device in a *washer-disinfector* ([3.58](#))

[SOURCE: ISO 11139:2018, 3.320]

3.60

washing

removal of contaminants from surfaces by means of an aqueous *fluid* ([3.21](#))

[SOURCE: ISO 11139:2018, 3.321]

3.61

works test

series of technical operations performed prior to delivery to demonstrate compliance of a piece of equipment with its specification

[SOURCE: ISO 11139:2018, 3.325]

3.62

z value

change in temperature of a thermal sterilization or *disinfection* ([3.14](#)) process that produces a tenfold change in *D* value

Note 1 to entry: It is expressed in degree Celsius (°C).

[SOURCE: ISO 11139:2018, 3.326]

4 Performance requirements

4.1 General

4.1.1 Conformity with the performance requirements shall be tested in accordance with the methods given in [Clause 6](#).

NOTE Conformity of a WD to this document and subsequent relevant parts of the ISO 15883 series 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 A WD conforming to ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7 shall use an operating cycle that includes cleaning, disinfection, rinsing and, when appropriate, drying.

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

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

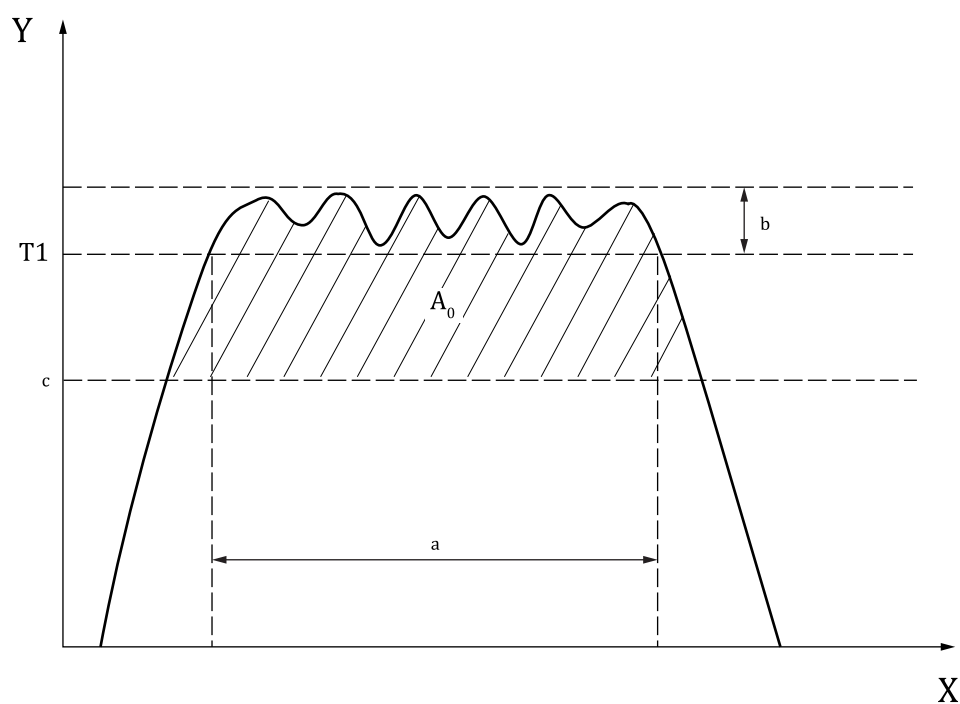
- a) cleaning, which may include pre-wash flushing, washing and rinsing stages (see [4.2](#));
- b) disinfection (see [4.3](#));
- c) final rinsing (see [4.4](#));
- d) drying, when appropriate (see [4.5](#)).

When appropriate, more than one of the functions listed in a) to d) can be combined in a single stage if so specified and validated for the items to be processed.

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

4.1.5 Disinfection is specified by reference to the evolution of the temperature through a specific contact time (temperature profile) for thermal disinfection or as time, temperature and concentration for chemical disinfection.

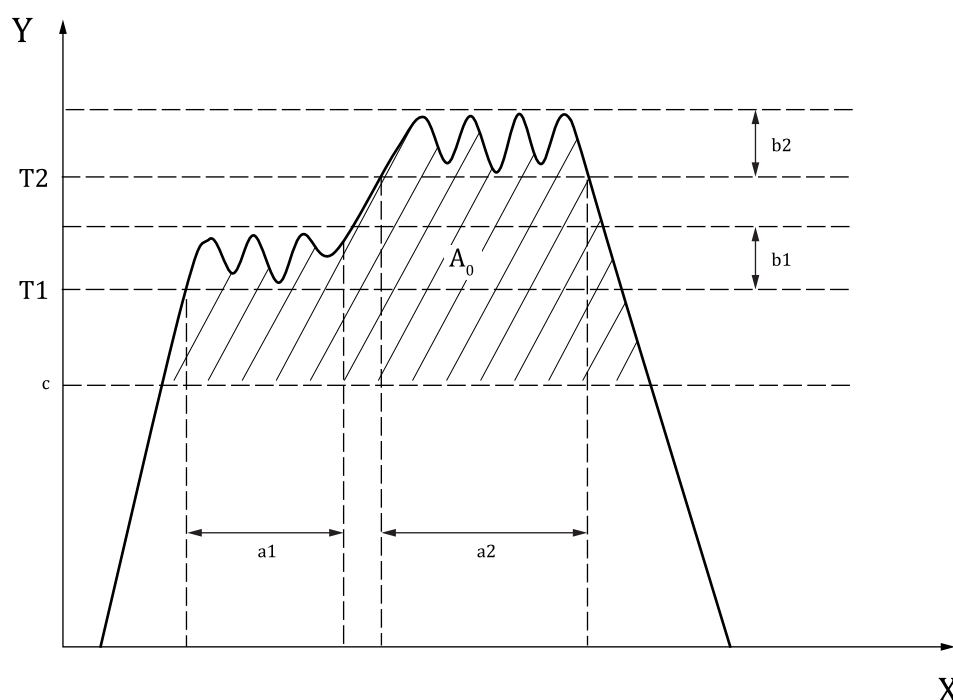
NOTE Several temperature profiles can prevail during the disinfection stage. Examples can include a specific temperature maintained for a specified holding time (see [Figure 1](#)) or several holding times and disinfection temperatures (see [Figure 2](#)).



Key

- X time
- Y temperature
- T1 disinfection temperature (see [3.15](#))
- a Disinfection time (see [3.16](#)).
- b Temperature band (see [3.51](#)).
- c 70 °C.

Figure 1 — Temperature profile including a single holding time and a single disinfection temperature



Key

X	time
Y	temperature
a1	Disinfection time 1 (see 3.16).
a2	Disinfection time 2 (see 3.16).
b1	Temperature band 1 (see 3.51).
b2	Temperature band 2 (see 3.51).
c	70 °C.
T1	disinfection temperature 1 (see 3.15)
T2	disinfection temperature 2 (see 3.15)

Figure 2 — Temperature profile including two disinfection temperatures and two holding times

4.1.6 Within the WD, each chamber that is used to contain the load shall be capable of being self-disinfected (see 4.7) under the control of the automatic controller.

The WD shall be designed and constructed so that during the disinfection and subsequent stages of the operating cycle there shall be no recontamination or transfer of microorganisms (and, if specified, bacterial endotoxins) from the WD to the load, to an extent that is unacceptable for the intended use of the load.

This shall be achieved by either of the following:

- ensuring that all parts of the WD that recirculate fluids to the load or chamber are disinfected during the normal operating cycle (see 4.7.2);
- by the provision of a separate self-disinfection cycle (see 4.7.1).

4.1.7 Chambers in which process fluid is present during the operating cycle shall be free draining (see 6.5.3 and 6.5.4).

4.1.8 A WD that is a continuous process machine shall be designed in such a way that the WD, the load carrier(s) and the load are not recontaminated 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.

NOTE Refer to [4.5.3](#) for means to control environmental air, e.g. by use of high efficiency particulate air (HEPA) filters.

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.

4.1.11 Load carrier(s), and if applicable their accessories, shall enable the arrangement and connection of the devices/loads intended to be processed so that all their outer surfaces, including joints and crevices, and if applicable, inner surfaces (e.g. lumen), are thoroughly irrigated.

4.1.12 The process chemicals and the quality of water (see [6.4](#)) used during product compatibility studies and testing shall be specified (see [8.2](#)) to demonstrate conformance of the WD with the requirements of this document.

4.1.13 The pressure or flow inside the pipework system shall be maintained above a specified minimum level for combination with the applicable load carrier(s).

4.2 Cleaning

4.2.1 General

Cleaning shall be deemed to have been achieved if the performance and test method requirements in ISO 15883-5:2021 have been met, as well as [6.10](#) of this document, and the relevant applicable requirements of ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7. Cleaning efficacy testing shall be performed in the WD and with washer-disinfector accessories specified in the design of the WD, in two phases:

- a) type testing under simulated use conditions with specified test soil(s), including the analyte(s) and representative test load(s) in accordance with ISO 15883-5:2021, 4.4.1;
- b) performance qualification testing with worst-case load(s) soiled by clinical use in accordance with ISO 15883-5:2021, 4.4.1, or if justified in accordance with ISO 15883-5:2021, 5.4.2, with surrogate product.

NOTE 1 Refer to [Annex A](#) for guidance on test programme.

NOTE 2 For details and exceptions, see ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7.

4.2.2 Pre-wash flushing stage

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

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

4.2.3 Washing stage

The temperature of washing solutions in contact with the load during the washing stage shall be controlled within limits (see [5.9.1](#)).

The temperature of the washing solutions shall be controlled within the maximum and minimum temperatures according to the instructions for use of the detergent(s). The detergent concentration(s) or volume shall be attained within the range specified in the relevant requirements in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7.

4.2.4 Rinsing stage

Rinsing shall take place between washing and disinfection unless it can be demonstrated that

- a) there is no adverse reaction between process chemicals being used for each of these stages;
- b) there is no adverse reaction between suspended or residual soiling that can compromise the disinfection stage.

4.3 Disinfection

4.3.1 Thermal disinfection

4.3.1.1 Thermal disinfection of the load and load carrier(s) shall be deemed to have been achieved if, when tested in accordance with [6.8.2](#) and the relevant requirements in ISO 15883-2, ISO 15883-3, ISO 15883-6, the specified minimum temperature for the specified minimum (holding) time, or the equivalent lethality (A_0 , see [Annex B](#) and Reference [\[47\]](#)), 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 when tested in accordance with [6.8.3](#) and the relevant requirements in ISO 15883-2, ISO 15883-3, ISO 15883-6, 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 continuously follow the temperature profile specified for the disinfection stage. For each disinfection temperature, the temperature shall be continuously maintained within the specified disinfection temperature band for the specified disinfection time.

4.3.1.4 The temperature on all surfaces of the load and load carrier(s) shall meet the requirements specified in [5.9.1 a](#)).

4.3.1.5 The temperatures recorded on the surface of the chamber wall shall meet the requirements specified in [5.9.2 a](#)).

The temperature for thermal disinfection shall be 70 °C or greater (see References [\[47\]](#) and [\[48\]](#)).

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. Any chemical disinfectant used shall be validated for this application.

NOTE 1 Demonstration that the disinfectant meets the above requirements can be based on methods in relevant published standards or other relevant publications, e.g. EN 13624,[\[19\]](#) EN 13727,[\[21\]](#) EN 14348,[\[23\]](#) EN 14476,[\[24\]](#) EN 14561,[\[25\]](#) EN 14562,[\[26\]](#) EN 14563,[\[27\]](#) EN 14885,[\[28\]](#) EN 17111,[\[29\]](#) EN 17126,[\[30\]](#) AOAC Use dilution tests,[\[32\]](#) AOAC Tuberculocidal test (965.12),[\[33\]](#) ASTM E2197 virucidal test,[\[35\]](#) OECD Guideline[\[42\]](#).

NOTE 2 Suitable methods also include, e.g. the AOAC sporocidal test (966.04),[\[34\]](#) ASTM E2111,[\[36\]](#) EN 13704,[\[20\]](#) EN 14347[\[22\]](#).

NOTE 3 National regulatory authorities can require different inactivation values in which case, the tests listed in NOTES 1 and 2 can need to be modified to demonstrate these values.

4.3.2.2 Chemical disinfection of the chamber walls and load carrier(s) 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 carrier(s).

4.3.2.3 The conditions of time, temperature and chemical disinfectant concentration shall be those specified, under the conditions of use of the disinfectant, as labelled, i.e. in the instructions for use (IFU).

Alternatively, the conditions of time, temperature and chemical disinfectant concentration that provide the required microbial reduction factor (see [4.1.5](#)) shall be determined.

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

4.3.2.4 Microbiological testing shall be performed to demonstrate conformity with the requirements specified for the corresponding load in accordance with ISO 15883-4 for thermolabile endoscopes and ISO 15883-7 for thermolabile non-critical devices.

4.3.2.5 Chemical disinfection temperature

4.3.2.5.1 For chemical disinfection, throughout the disinfection stage and when tested as described in [6.8](#), the temperature recorded on the surface of the chamber and on all surfaces of the device being processed shall follow the temperature profile specified for the disinfection stage and shall be:

- a) not lower than the disinfection temperature specified for the WD and disinfectant;
- b) not higher than the maximum temperature specified for the disinfectant;
- c) not higher than the maximum temperature specified for the types of loads for the particular type of disinfectant.

4.3.2.5.2 At temperatures above 70 °C, an important part of the disinfection efficacy is attributed to thermal disinfection and should be evaluated as such to demonstrate the efficacy of the chemical disinfectant (see [5.9](#) and [Annex B](#)).

4.3.2.5.3 The temperature on all surfaces of the load and load carrier(s) shall meet the requirements specified in [5.9.1](#) c) when tested in accordance with [6.8.2](#).

4.3.2.5.4 The temperatures recorded on the surface of the chamber wall shall meet the requirements specified in [5.9.2](#) b) when tested in accordance with [6.8.3](#).

4.4 Final rinsing

4.4.1 The WD shall be provided with a rinsing stage that removes any residual soils from the load and also reduces the concentration of process chemicals on the load to a level not exceeding that specified for 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 [6.10.5](#) and with the relevant requirements in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7, 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 in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7, be provided with a drying stage, which removes moisture from the outer, and where applicable, inner surfaces of 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 ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7, no residual moisture 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 filtered air.

4.5.4 When air filters are fitted, means shall be provided to enable the integrity of the filtration system to be verified at the point of use (see [6.11](#)).

NOTE Many WD are fitted with air filters to remove particulate material from the air supplied to the drying stage. These filters are often HEPA filters (Class H13 or higher as specified in EN 1822-1:2019[18]) of the type used to remove bacterial contamination from an air supply.

4.6 Process chemicals

Process chemicals shall be validated through type testing. If process chemicals other than those tested during type testing are used, then the relevant parts of type testing shall be repeated.

NOTE 1 The relevant type testing can include cleaning efficacy, disinfection and process residues.

Any requirements for compatibility, safe handling, data on the maximum permitted residual level on devices and the method of detection to be used for determining process residuals shall be specified for each process chemical [see [8.2 g](#)]. 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.

The instructions for use of the process chemical(s), e.g. regarding the concentration, temperature and water quality, shall be followed.

All process chemicals shall be stored and used in accordance with the process chemical instructions for use.

NOTE 2 For example, changes in temperature can affect the concentration of active ingredients or its viscosity.

4.7 Self-disinfection

4.7.1 A self-disinfection cycle shall be provided to ensure that the WD does not become a focus for contamination of the load and to provide a means of disinfecting the WD after interventions for maintenance, repairs or testing.

NOTE 1 The self-disinfection process is intended also to deal with the situation where the WD has become contaminated. The internal piping in a WD, if contaminated, can easily develop a layer of biofilm containing many microorganisms in a state in which they are highly resistant to disinfection.

NOTE 2 Thermal disinfection using moist heat is the preferred method. The temperature used can be higher than the normal maximum operating temperature available for the loaded WD. If the use of thermal disinfection is not possible, a disinfectant can be used (see ISO 15883-4).

NOTE 3 Disinfection cannot be relied upon to inactivate all bacterial endospores.