



**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  
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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](http://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](http://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](http://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](http://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.

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# 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 15883-2<sup>1)</sup>, *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 15883-7<sup>2)</sup>, *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 disinfecter**

*washer-disinfecter* (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**

**$D_{10}$  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](#)).

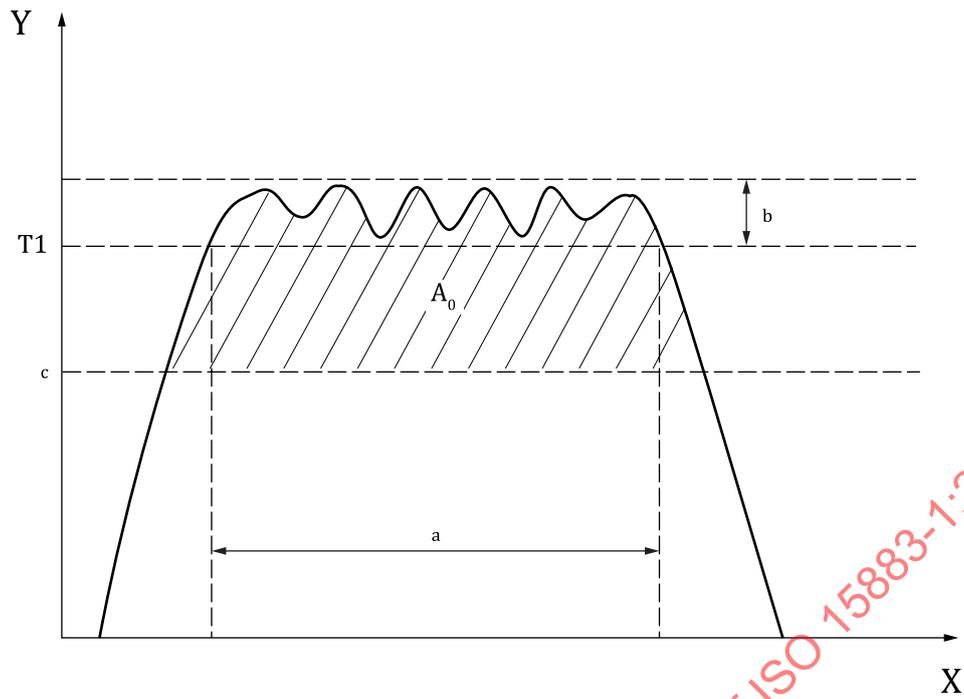
When appropriate, more than one of the functions listed in a) to d) can be combined in a single stage if so specified and validated for the items to be processed.

**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](#)).

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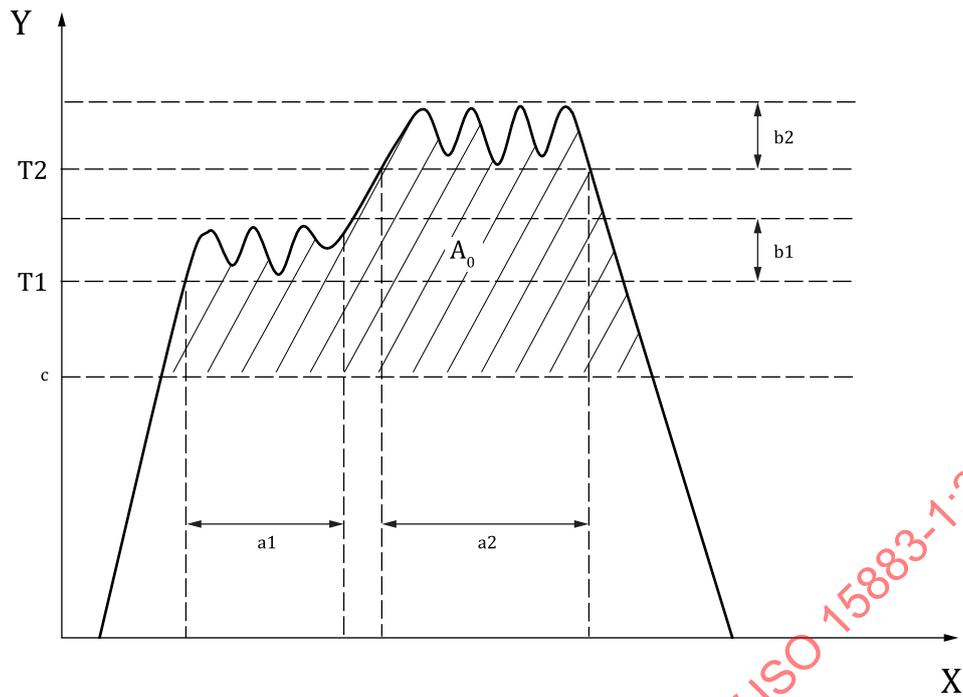


**Key**

- 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**

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#### 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<sup>[18]</sup>) 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.

**4.7.2** A WD in which the operating cycle provides for disinfection of the chamber and all piping and tanks that come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load, shall be deemed to meet this requirement without the provision of an additional self-disinfection cycle.

**4.7.3** Details shall be provided of the parts of the WD subjected to the self-disinfection cycle and whether this cycle includes the water treatment equipment that is integral to the WD.

**4.7.4** Thermal self-disinfection of the chamber walls and all piping and tanks which come into contact with the water or solutions used for cleaning, disinfecting and rinsing shall be deemed to have been achieved if, when tested in accordance with [6.8.3](#) and ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6 and ISO 15883-7, the specified minimum temperature is attained for the specified minimum time, or the equivalent lethality ( $A_0$ ), is achieved.

**4.7.5** Thermal self-disinfection systems shall be evaluated by thermometric monitoring of the system with sensors placed at those parts of the system specified as representative of the lowest temperatures in the system (see [6.8](#)).

**4.7.6** When different from the normal operating cycle, the WD self-disinfection cycle shall:

- a) be operated under the control of the automatic controller;
- b) be a user selectable cycle;
- c) provide for disinfection of the chamber and all piping and tanks that come into contact with the water or solutions used for cleaning, disinfecting and rinsing the load;
- d) include means to warn the user that the WD shall be operated without any load in the chamber and, so far as is practicable, include means to verify that no device is present before the cycle will operate.

**4.7.7** Information shall be provided for the use of a self-disinfection cycle (see [4.7.2](#)) prior to use when the WD has not been used for a period of 24 h or more [see [8.3 b](#))].

## **5 Mechanical and process requirements**

### **5.1 Materials, design and manufacture/construction**

#### **5.1.1 Materials**

**5.1.1.1** The materials used in the WD and its washer-disinfector accessories, including load carrier(s), shall tolerate the chemical, mechanical and thermal strains encountered during normal use as specified (see [Clause 8](#)).

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

All parts of the WD that come into contact with the water, chemicals or steam shall be able to withstand the possible corrosive actions of these substances.

**NOTE** The material used can have an effect on the aggregation or accumulation of microorganisms or organic load.

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.

**5.1.1.2** The components of the system used to contain and dispense process chemicals 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.

## **5.1.2 Design and manufacture/construction**

**5.1.2.1** Unless otherwise specified, the chamber shall be designed to withstand no less than 10 000 operating cycles without suffering failure when operated and maintained in accordance with the WD instructions.

Conformity shall be established by review of the design verification data (see ISO 13485).

**5.1.2.2** Floor mounted WD shall be provided with means to compensate for irregular surfaces on floors. The maximum deviation from a plane horizontal surface that can be accommodated shall be specified [(see [8.2 j](#))].

**5.1.2.3** The maximal floor loading for operating the WD shall be specified.

**5.1.2.4** 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. Panels should be easily removed and reinstalled. Information supplied prior to installation should indicate if the machine's location restricts access to the machine, e.g. it is located against a wall [see [Clause 10 m](#)].

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

External surfaces of the WD should have a smooth finish.

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

**5.1.2.7** The chamber shall not leak (see [6.5.2](#)).

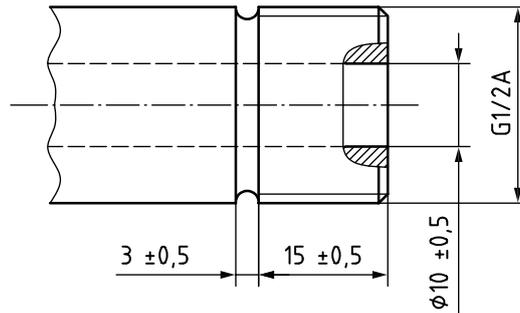
**5.1.2.8** An entry port shall be provided to enable temperature sensors to be inserted into the chamber. This shall be a straight connecting sleeve provided at an accessible point. The port shall be wide enough to insert enough sensors to execute testing. If other technology is used, an explanation of the methodology shall be provided.

The port shall be self-draining and sealed when not in use.

### EXAMPLE

In this example, the connecting sleeve has an internal diameter of  $(10 \pm 0,5)$  mm, an external male thread extending for a length of  $(15 \pm 0,5)$  mm with a clear distance of  $(3 \pm 0,5)$  mm before any increase in diameter of the sleeve (see [Figure 3](#)).

The connecting sleeve with its O-ring seal or flat seal is designed to be closed with a cap, and a temperature proof and mechanically resistant seal.



**Figure 3 — Entry port for temperature sensor leads**

### 5.1.3 Load carrier(s)

**5.1.3.1** Load carrier(s) shall be provided to locate the load during the operating cycle. If interchangeable load carrier(s) are provided, each carrier load shall be capable of being fitted and removed from the WD manually or by automated equipment.

When the load carrier(s) has/have pipework supplying process fluids, the connection shall be verifiable by the automatic controller or visually as specified in IFU.

**5.1.3.2** The load carrier(s) shall be designed to be cleaned and disinfected together with the load during the normal operating cycle and not obstruct the flow of water to the drain [see 5.9.1 a), c) and f)] in order to minimize transfer of water into the subsequent process stage (see 6.10.5).

The load carrier(s) shall not prevent either the attainment of the pre-set process parameters or the penetration of process fluids into the load.

Conformity shall be verified by testing in accordance with 6.5.3, 6.5.4, 6.8.2 and 6.10.2.

**NOTE** Any contact between load and load carrier(s) or between load items can compromise the efficacy of the process.

**5.1.3.3** The pipework of the load carrier(s) shall be designed so that the dead volume and transfer (i.e. carry-over) of process fluids from one process stage to the next is minimized. If necessary, means shall be provided to allow for removal of deposits within load carrier pipework.

**5.1.3.4** If applicable, for cleaning and disinfection of hollow and lumen devices, the load carrier(s) shall be equipped with the required connectors and load supports which allow sufficient flow of process fluids into the inner areas of these devices.

**5.1.3.5** Load carrier(s) connected to the process fluid circulation system shall be designed and constructed so that they align correctly in the WD (see 6.7.1).

**5.1.3.6** Load carrier(s) with pipework shall have a reference connection to enable verification of sufficient process fluid supply by a specified static pressure measurement.

## 5.2 Safety

**5.2.1** The WD shall conform with the requirements of IEC 61010-2-040:2020, Clauses 4 to 17.

**NOTE** WD are not Medical Electrical Equipment, as defined, and therefore, IEC 60601-1 is not required for safety compliance, and IEC 60601-1-2 is not a requirement for EMC compliance.

**5.2.2** WD shall conform with IEC 61326-1:2020 regarding electromagnetic compatibility (EMC).

WD operating in areas intended for medical electrical equipment or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified by IEC 61326-1:2020.

The immunity performance criteria selected shall ensure that WD performance as specified by [Clause 4](#) of this document is met when exposed to disturbance phenomena of IEC 61326-1:2020, Table 2.

**5.2.3** Risk analysis shall address the specific WD design and features. Measures taken for risk reduction shall consider aspects such as handling of process chemistry, heat or burning risks to user, ease of use, ergonomics and the knowledge, experience and training of the user.

NOTE ISO 12100<sup>[8]</sup> or IEC 61508-1<sup>[18]</sup> can provide further helpful information.

**5.2.4** Risk assessment and risk control for WD design and software shall be performed following the procedures and requirements given in ISO 14971. Specific requirements and results shall be established and documented.

**5.2.5** Application of usability engineering/human factors shall be considered during WD and WD software design.

NOTE See IEC 62366-1.<sup>[15]</sup>

## **5.3 Tanks**

**5.3.1** Tanks for storing process water within the WD shall be:

a) free-draining;

NOTE Any residual water can be a source for growth of microorganisms.

b) located such that they can be cleaned and disinfected without dismantling any part of the machine other than normally removable panels and retainers;

c) either drained down automatically when the machine is switched off or fitted with a manual drain system accessible to the user;

d) fitted with a means to indicate to the operator that a tank is overflowing;

e) fitted with a means to indicate to the operator the level of water remaining in the tank.

**5.3.2** Water quality shall be considered in accordance with [5.23](#).

**5.3.3** When water is to be heated, the temperature to which it is heated shall be controlled within the limits specified for the process.

**5.3.4** When heat sources are installed, they shall be accessible for maintenance.

**5.3.5** In order to meet microbial specifications, rinse water used in the final stage after disinfection shall be of potable quality (see Reference [\[18\]](#)), or better, and may be taken from a built-in water tank only under at least one of the following conditions:

a) the rinse water in the tank is kept constantly at a minimum of 70 °C;

NOTE 1 In order to maintain a minimum temperature of 70 °C the tank would have to be maintained at a higher temperature, e.g. 75 °C, so that when the supply is replenished by incoming cold water the temperature remains above 70 °C.

b) the rinse water is automatically disinfected in the process immediately prior to the rinse;

NOTE 2 See [5.23](#) for specific requirements for water supply.

c) the rinse water is filtered to remove suspended particles of a size greater than 0,2 µm.

## 5.4 Loading and unloading doors and their controls

### 5.4.1 General

5.4.1.1 The arrangement of doors shall be as specified [see [Clause 10 n](#)].

WD can be fitted with either one door, which serves for both loading and unloading, or be double-ended.

NOTE Continuous process machines do not have conventional doors (see [5.4.5](#)).

5.4.1.2 The door-seal shall prevent liquid passing the seal interface during an operating cycle, e.g. by means of a gasket or a labyrinthine (tortuous path) system.

For the purposes of maintenance and replacing a door-seal gasket, provision shall be made to permit access to the contact surfaces.

Requirements for the door interlock system in association with supply of services (e.g. steam, compressed air, circulating water) to the chamber are specified in IEC 61010-2-040:2020, Clause 15.

When tested in accordance with [6.5.2](#), there shall be no escape of process fluids sufficient to impair the process.

The design of door(s) and door opening(s) shall ensure that any residual water present when the door(s) is/are opened will be discharged to drain.

5.4.1.3 The instructions for use shall provide sufficient details of the setting of all interlocks to allow their correct function to be verified [see [8.3 f](#)].

5.4.1.4 After initiation of an operating cycle the doors for loading and unloading shall be capable of being unlocked and opened only after completion of the operating cycle.

Conformity shall be tested by the method described in [6.3.2](#), [6.3.4](#) and [6.3.7](#).

5.4.1.5 If a fault occurs during an operating cycle, it shall be displayed and access to the load shall be restricted (see [6.3.5](#), [6.3.7](#)).

5.4.1.6 For WD in which access to the load is restricted by means of locked doors this shall require the use of an access device to release the door lock and gain access to the load (see [6.3.7.3](#)).

5.4.1.7 A device, or devices, shall be fitted to enable the secure fastening of a door in the open position and shall be in accordance with the requirements of IEC 61010-2-040:2020, 7.101 and 7.102.

5.4.1.8 It shall not be possible for the operator to start the process if the doors are not locked. Conformity shall be tested in accordance with [6.3.1](#).

The control system can include provision of an override facility for maintenance purposes.

5.4.1.9 Means shall be provided to enable the door(s) to be opened manually if the WD becomes isolated from any of the services powering the door mechanism (see also IEC 61010-2-040:2020, 7.101, 7.102, 7.106, 7.107, 7.110 and 13.1.102).

Details of this procedure shall be provided in the IFU.

## 5.4.2 Control of manually operated doors

An explanation of the manual action required to lock the door shall be provided for the operator. In addition, if the unlocking procedure is not the reverse of the locking procedure, there shall be an indication to the operator of the manual action required to unlock the door.

If necessary, the indication should be clearly displayed either on the door or on its handle or hand-wheel. Explicit instructions should be displayed on the facing panel adjacent to the door or on the operator's control panel.

## 5.4.3 Control of doors of a double-ended WD

**5.4.3.1** The control initiating the operating cycle shall be at the loading side of the WD only. When the loading door is closed and locked, it shall not be possible to open the unloading door until the WD has completed a successful operating cycle, i.e. without showing a fault (see [6.3.3](#) and [6.3.4](#)).

**5.4.3.2** If a fault develops, it shall only be possible to open the loading door (see [6.3.5](#) and [6.3.7](#)).

**5.4.3.3** It shall not be possible for an operator at one end of the WD to open or close a door at the opposite end unless it does not present a hazard and potential for harm. In addition, it shall not be possible for the doors of a WD to be opened simultaneously to permit free passage of air through the WD, under normal operation.

**5.4.3.4** A visual display shall be provided at each end of the WD to indicate when the cycle is in progress.

**5.4.3.5** The indication "cycle complete", or an equivalent indication, shall be cancelled when the unloading door is unlocked, and the loading door shall remain locked until the unloading door has been locked again (see [6.3.4](#)).

## 5.4.4 Internal doors and access ports

If any internal doors or access ports can be opened and closed by an operator without the use of a tool, then means shall be provided to prevent their opening if this is likely to adversely affect the load or the environment in which the WD is located.

NOTE Such doors can be located between consecutive sections of multisection WD or access ports can be located on the outside of a WD.

## 5.4.5 Continuous process machine without doors

**5.4.5.1** WD without doors shall have means to prevent the transfer of contamination from the loading to the unloading side.

**5.4.5.2** WD without doors shall have means to prevent the operator from gaining access to the load during a normal operating cycle before its completion.

**5.4.5.3** WD without doors shall have means to prevent the escape of fluid (e.g. liquids, aerosols and vapours) from the WD during an operating cycle.

**5.4.5.4** For WD in which access to the load is not restricted by means of doors, the method of precluding access during an operating cycle (see [5.4.4](#)) shall not be circumvented without requiring the use of a key, code or tool if a fault occurs.

## 5.5 Pipework and fittings

**5.5.1** The pipework, pumps, valves and fittings of the WD, and if applicable, of the load carrier(s), shall be constructed, installed and/or operated so that any residual liquid will flow towards a drain discharge point (see [6.5.4](#)).

NOTE Residual water that does not drain from the internal pipework of the WD can provide an environment for microbial growth; these microorganisms can then be available to recontaminate the disinfected load. Also, residual fluids can lead to corrosion.

**5.5.2** The pipework shall be so constructed that the dead volume is minimized. Conformance shall be established by review of the design.

## 5.6 Spray systems

**5.6.1** Spray nozzles shall be positioned to ensure complete contact of the spray with all parts of the load together with the appropriate load carrier(s) when loaded in accordance with the WD instructions for use.

**5.6.2** Nozzles and narrow lumen devices shall be protected from blockage by the passage of particles, e.g. by the provision of a filter upstream of the nozzle(s) or lumen device(s) which will remove particles of a size which could block the nozzles.

**5.6.3** All pipes containing nozzles shall be demountable, complete with bayonet, screw or other fittings, with all inside and outside surfaces easily cleanable and disinfectable.

**5.6.4** All nozzles, which are intended to be removable by the user, shall be designed to be suitable for a minimum of 250 matings.

Conformance shall be established by review of the design verification data.

Means shall be provided of identifying that removable nozzles have been installed in their correct position.

All fittings shall be designed to prevent misalignment when nozzles and associated systems are assembled or reassembled.

**5.6.5** It shall be possible to check that the spray nozzles are not blocked and that the spray arms are free to move to the extent specified. The method to be used shall be specified in the instructions for use [see [8.3 b](#)]).

**5.6.6** It shall be possible to check that fixed nozzles intended to provide fluids for the irrigation of hollow and lumen devices provide the specified flow of water and/or aqueous solutions. The method to be used shall be specified in the instructions for use [see [8.3 b](#)]).

## 5.7 Dosing systems

**5.7.1** The WD shall be fitted with dosing systems for controlling the admission of all necessary process chemicals.

**5.7.2** Each system shall be provided with means to adjust the volume admitted. Access to the means of adjustment shall require the use of an access device.

The means of adjustment shall be manual or automatic.

NOTE Access to the means of adjustment can be restricted, e.g. to the manufacturer, their agent, or authorized person.

**5.7.3** The stage(s) of the operating cycle and other specific conditions, if applicable (e.g. temperature, time) at which each dosing system admits chemical to the WD shall be under the control of the automatic controller.

**5.7.4** Each dosing system shall be provided with means to determine, directly or indirectly, that the volume admitted and the time within the operating cycle when the admission occurred were as programmed in the automatic controller.

Failure to admit the specified minimum volume shall cause a fault to be indicated.

Conformity shall be tested in accordance with [6.9.1](#) or by a specified method of demonstrated equivalence.

**5.7.5** The measurement accuracy and reproducibility of the control of volume admitted for each of the dosing systems shall be specified.

Conformity shall be tested in accordance with [6.9](#) or by a specified method of demonstrated equivalence.

**5.7.6** The WD shall be fitted with a system that will indicate when there is (are) insufficient process chemical(s) available for the next cycle.

Conformity shall be tested in accordance with [6.9.2](#).

## **5.8 Load temperature protection**

**5.8.1** WD intended to process items that can be damaged if the pre-set temperatures are exceeded, shall be provided with one or more temperature cut-outs to protect the load from exposure to excessive temperature.

These should be set to operate at a temperature low enough to prevent damage to thermolabile equipment intended for processing.

**5.8.2** The temperature cut-outs shall be capable of being manually reset.

**5.8.3** When used to limit the temperature of any medium coming into contact with the load, temperature cut-outs shall operate at a temperature not more than 5 °C higher than the highest temperature provided by any temperature control or temperature-limiting device (see [6.8.5](#)).

This requirement shall apply to both non-adjustable and adjustable temperature cut-outs, when set at their minimum temperature, and pre-set temperature cut-outs.

**5.8.4** For WD in which the load is heated and/or thermally disinfected by steam heating, the chamber shall be protected against a rise in pressure above the designed working pressure of the chamber when tested in accordance with [6.5.5](#). A chamber designed to work at atmospheric pressure shall not exceed atmospheric pressure by more than 20 kPa [see ISO 61010-2-040:2020, 7.105].

## **5.9 Process temperature control limits**

**5.9.1** When tested in accordance with [6.8.2](#), the process shall meet the following requirements:

- a) for thermal disinfection, the temperatures recorded on the surface of the load and load carrier(s) follow the temperature profile specified for the disinfection stage and are within -0 °C and +5 °C of the set disinfection temperature for each specific disinfection temperature;
- b) for chemical disinfection, through the disinfection stage and when tested as described in [6.8](#), the temperature recorded on all surfaces of the device being processed shall follow the temperature profile specified for the disinfection stage and shall be
  - 1) not lower than the disinfection temperature specified for the WD and disinfectant;

- 2) not higher than the maximum temperature specified for the disinfectant;
- 3) not higher than the maximum temperature specified for the types of loads for the particular type of disinfectant.

NOTE 1 Several disinfection temperatures can be set for the disinfection stage.

- c) the temperatures recorded on the surface of the load and load carrier(s) for all the other stages and are within  $-0\text{ }^{\circ}\text{C}$  to  $+5\text{ }^{\circ}\text{C}$  of the relevant set temperature profile for each stage;

NOTE 2 Several temperatures can be set for a specific stage.

If the washing temperature band is wider than  $5\text{ }^{\circ}\text{C}$ , the cleaning efficacy of the washing stage with a specified detergent shall be demonstrated during type testing at the minimum and maximum temperature of the specified washing stage temperature band (see [4.2.1](#)).

- d) the temperature profile obtained for the temperature controlled stages of the operating cycle shall be consistent within  $\pm 2,5\text{ }^{\circ}\text{C}$  for the last three of four test cycles (see [6.8.2.3](#));
- e) the holding time(s), as determined from the measured temperatures on the surface of the load items, is not less than that specified for each disinfection temperature that prevails during the disinfection stage (or the specified  $A_0$  value has been obtained);
- f) during each disinfection holding time the measured temperatures on the surface of the load and load carrier(s) are within the disinfection temperature band specified (or the specified  $A_0$  value has been obtained);
- g) during each temperature controlled holding time, the temperatures shown on the chamber temperature indicator and/or recorder are within  $\pm 2\text{ }^{\circ}\text{C}$  of the temperature measured at the automatic control sensor;
- h) the temperature indicated/recorded by the WD instruments are within  $\pm 2\text{ }^{\circ}\text{C}$  of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout each holding period for the cleaning and disinfection stage;
- i) during each holding time the temperature measured on the surface of each load item does not fluctuate by more than  $4\text{ }^{\circ}\text{C}$  and does not differ from that in other load items by more than  $4\text{ }^{\circ}\text{C}$ ;
- j) at the end of the operating cycle the temperature sensors are found to have remained in position.

**5.9.2** When tested in accordance with [6.8.3](#) the temperatures attained on the chamber walls throughout the process shall meet the following requirements:

- a) for thermal disinfection the temperatures recorded on the surface of chamber follow the temperature profile specified for the disinfection stage and are within  $-0\text{ }^{\circ}\text{C}$  and  $+5\text{ }^{\circ}\text{C}$  of the set disinfection temperature for each specific disinfection temperature;
- b) for chemical disinfection, throughout the disinfection stage and when tested as described in [6.8](#), the temperature recorded on the surface of the chamber shall be:
  - 1) not lower than the disinfection temperature specified for the WD and disinfectant;
  - 2) not higher than the maximum temperature specified for the disinfectant;
- c) the temperature profile obtained for the temperature controlled stages of the operating cycle shall be consistent within  $\pm 2,5\text{ }^{\circ}\text{C}$  for the last three of four test cycles (see [6.8.2.3](#)).

## 5.10 Switches, gauges and indicating devices

**5.10.1** The operating cycle shall be started by a method which is clear to the operator but prevents accidental operation. Examples include a physical switch, touchscreen interface or an electronic ID method.

**5.10.2** The user interface intended to be used by the operator shall be marked with an appropriate symbol or labelled with a description of the function. The instrument reading and legend shall be legible at a distance of 1 m from the machine when tested in accordance with [6.6.2](#).

**5.10.3** The symbols to be used shall conform to the requirements of IEC 60417-DB or ISO 7000. When new symbols are defined these shall be designed in accordance with the requirements of IEC 80416-1.

## **5.11 Process verification**

**5.11.1** The WD shall be fitted with means to verify and/or record the attainment of the specified process conditions.

**5.11.2** The nature and extent of monitoring shall be commensurate with the intended use of the load and the risk arising from not detecting a failure to attain the specified value of one or more critical process variables.

**5.11.3** The choice of process verification system shall be based on a documented risk analysis in accordance with ISO 14971, which shall include consideration of the intended use of the WD and the nature of the WD control system.

**5.11.4** One of the following three levels of process verification [a), b) or c)] shall be used:

a) verification by the operator of the attainment of cleaning and disinfection:

- the WD shall be equipped with a temperature indicator, independent from the controller, to allow the operator to verify attainment of the programmed cleaning and disinfection temperatures;

NOTE 1 This can be used when, because of the nature and intended use of the load, the risk arising from use of the product, after cleaning and disinfection stages not achieving predefined values, is low.

b) verification of process variables, independent from the controller, of the attainment of cleaning and thermal disinfection conditions:

- the WD shall be equipped with a temperature and pressure recording system, separate to, or part of the main controller, with sensors and signal processing independent from the controlling system, to record the attainment of the programmed cleaning and disinfection conditions;

This shall be used when, because of the nature and intended use of the load, it is necessary to provide confirmatory evidence that the cleaning and disinfection stages have taken place within the limits established during validation.

NOTE 2 This provides no verification of the adequacy of the cleaning stage; cleanliness of the load can be established by assessment of cleaning.

c) verification of process variables, independent from the controller, of the attainment of those process variables affecting both the cleaning and disinfection conditions:

- the WD shall be equipped with a recording system, separate to, or as part of the main controller, with sensors and signal processing independent from the controlling system, to record the critical process variables. The selection of monitored variables shall be based on a documented risk analysis as being critical to the satisfactory outcome of cleaning and disinfection processes (see also [5.18.2.6](#) and [5.18.2.7](#));

NOTE 3 The control sensor and the verification sensor can be linked to the same control system provided that the signal treatment of each sensor is treated by distinct software tasks.

NOTE 4 This can be used when, because of the nature and intended use of the load, it is necessary to provide confirmatory evidence that both cleaning and disinfection stages have taken place within the limits established during type testing.

NOTE 5 This includes WD for products which will be used without further processing and where the risks arising from an unsatisfactory cleaning and/or disinfection stage are unacceptable.

NOTE 6 This verification of the cleaning process provides assurance of cleaning for those items that cannot be visually inspected (e.g. those with long narrow lumens). Also, verification of the cleaning process can enable the use of a statistical sampling approach to the inspection for cleanliness of other load items.

## 5.12 Instrumentation and controls

**5.12.1** Instruments and controls shall be designed, positioned and protected so that their performance as specified in this document is maintained when operating in an ambient temperature range of 5 °C to 40 °C and with a relative humidity not exceeding 80 % for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C.

**5.12.2** Each gauge and indicating device shall be marked or labelled with a description of its function and, if used for thermometry, shall identify the location of its sensor. If an instrument is connected, in turn, to more than one sensing point, these points shall continuously indicate the active sensor that is being monitored.

The identification of sensor location shall be sufficient to allow the operator to understand the significance of the instrument reading, e.g. “pre-rinse temperature”.

**5.12.3** The characters on each indicating instrument or display shall be clearly visible at viewing distances of 0,25 m and 1,0 m when tested in accordance with [6.6.2](#).

**5.12.4** For calibration purposes, each instrument system shall be provided with a means of adjustment without removing it from its position. The system of adjustment shall be protected, e.g. by means of a cover or a locking screw, against inadvertent readjustment.

The connected sensor shall be easily removable or replaceable.

Calibration, adjustment and verification of calibration should be carried out only by trained and authorized personnel.

**5.12.5** Means shall be provided to enable the calibrated instruments and process controls to be independently verified during an operating cycle.

**5.12.6** At least one temperature sensor shall be located in a position which was previously determined as being representative of the lowest temperature achieved within the load. This shall make it possible to determine that all surfaces which are required to be cleaned and disinfected throughout the load and chamber will attain the cleaning and disinfection temperatures for the required time.

For a method of testing, see ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7.

Sensing points additional to those specified may be required for the purpose of controlling interlocks.

**5.12.7** The manner in which the temperature sensors are connected to the controller, indicator and recorder (if fitted) shall ensure that any difference between the measured temperatures that exceed 2 °C during the holding period of any stage can be determined. This shall be achieved either by comparison of the displayed temperatures on the recording and indicating thermometers or by the indication of a fault at the end of the operating cycle.

**5.12.8** At least the following status indicators shall be located at the loading end of the WD:

- a) visual display indicating “in-process”;
- b) visual display indicating “fault”;
- c) hours run meter or cycle counter that cannot be re-set by the user;

- d) visual display indicating “operating cycle complete”;

NOTE “Operating cycle complete” is not applicable to a continuous process machine.

- e) “insufficient process chemicals to complete cycle” indicator;
- f) a temperature indicator showing the temperature attained at a reference point within the WD during at least the cleaning, disinfection and drying stages of the operating cycle.

In addition, an audible indication, capable of being muted (i.e. reduced in volume), can be fitted.

Visualisation of the hours run meter or cycle counter can require interrogation of the process controller.

**5.12.9** The following instruments and status indicators shall be located at the unloading end of the double-ended WD:

- a) visual display indicating “in-process”;
- b) visual display indicating “operating cycle complete”;

NOTE “Cycle complete” indication is not applicable to a continuous process machine.

- c) visual display indicating “fault”.

In addition, an audible indication, capable of being muted, can be fitted.

**5.12.10** Failure of any control sensor during any stage of the process shall cause a fault to be indicated. This shall be tested as described in [6.3.5](#).

**5.12.11** The location of sensors shall be determined to ensure that the conditions sensed are representative of the process conditions that are to be controlled e.g. flow through hollow and lumen devices, spray pressure, foam limitation.

### 5.13 Temperature indicating systems

**5.13.1** Temperature sensors shall be either platinum resistance types conforming with Class B of IEC 60751:2008 or thermocouples conforming with one of the international tables specified in Tolerance Class 2 of IEC 60584-1:2013 or other systems of demonstrated equivalence.

**5.13.2** The WD chamber temperature indicating system shall:

- a) be either digital or analogue;
- b) be graduated in degrees Celsius;
- c) have a scale which includes the range 5 °C to 99 °C;  
NOTE 1 WD with a drying stage can have a scale range greater than 99 °C.
- d) have a measurement accuracy of  $\pm 1$  °C over the scale range;
- e) for analogue instruments, be graduated in divisions not greater than 1 °C;
- f) for digital instruments, have a resolution of at least 1 °C;
- g) when used for a control function, have broken sensor protection to fail safe in its control function application;
- h) have an ambient temperature error compensation not exceeding 0,08 K/K;
- i) have means to be adjusted in situ by the use of an access device.

NOTE 2 It is unlikely that these performance requirements can be met by bi-metallic-type indicating thermometers.

## 5.14 Pressure indicating systems

Pressure indicating systems when fitted shall:

- a) be either digital or analogue;
- b) be graduated in kilopascal (kPa) (graduation in mbar or bar is an acceptable alternative);
- c) have a measurement accuracy of  $\pm 5$  kPa;
- d) have a scale range such that the maximum intended operating pressure does not exceed 80 % of full scale;
- e) for analogue instruments be graduated in divisions not greater than 20 kPa;
- f) for digital instruments have a resolution of 1 kPa or better;
- g) be adjusted to a measurement accuracy of at least  $\pm 5$  kPa at the operating pressure;
- h) when used for a control function, have broken sensor protection to fail safe in its control function application;
- i) have means to adjust in situ by the use of an access device.

When digital pressure indicators are used, an additional mechanically actuated indicator can be required to comply with national pressure vessel regulations. When an analogue instrument is provided only for this purpose, the requirement for adjustment in situ is waived.

If a kPa scale is used, then the instrument should be labelled to indicate whether this measurement is absolute or gauge pressure.

## 5.15 Volume/flow indicating devices

**5.15.1** Volume/flow indicating devices shall measure volume of process fluids or air either accumulative or as a flow-rate depending upon the requirements of the specific application within the WD.

**5.15.2** Volume indicating devices shall:

- a) be materially compatible with process fluids, air, temperatures and pressures intended to come into contact with the volume indicating device used within the WD;
- b) be measured in litres or ml when indicating a displayed measured volume;
- c) clearly indicate 'go/no go' circumstances when used for gauging purposes;
- d) be calibrated in place or be easily removable for calibration with
  - measurement accuracy:  $\pm 5$  % of full scale;
  - measurement resolution:  $\pm 1$  % of full scale;
  - temperature compensation: 0 °C to 95 °C.

NOTE Volume can be determined using a flow indicating device (see [5.15.3](#)).

**5.15.3** Flow indicating devices shall:

- a) be materially compatible with process fluids, air, temperatures and pressures intended to come into contact with the volume indicating device used within the WD;
- b) display flow in litres or ml per unit time;

- c) be calibrated in place or be easily removable for calibration with
  - measurement accuracy:  $\pm 5$  % of full scale;
  - measurement resolution:  $\pm 1$  % of full scale;
  - sampling rate: at least every 5 s;
  - temperature compensation: 0 °C to 95 °C.

## 5.16 Timing equipment

**5.16.1** Process control timers shall have a measurement accuracy and repeatability at least an order of magnitude better than the time intervals which they are intended to measure.

**5.16.2** Time indicators, including chart recorders shall:

- a) be graduated in seconds or minutes;
- b) have a measurement accuracy of  $\pm 2,5$  % for periods up to 5 min and for periods above 5 min of  $\pm 1$  %;
- c) have means to adjust in situ by means of an access device.

## 5.17 Operating cycle indicating equipment

**5.17.1** There shall be a visual indication of the stage reached in the operating cycle.

**5.17.2** The operating cycle counter or hours run meter shall display a minimum of five digits and shall not be capable of being reset by the user.

## 5.18 Recording systems (if fitted)

### 5.18.1 Cycle control recorders

When a cycle control recorder is fitted the sensors and/or signal amplifiers and/or A to D (Analogue to Digital) converters used to provide the recorded information shall also be used to provide the input to the control system.

**NOTE** These recorders only provide evidence of the parameters set for the operating cycle and that the process has been carried out in accordance with the programme; they do not provide independent evidence that the required parameters, e.g. disinfection temperature, were obtained. In the event that a sensor, or the signal processing system associated with it is out of calibration and providing an erroneous indication of the conditions within the WD, this will not be apparent from the cycle control record.

### 5.18.2 Process verification system

**5.18.2.1** The sensors connected to the process verification system shall be independent of the sensors used for process control functions.

Two or more sensors located in the same housing can be considered as separate sensors.

**5.18.2.2** When a microprocessor based system is used any signal amplifier and A to D converter shall be separate from those used by the controller.

**5.18.2.3** When the same microprocessor is used for the controller and process verification recorder the system shall include a watchdog timer.

**5.18.2.4** The process verification recording system shall be fitted to record the key variables of the process throughout the operating cycle.

**5.18.2.5** The measuring systems shall have an accuracy and resolution not less than the accuracy and resolution of measurement required to control the WD.

**5.18.2.6** When entire process verification recording is required, the process variables known to affect performance shall be measured.

These should include at least:

- a) the temperature of water or air in each chamber at each stage in the operating cycle;
- b) the volume of water and each process chemical admitted, together with the point in time at which it was admitted during each stage of the operating cycle;

NOTE The process chemical can be recorded as a volume or a concentration.

- c) the temperature of water in each heated storage tank;
- d) the pressure and/or flow of water/aqueous solutions supplied to each load during washing and rinsing stages;
- e) the electrical conductivity of the final rinse water.

**5.18.2.7** The minimum performance characteristics of the measurement systems shall meet or exceed the following requirements.

- a) Temperature
  - measurement accuracy:  $\pm 1$  % over the range 0 °C to 100 °C;
  - resolution: 1 °C or better;
  - sampling rate: at least every 5 s.
- b) Pressure
  - measurement accuracy:  $\pm 5$  % over the range 10 kPa to 1 000 kPa;
  - resolution: 1 kPa or better;
  - sampling rate: at least every 5 s.
- c) Conductivity
  - measurement accuracy: not specified when  $< 5$   $\mu\text{S}/\text{cm}$ ;  
 $\pm 2,5$   $\mu\text{S}/\text{cm}$  over the range 5  $\mu\text{S}/\text{cm}$  to 50  $\mu\text{S}/\text{cm}$ ;  
 $\pm 5$  %  $> 50$   $\mu\text{S}/\text{cm}$ ;
  - resolution: 1 % of reading or 0,1  $\mu\text{S}/\text{cm}$  whichever is greater;
  - sampling rate: at least every 5 s;
  - temperature compensation: over the WD operating range.
- d) pH
  - measurement accuracy:  $\pm 0,5$  pH units;
  - resolution: 0,1 pH units;

- sampling rate: at least every 5 s;
- temperature compensation: over the WD operating range.

e) Volume/flow

- measurement accuracy:  $\pm 5$  % of full scale;
- resolution: 1 % of full scale;
- sampling rate: at least every 5 s;
- temperature compensation: over the WD operating range.

**5.18.2.8** The recorder shall produce a record that shall remain permanent for the time and storage conditions specified [see [8.3 e\) 3](#)].

NOTE The user can require the information from the digital recorder to link into their system, for example, an instrument management system or 'track&trace-system'.

A unique identifier shall be used that will allow identification of each operating cycle (e.g. operating cycle number).

**5.18.2.9** The recording of data shall be sufficient to ensure that any deviation outside the permitted tolerances can be identified (see [5.22](#)).

**5.18.2.10** For calibration, adjustment and verification of calibration, means shall be provided to allow adjustment of the recorder by the use of an access device.

**5.18.2.11** Unless otherwise specified, if a printed record is created for a double-ended WD, then it should be produced on the unloading side of the WD.

## 5.19 Control systems

**5.19.1** The WD shall be provided with an automatic controller.

**5.19.2** The control system(s) shall be capable of being programmed with the conditions pre-set, where relevant, for each stage of the operating cycle.

**5.19.3** The automatic controller shall check the attainment or otherwise of the pre-set process parameters, within pre-determined limits, essential to the efficacy of the operating cycle.

**5.19.4** The values shall be specified for each cycle variable programmed into the automatic controller such that the performance requirements in [Clause 4](#) are met.

**5.19.5** The automatic controller shall ensure that the operating cycle is reproducible within the specified limits during each subsequent cycle.

**5.19.6** It shall not be possible to adjust the process parameters during the progress of an operating cycle.

**5.19.7** Recording instruments shall be selected to be compatible with the automatic controller.

**5.19.8** Access to control devices, including access for the purpose of setting the cycle variables, that can be operated without dismantling the control or moving it from its fixed position on the machine, shall only be by means of an access device.

**5.19.9** When WD are programmed for a number of operating cycles, the required cycle shall be selected by key, code tool.

**5.19.10** For maintenance, test purposes, and in cases of emergency, means shall be provided to permit manual progression of the automatic controller programme. The selection of this manual facility shall be by means of an access device different from the one specified in [5.19.9](#).

**5.19.11** When manually operated for maintenance, test purposes and in cases of emergency, the automatic programme sequence shall automatically switch off.

**5.19.12** Any control which is pre-set, but adjustable, shall either be located behind a lockable panel or require the use of an access device for its adjustment.

**5.19.13** The manual advance system shall only allow the sequential selection of one stage at a time.

**5.19.14** With the exception of continuous process machines, the controller, at the completion of a successful operating cycle, shall indicate "cycle complete". This indication shall be failsafe in the event of failure of any service, i.e. air steam, electricity, water or drainage.

## **5.20 Override of automatic control**

**5.20.1** The override control accessible to the operator from the control panel shall:

- a) remain inoperative unless a fault has occurred;
- b) allow the manual control of the door(s);
- c) only be activated by the use of a key, code or tool, different from that required for the operating cycle.

**5.20.2** When an override control is provided, which is intended for use during testing of the WD by a trained and authorized person, operation of this override shall

- a) require an access device, different from those specified in [5.19.8](#), [5.19.12](#) and [5.20.1 c](#));
- b) not be dependent on a fault having occurred.

When using the access device specified in item a) it shall be possible for a trained or authorized person to view the WD sensor indications simultaneously.

## **5.21 Microprocessor control systems**

When a microprocessor control is used, the following shall apply:

- a) Access shall be restricted by a code and/or mechanically to prevent unauthorized alterations to programmes.
- b) It shall be provided with means to monitor the voltage or current present at each output and the condition of each output.
- c) It shall be provided with means to isolate digital inputs and outputs from the microprocessor electrically, e.g. opto-isolators, and with means to monitor the condition of each input and the adjustment or performance of each sensor. A "manual" mode of the controller giving visual access to input states would be appropriate to meet the requirements of items a) and b).
- d) It shall not be possible to change process parameters without use of codes or keys, and the control shall not require the use of additional external equipment. If the variable process parameters are affected by internal automatic controller action or by remote control functions, they shall be protected such that their value is not changed beyond those limits set that will prevent the process integrity or safety being

prejudiced. Where such a process parameter is adjustable by more than one control, any value displayed shall be the value currently active or shall have a clear indication that this is not the current value. Documentation shall explain the effects and sources of such adjustments.

- e) It shall be provided, where applicable, with batteries for maintaining the programme data memory. Such batteries shall be charged by the control system and have a lifetime of not less than 5 years. Means shall be provided to retain the programme memory. The loss of battery power shall not cause a fault condition which could affect the process or cause a safety hazard and shall be evident to the operator.
  - f) It shall contain all the components necessary for its function (excluding sensors and their controller).
  - g) It shall be provided with a watchdog system for the safe operation of the process. The microprocessor shall monitor all sensors, at an interval not greater than 5 s.
  - h) It shall be provided with an indication system for displaying faults and errors. The display shall identify the fault or error by means of a code or in plain language (local).
  - i) Embedded software shall be validated using state of the art processes and taking into account the principles of development life cycle, risk management, validation and verification.
- NOTE IEC 62304:2006/A1:2015 <sup>[14]</sup> can support activities to be performed.
- j) Control system software shall possess adequate measures to mitigate against external security threats when connected to external networks or media devices.

## 5.22 Fault indication systems

**5.22.1** If the values of the cycle variables are outside the specified limits (see [Clause 4](#)), or a failure of a service occurs sufficient to prevent the attainment of these variables, the automatic controller shall:

- a) cause a visual indication that a fault has occurred (additionally, an audible alarm system, which should be mutable, can be provided);
- b) cause a visual indication of the stage of the cleaning/disinfection cycle at which the fault occurred, or the nature of the fault.

**5.22.2** If the WD is fitted with a printer, the indication of fault shall also be printed and readily identifiable.

**5.22.3** After a fault has been indicated, the automatic controller shall allow the WD operating cycle to be terminated without causing a safety hazard. Any user intervention shall require the use of an access device. A visual display of fault shall continue at least until the door-locking mechanism is released by the use of an access device.

NOTE It is assumed that the WD load has not been subjected to the disinfection stage.

**5.22.4** For double-ended WD, after a fault has occurred, any load that has not been satisfactorily processed, shall be discharged on the loading side of the WD.

## 5.23 Water supply

**5.23.1** The quality of water required for each process stage shall be specified. When necessary for the efficacy of the process, means shall be provided to monitor the attainment of this water quality in the WD, either periodically or continually for each cycle.

NOTE 1 The quality of water can include consideration of chemical purity, hardness, particulates, temperature, microbial contamination, etc. Specific recommendations are given in country-specific guidances ANSI/AAMI ST 108<sup>[36]</sup> and Reference <sup>[39]</sup>.

NOTE 2 The water treatment process can adversely affect the efficacy of the WD.

The monitoring function may be provided by equipment external to the WD, installed on the water supply system.

**5.23.2** The WD shall be designed to operate with the quality of water as specified (see [5.23.1](#)).

NOTE 1 Some WD can require treatment of potable water for use in the WD. Water treatment equipment can include, e.g. a softener, de-ionizer or reverse osmosis plant.

NOTE 2 Many of the attributes of the water supplied to the WD can affect the efficacy and or efficiency of the process. These can include variations in water hardness, pH, and microbial contamination.

Specific requirements for particular applications are specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7.

**5.23.3** The quality of the water available for supply to the WD shall be tested in accordance with [6.4](#).

NOTE Local regulations can exist. For example, EN 1717<sup>[22]</sup> gives requirements for backflow protection.

## 5.24 Venting and drainage systems

**5.24.1** The WD shall be vented in one of the following ways:

- a) directly to the atmosphere external to the building;
- b) indirectly into the drainage system via a condenser;
- c) into the working area without adversely affecting the safety of the operator.

Where a vent discharges into the working area, a condenser or microbiological filter can be required.

If specified by the purchaser, ductwork can be supplied [see [6.5.5](#) and [10.o](#)].

In case of noxious discharges, attention is drawn to the requirements of IEC 61010-2-040:2020, 13.1.101.1.

**5.24.2** The design of the venting system shall ensure that the pressure within the chamber is discharged solely through the vent when tested as described in [6.5.5](#).

**5.24.3** If a condenser is used for indirect venting, the water seal between the chamber and the drain shall not be discharged.

**5.24.4** When a ductwork connection is required the connection shall ensure that any condensate will not discharge onto the outer surface of the WD.

**5.24.5** Means shall be provided to ensure that any condensate draining from the ductwork will not contact the load (see [6.5.6](#)). When tested in accordance with [6.5.6](#) all surfaces of all items in the load shall be free from detectable traces of water.

## 5.25 Drainage

**5.25.1** The design of the drainage trap shall include:

- a) a water seal;

NOTE 1 Local regulations applicable to the water seal can exist.

- b) a trap which is removable for cleaning and disinfection or is fitted with an accessible cleaning and disinfection port.

NOTE 2 This can be provided as part of the building installation.

**5.25.2** If after completion of an operating cycle the water level within the chamber remains above the lowest point of the chamber door seal the control system shall cause a fault to be indicated.

When tested in accordance with [6.3.8](#), a fault shall be indicated once the water level is above the lowest point of the door seal at the end of the operating cycle and it shall not be possible to open the door without the use of an access device.

NOTE Blocked drain protection is intended to prevent spillage and minimize the risk of cross-contamination.

It is possible that this test will not be required if the design of the WD prevents the fluid level within the WD chamber reaching the level of the door.

## **5.26 Air filters installed within the WD**

When the WD is fitted with microbial retentive air filters, then the filter installation shall be tested in accordance with [6.11](#).

The filter shall be readily accessible and easily removable for cleaning, testing and replacement.

## **5.27 Load handling and supports for use within the WD**

**5.27.1** When the WD is supplied with a system for supporting the load and/or a system for transferring the load into or out of the chamber the following shall apply:

- a) The load shall be wholly supported and retained within the usable chamber space for the duration of the operating cycle;
- b) The load carrier(s) shall either
  - 1) be retained in the chamber by a mechanism which is only released when the transfer system is in place, or
  - 2) remain stable when partially withdrawn and be fitted with a retaining device, which has to be released if the load is to be withdrawn further. The extent to which the load carrier(s) may be withdrawn and remain stable shall be stated.
- c) The force required by the operator, either directly or by the application of a mechanical device supplied with the equipment, to remove the load from the chamber does not exceed 250 N when fully loaded and operated in accordance with the manufacturer's instructions (see [6.7.1](#)).

**5.27.2** Means shall be provided to ensure that the transfer of the load into and out of the chamber does not cause damage to the chamber or the load.

NOTE Systems which cause high levels of local stress, e.g. point loadings, can also initiate corrosion in stainless steel materials.

## **5.28 Trolleys**

**5.28.1** If trolleys are used in conjunction with the WD to move loads and/or load carrier(s), then the requirements in [5.28.2](#) to [5.28.8](#) shall apply.

**5.28.2** The trolley shall be designed to allow the operator easily to align the trolley with the WD for loading and unloading [see [6.7.2.2](#) b)].

**5.28.3** The trolley shall be provided with means to collect liquid residues from the load to prevent these from dripping onto the floor. The means provided shall be detachable for cleaning and disinfection [see [6.7.2.2](#) c)].

**5.28.4** The trolley shall be provided with swivel wheels or equivalent means to facilitate manoeuvring.

**5.28.5** The trolley shall be designed to secure the load carrier(s) on the trolley during loading and unloading and while traversing a gradient at a slope of up to 1 in 20 [see [6.7.2.2 e](#)].

**5.28.6** The trolley shall be designed to remain stable when subjected to a force not exceeding 250 N applied horizontally in any direction to the trolley whilst it is supporting its maximum design load [see [6.7.2.2 a](#)].

**5.28.7** The trolley shall be fitted with a parking brake capable of retaining the fully loaded trolley on a slope with a gradient of 1 in 20 [see [6.7.2.2 f](#)].

**5.28.8** Trolleys for use with WD shall be designed and constructed to facilitate cleaning and disinfection of the trolley between uses.

## **5.29 Environment**

Unless otherwise specified, the WD shall be designed to operate in an ambient temperature and humidity from 5 °C up to 40 °C and up to 80 % relative humidity for temperatures up to 31 °C decreasing linearly to 50 % relative humidity at 40 °C (see IEC 61010-2-040:2020, 1.4).

## **6 Testing for conformity**

### **6.1 General**

#### **6.1.1 Inter-relationship of tests**

The tests described in this clause are reference tests intended for use in demonstrating conformity with the specified requirements of this document. They may be used in type tests, works tests, and in validation and requalification tests, or in routine tests. Other tests and methods providing equivalent assurance may be used by the manufacturer as the basis of claiming conformity with this document. In any case of dispute, the reference tests given in this document shall be used.

The inter-relationship of the various test programmes, and guidance on the location where they would usually be conducted and on the responsibility for conducting the tests are shown in [Annex A, Figure A.1](#).

#### **6.1.2 Conformity of WD, as supplied, with ISO 15883-1**

Documentary evidence that the WD conforms with the requirements of both this document and the relevant part of the following documents ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7 shall be supplied.

Testing on cleaning and disinfection efficacy of specific loads, if applicable, shall be carried out to substantiate any performance claims made for the WD.

#### **6.1.3 Conformity of WD, as installed, with ISO 15883-1**

##### **6.1.3.1 Validation**

**6.1.3.1.1** For WD, validation shall be considered as a total programme which consists of installation qualification, operational qualification and performance qualification carried out on machines for which there is documentary evidence from the manufacturer that they conform with the requirements of this document.

The documentary evidence may be based on data from type tests and works tests, as appropriate.

**6.1.3.1.2** A programme of validation tests shall be applied to all WD claiming conformity with this document.

**6.1.3.1.3** If the WD has different operating cycles, the tests shall be carried out for each cycle type. Cycles with similar parameters and load carrier(s) may be performed using worst case condition and load. A justification shall be documented.

**6.1.3.1.4** In the case where operating cycles using the same load configuration only differ by the length of the different stages, the cycle being tested will be the shortest one proposed for validation and the longer cycles will be validated by extrapolation.

**6.1.3.1.5** The data from the manufacturer (including where applicable the results of type tests and works tests) and data generated by tests undertaken as installation tests, operational tests and performance tests shall be retained for comparison with subsequent tests to verify continued attainment of the required performance by the WD.

### **6.1.3.2 Installation qualification**

Prior to undertaking operational and performance tests on an installed WD, installation tests shall be carried out to ensure that all necessary services have been correctly supplied and connected and that the WD is safe to operate (see IEC 61010-2-040:2020, 5.4.3).

The tests and checks to be performed during installation qualification shall be specified, documented and recorded.

### **6.1.3.3 Operational qualification**

The tests and checks to be performed during operational qualification shall be specified, documented and recorded.

Guidance on those tests that should be included in operational qualification is given in [Annex A, Table A.1](#).

The tests specified in this document apply except insofar as the test methods and requirements are modified by the requirements of ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7. When no relevant subsequent part of the ISO 15883 series exists, all relevant parts of the test programmes in this document should be applied.

### **6.1.3.4 Performance qualification**

**6.1.3.4.1** Performance qualification shall be performed after completion of installation qualification and operational qualification.

Guidance on those tests that should be included in performance qualification is given in [Annex A, Table A.1](#).

**6.1.3.4.2** Performance qualification shall be performed on the introduction of new or modified items to be cleaned and disinfected, or new loading systems unless equivalence either to a validated reference load or to a previously validated item or loading system has been demonstrated.

**6.1.3.4.3** Performance qualification shall be performed on the introduction of new process parameters (including process chemicals).

**6.1.3.4.4** Performance qualification shall demonstrate the attainment of the required

- a) cleaning efficacy;
- b) disinfection efficacy;
- c) drying efficacy, where applicable;

d) absence of process residues (see [6.10.5](#)).

**6.1.3.4.5** Each cleaning and disinfection stage and each type of load and loading pattern for which the process is valid shall be specified and documented. The limits for acceptable cycle variations shall be specified and documented also.

Cleaning and disinfection performances specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7 are minimum requirements.

NOTE Regulatory authorities can specify more stringent requirements within the jurisdictions for which they are responsible.

**6.1.3.4.6** For thermal disinfection processes, the specified disinfection conditions shall be based on either:

- a) one or more specified disinfection temperature(s) and a minimum time for which the surfaces to be disinfected will be subjected to at each temperature; or
- b) a specified  $A_0$  value.

**6.1.3.4.7** For chemical disinfection processes, the specified disinfection conditions shall be based on a specified minimum disinfectant concentration for a specified minimum contact time either:

- a) within a specified temperature range, or
  - b) above a specified minimum temperature,
- and verified by confirmation of microbial inactivation.

#### **6.1.4 Confirmation of validation**

Installation qualification, operational qualification and performance qualification reports shall be prepared and approved by persons competent and responsible for preparing, reviewing and accepting the reports.

NOTE Regional or national regulations can also address these requirements, e.g. DIN 58341.<sup>[38]</sup>

#### **6.1.5 Requalification**

Requalification shall be carried out

- a) if changes or engineering work are carried out on the equipment and installation that could affect the performance of the WD;
- b) if results of routine tests of WD are out-of-specification compared to data determined during initial validation;
- c) if WD performance is out-of-specification;
- d) if process conditions (e.g. process chemicals) are changed;
- e) at defined intervals.

NOTE The defined interval can be determined by regulatory authorities or by risk analysis. Typically, requalification is performed annually.

#### **6.1.6 Routine and periodic tests**

All calibration, maintenance and performance qualification shall be successfully completed, documented and approved by a designated person before the WD is used.

Procedures for the routine testing of the WD, including all tests and checks and materials to be used, shall be documented.

WD shall be tested periodically in accordance with a documented schedule to demonstrate the continued reproducibility of the validated operating cycle.

Guidance on those tests which should be included in process control and monitoring is given in [Annex A, Table A.1](#) under "Routine test". The recommended minimum frequency for routine testing is given in [Annex A, Table A.1](#) under "Routine test".

## 6.2 Instrumentation for testing

### 6.2.1 Temperature sensors

6.2.1.1 Temperature sensors shall be used to sense the temperature in locations specified in the tests described in this document.

6.2.1.2 Temperature sensors shall be either platinum resistance elements and conform with IEC 60751:2008, Class A, or shall be thermocouples and shall comply with the relevant international table specified in IEC 60584-1:2013, Tolerance Class 1, or other sensors of demonstrated equivalence.

6.2.1.3 The performance characteristics of the temperature sensor shall not be adversely affected by the environment in which it is placed, e.g. pressure, hot detergent solution.

6.2.1.4 The output from the temperature sensors shall be verified by immersing the temperature sensors in a temperature source at a temperature known within  $\pm 0,1$  K and within the cleaning and disinfection temperature band. After calibration and adjustment the temperatures indicated by the temperature measuring equipment connected to the temperature sensors shall not differ by more than 0,5 K.

6.2.1.5 In order to avoid undue disturbance of the system being measured, the major diameter of the temperature sensors and their connecting leads which will be located within the WD shall not exceed 2 mm.

### 6.2.2 Temperature recording instruments

6.2.2.1 One or more temperature recording instrument(s) shall record the temperature from the minimum number of temperature sensors at locations as specified in [6.8](#). They may also be used to verify the readings obtained from instruments fitted to the WD.

6.2.2.2 The temperature recording instrument(s) shall record the temperature from a minimum of twelve temperature sensors. The channels may be multiplexed or independent of one another. The data recording interval for each channel shall not exceed 2,5 s. All data sampled shall be used for the interpretation of results.

6.2.2.3 The scale range shall include 0 °C to 100 °C. The limit of error for the recording instrument, excluding temperature sensors, between 0 °C and 100 °C shall not exceed  $\pm 0,25$  K when tested in an ambient temperature of  $(20 \pm 3)$  °C.

The additional error due to changes in environmental temperature shall not exceed 0,04 K/K.

6.2.2.4 For analogue instruments, the minor mark interval shall not exceed 1 K and the chart speed shall be no less than 15 mm/min. The resolution shall be no less than 0,5 K.

6.2.2.5 Digital instruments shall register and record in increments of no more than 0,1 K.

### 6.2.3 Calibration

6.2.3.1 Calibration shall be carried out in accordance with the calibration instrument's instructions by a validated method using a working or reference standard that is traceable to a national standard.

**6.2.3.2** The calibration instrument shall have a valid test certificate and the calibration data shall include a temperature within the cleaning and disinfection temperature band.

**6.2.3.3** Before and after each series of tests the temperature recording system shall be verified by comparison with an independent temperature reference source at a temperature within the cleaning and disinfection temperature band.

### **6.3 Tests on doors, interlocks and fault indications**

#### **6.3.1 Operating cycle start interlock**

**6.3.1.1** Make an attempt to initiate an operating cycle both with the door(s) open and then with the door(s) closed but unlocked. For machines with double doors make the attempt to initiate an operating cycle with each door left unlocked in turn and with both doors unlocked.

**6.3.1.2** On WD in which the door locking mechanism is automatically activated after the door is closed and an operating cycle is initiated, the door locking mechanism shall be disabled for the purposes of this test.

**6.3.1.3** For WD not fitted with doors, any guard or interlock intended to have similar effect to a door i.e. preventing access to the chamber and load during the operating cycles, shall be tested in a similar manner.

**6.3.1.4** Check for conformance with [5.4.1.8](#) by establishing whether it was possible to initiate an operating cycle with one or more doors open.

#### **6.3.2 Door locking during operating cycle**

Close and lock the door(s) and start the operating cycle. While the operating cycle is in progress, make an attempt to unlock each door. Report whether it was possible to unlock any of the doors (see [5.4.1.4](#)).

When practicable, the interlocks should be visually inspected to verify engagement before attempting to open the door.

#### **6.3.3 Door interlocks on double-ended WD**

**6.3.3.1** During an operating cycle make an attempt to open both the loading door and unloading door of the double-ended WD.

Between operating cycles make an attempt to open both loading and unloading doors simultaneously.

Inspect the operator controls to establish whether either the loading or unloading door can be operated from the opposite end of the WD.

After a successful operating cycle

- a) during unloading, observe whether the loading door remains locked when the unloading door is unlocked;
- b) during unloading and loading, observe when the indication "cycle complete" is cancelled.

##### **6.3.3.2 Report:**

- a) whether it was possible:
  - 1) to open either the unloading door after initiation of an operating cycle before this cycle had been completed satisfactorily (see [5.4.3.1](#));
  - 2) for both doors to be open simultaneously (see [5.4.3.3](#));

- 3) for an operator at one end to operate the door at the other end (see [5.4.3.3](#)) unless it is not hazardous to the operator. Details shall be documented to explain why it is not hazardous;
- b) whether the loading door remains locked until the unloading door was locked (see [5.4.3.5](#));
- c) whether the indication “cycle complete” was cancelled when the unloading door was opened (see [5.4.3.5](#)).

### 6.3.4 Cycle complete door interlocks

6.3.4.1 During an operating cycle, make an attempt to open the door(s).

6.3.4.2 Report whether it was possible to open the door(s) before the operating cycle was completed.

6.3.4.3 Report whether the cycle complete indication was cancelled when the unloading door was opened (see [5.4.1.4](#), [5.4.3.1](#) and [5.4.3.5](#)).

### 6.3.5 Fault indication on sensor failure

#### 6.3.5.1 Principle

Each sensor providing information to the automatic controller is disabled in turn to establish that a fault is indicated using a method that does not increase risk of harm to the test person.

Risk assessment shall be documented.

#### 6.3.5.2 Procedure

Carry out the testing of each sensor as follows:

- a) start an operating cycle;
- b) during, or before, the stage of the operating cycle at which the sensor is intended to provide data used to determine the control of the cycle, disable the sensor as specified.

Test each sensor in both “open circuit” and “short circuit” failure modes.

#### 6.3.5.3 Results

Report whether a fault was indicated during or at the end of the operating cycle (see [5.4.1.5](#)). Report whether it was possible to open the door on a single-ended WD or the unloading door of a double-ended WD (see [5.4.1.5](#) and [5.4.3.2](#)).

### 6.3.6 Fault indication on service failure

#### 6.3.6.1 Procedure

Start an operating cycle. During, or before, the stage of the operating cycle at which the service is required, interrupt the service supply. Carry out the test for each service required by the WD.

#### 6.3.6.2 Results

Report whether a fault was indicated (see [5.4.1.5](#) and [5.19.14](#)).

## 6.3.7 Failed cycle interlock

### 6.3.7.1 General

This test is intended to verify that the interlock provided to prevent an operator from removing a load in the normal manner at the end of an operating cycle that failed is functioning.

### 6.3.7.2 Procedure

During an operating cycle impair the operation of the WD sufficiently to cause a cycle failure.

### 6.3.7.3 Results

Report whether a “fault” was indicated. Report whether it was possible to open the unloading door (if fitted), and if it was possible to open the loading and/or unloading door only by means of an access device (see [5.4.1.5](#), [5.4.1.6](#) and [5.4.3.2](#)).

## 6.3.8 Blocked drain protection

### 6.3.8.1 General

This test is intended to verify that the interlock provided to prevent the door being opened if on completion of an operating cycle the water level within the chamber remains above the lowest point of the chamber door seal (see [5.25.2](#)) is functioning.

### 6.3.8.2 Procedure

Block the drain to prevent discharge of water from the chamber of the WD.

Close the door and start the operating cycle.

On completion of the operating cycle, attempt to open the door using the normal door release procedure.

If the door opens and the level of the retained water is below the door seal close the door and start another operating cycle.

Repeat the operating cycle as many times as necessary for either the water level at the end of the cycle to be above the level of the door seal or for a fault to be indicated.

For WD without sealed doors, the operating cycles should be repeated until either water has spilled from the machine or a fault has been indicated.

### 6.3.8.3 Results

Report whether a fault was indicated before the water level reached the level of the door seal and whether the door could be opened using the normal release procedure.

For WD without sealed doors, report whether a fault was indicated before water spilled from the machine, whether the operating cycle was stopped preventing further inflow of water and whether a tool, key or code was required to restart the machine.

## 6.4 Tests on water quality and water volume

### 6.4.1 General

When specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7, the tests described in [6.4.2](#) to [6.4.4](#) shall be applied.

NOTE 1 Local requirements can apply.

These tests shall also be used for initial assessment of the available water supply.

NOTE 2 Additional tests can be required on water used for cleaning and disinfection stages, when specified by local requirements, or required by the WD manufacturer (see [5.23](#)).

## 6.4.2 Quality of final rinse water

### 6.4.2.1 Sampling

The sample shall be taken from the supply line as close as practicable to the WD. When the rinse water is stored in a tank within the WD, heated in a calorifier in the WD or otherwise treated within the WD, samples shall also be taken from the discharge point into the chamber.

### 6.4.2.2 Tests for chemical purity

Tests for chemical purity shall include tests for those determinants known to influence the efficacy of the process.

NOTE This can include, but is not limited to, tests to determine the value of the following:

- a) conductivity;
- b) pH;
- c) oxidizable substances [determined by the European Pharmacopoeia (Ph.Eur.) method or as redox potential determined by the United States Pharmacopoeia (USP) method];
- d) total hardness (salts of  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{Sr}^{2+}$  expressed as  $\text{mmol CaCO}_3/\text{l}$ );
- e) total dissolved solids (TDS) determined as evaporative residue;
- f) inorganic phosphate [ $\text{P}_i$ ] and inorganic silicate [ $\text{SiO}_2$ ], determined as the molybdate reactive species;
- g) chloride [ $\text{Cl}^-$ ].

### 6.4.2.3 Tests for bacterial endotoxins

If a requirement for the level of bacterial endotoxins in the final rinse water is given in ISO 15883-4 or ISO 15883-7, determine the level by the limulus amoebocyte lysate (LAL) test with a sensitivity of 0,25 EU/ml, or better, using the method given in the European Pharmacopoeia (Ph.Eur.) or United States Pharmacopoeia (USP).

### 6.4.2.4 Tests for microbial quality

If a requirement for the level of microorganisms in the final rinse water is given in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7 perform a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R2A medium in accordance with [Annex C](#), or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophilic viable count.

NOTE Other methods, including rapid methods that have been validated to be at least equivalent to the above method in terms of both specificity and sensitivity can also be used.

## 6.4.3 Volume of water used per stage

Measure the volume of water used at each stage of the operating cycle using suitable volumetric measuring vessels. The measurement accuracy of the vessels shall be equal to, or better than, 1 % of the volume to be measured, as specified.

Alternatively, the volume may be measured by interposing a total volume flow meter(s) in the pipe(s) supplying the WD and determining the volume used from readings taken immediately before and after each stage of the operating cycle.

The meter should be in a known state of calibration, suitable for the operating pressure range of the WD and designed for connection within a supply pipe of the diameter used on the WD. The meter shall be located on a straight section of pipe with no less than 20 pipe internal diameters from the nearest bend or obstruction on either side of the meter.

Volume/time flow meters should not be used since the calculation of the total volume from measurements of time and varying flow are unlikely to be sufficiently accurate.

#### 6.4.4 Quality of water used during testing

Prior to carrying out operational qualification and performance qualification testing, determine the quality of water used at each stage of the operating cycle other than the final rinse (see also [6.4.2](#)). Tests for chemical purity shall include tests for those determinants known to influence the efficacy of the process.

NOTE This can include, but is not limited to, tests to determine the value of the following:

- a) conductivity;
- b) pH;
- c) oxidizable substances [determined by the European Pharmacopoeia (Ph.Eur.) method or as redox potential determined by the United States Pharmacopoeia (USP) method];
- d) total hardness (salts of  $\text{Ca}^{2+}$ ,  $\text{Mg}^{2+}$ ,  $\text{Sr}^{2+}$  expressed as mmol  $\text{CaCO}_3/\text{l}$ );
- e) total dissolved solids (TDS) determined as evaporative residue.

### 6.5 Tests on pipework

#### 6.5.1 Estimation of dead volume pipework

##### 6.5.1.1 General

The test is intended to verify the stated volume. The test shall be carried out after the checks for free drainage specified in [6.5.3](#).

NOTE The test can also be of value when investigating problems such as carry over of detergents or microbial contamination occurring in a WD.

##### 6.5.1.2 Equipment

Volumetric measuring vessels of appropriate size.

##### 6.5.1.3 Procedure

Flush the pipework of the WD which is known to be dry (either following disassembly and re-assembly or purging with compressed air for no less than 30 min) with a known volume of water (simulating the flow that would occur in normal use). The volume of water flushed through the system should be twice that determined as the volume used per operating cycle (see [6.4.3](#)). Measure the volume of water discharged and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

The testing shall be done with load carrier(s) demonstrated to have highest retention of water.

When the WD has two or more pipework systems which are entirely separate, e.g. for flushing water, wash water, rinse water, cleaning and chemical disinfectant solutions, each system may be tested separately.

##### 6.5.1.4 Results

Report whether the volume of retained water was equal to or less than the stated maximum retained volume.

## 6.5.2 Leakage

During type testing as specified in this document and ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7, visual inspection shall be conducted for the presence of leakage. During each of these tests, there shall be no leakage from the chamber or associated pipework.

NOTE Foaming conditions caused by detergent and/or presence of protein during testing can increase leakage from chamber and associated pipework.

## 6.5.3 Free draining [chamber, load carrier(s), tanks]

### 6.5.3.1 General

The following checks shall be carried out to verify that, as designed, built and installed, the WD will effectively discharge all the water from the system.

### 6.5.3.2 Free draining of chamber and load carrier(s)

At the end of an operating cycle, aborted before the commencement of any drying stage (if applicable), visually inspect the chamber and load carrier(s) for retained water. Droplets on vertical and sloping surfaces that slowly coalesce and drain away are not considered to be retained water.

### 6.5.3.3 Free draining of tanks

Fill all tanks and reservoirs intended to contain water or aqueous solutions during normal use, with water to the maximum level required for a normal operating cycle and then allow them to drain. Inspect the tanks for evidence of retained water.

## 6.5.4 Pipework flow to discharge point

Visually inspect all pipework to determine whether the slope (i.e. the angle made with the horizontal) is such that any contained liquid will tend to drain towards the discharge point. When necessary, use a spirit level to determine whether the slope is in the required direction.

## 6.5.5 Venting

### 6.5.5.1 Equipment

Pressure gauge (if the WD chamber is not already equipped with a pressure gauge in a known state of calibration).

### 6.5.5.2 Procedure

Close and seal the chamber of the WD in the specified manner and start an operating cycle.

Override the automatic controller to allow the continuous admission of steam to the chamber.

Observe where steam is vented.

Note the maximum value obtained on the pressure gauge.

### 6.5.5.3 Results

Check for conformity with [5.8.4](#) and [5.24.2](#).

## 6.5.6 Load contamination from ductwork of the WD

### 6.5.6.1 Equipment and materials

The equipment and materials shall consist of

- a) vessel of no less than 500 ml capacity having a discharge port at its base connected to a flexible tube fitted with an on/off valve and a flow control valve;
- b) stopwatch;
- c) load carrier(s) and full load for the WD;
- d) paper towels.

### 6.5.6.2 Procedure

Disconnect the external ducting to the WD 1 m above the chamber. If it is not possible to disconnect the ducting at this position, the ducting should be disconnected at the chamber and a spare 1 m length of ducting should be connected to the chamber.

Position the vessel approximately 1 m above the level of the chamber discharge to the vent. With the on/off valve closed, fill the vessel with  $(200 \pm 20)$  ml of cold water. Open the valve and adjust the flow control valve so that the contents of the vessel are discharged in  $(60 \pm 5)$  s.

Refill the vessel with  $(200 \pm 20)$  ml of cold water. Feed the flexible tube into the ducting so that the open end of the flexible tube is 600 mm to 800 mm above the top of the chamber.

Load the chamber with a full load of dry load items in accordance with the manufacturer's instructions. Close the chamber door and then open the on/off valve. Record the time required for the vessel to empty.

Within 1 min of the vessel emptying, open the chamber door and remove the load and any removable load containers. Place all the removed items on absorbent paper and examine all surfaces of the load and the absorbent paper for traces of water.

Repeat the above procedure for the full range of load carrier(s) which the WD is designed to process.

### 6.5.6.3 Results

Report whether the results conform with [5.24.5](#), i.e. there is no visible water on the load or load carrier(s).

## 6.6 Tests on instrumentation fitted to the WD

### 6.6.1 Verification of calibration

Verify the calibration of all measuring equipment fitted to the automatic controller or process verification system by comparison with a calibrated test instrument or standard test solution.

The test instrument shall be in a known state of calibration in accordance with ISO 10012, traceable to a relevant national standard for the level of measurement accuracy specified in this document.

Carry out the verification of calibration with the sensor of both the WD system and the test instrument maintained under steady state conditions. The steady state condition shall be at the value at which readings will be made during an operating cycle, or at two or more values in the range of values over which readings will be made during an operating cycle, as specified. Compare the readings obtained from the test instrument and the WD system.

## 6.6.2 Legibility

Determine the legibility of all indicating systems and measuring instruments fitted to the WD by visual observation. An observer with normal vision, corrected if necessary, shall view the indicator or gauge under diffuse illumination of  $(300 \pm 100)$  lx at a distance of 0,25 m (-0,0 m to +0,05 m) and at a distance of 1,0 m (-0,05 m to +0,0 m) to determine whether the reading is legible (see [5.10.2](#) and [5.12.3](#)).

## 6.7 Tests on load carrier(s) and trolleys

### 6.7.1 Load carrier(s) used within the chamber

#### 6.7.1.1 Equipment

Force measuring instrument (e.g. spring balance or force gauge) calibrated with a range including 0 N to 300 N and with a measurement accuracy of  $\pm 10$  N over the range 0 N to 300 N, attached to the load carrier(s) with a non-extensible means of attachment.

#### 6.7.1.2 Procedure

Carry out the test as follows:

- a) Fully load the system for supporting the load within the chamber or transferring the load into or out of the chamber and operate it in the specified manner. During loading and after operating cycle completion carry out an inspection to see if the requirements of [5.27](#) are met. This shall include establishing that:
  - 1) the load remained wholly supported and retained within the usable chamber space for the duration of the operating cycle;
  - 2) the load carrier(s) was/were retained in the chamber by a mechanism which was only released when the transfer system was in place;
  - 3) the load carrier(s) remained stable when withdrawn for a specified distance, and was/were fitted with a retaining device, which had to be released if the load was to be withdrawn further;
  - 4) the load carrier(s) could not be mis-positioned in a manner which would prevent the free drainage of water and the penetration of water or steam into the load by connection to service supplies within the chamber in the manner intended by the manufacturer.
- b) Measure the force required to remove the load from the chamber using the balance according to [6.7.1.1](#).

### 6.7.2 Trolleys

#### 6.7.2.1 Equipment

Force measuring instrument (e.g. spring balance or force gauge) calibrated with a range including 0 N to 300 N and with a measurement accuracy  $\pm 10$  N or better over the range 0 N to 300 N attached to the load carrier(s) with a non-extensible means of attachment.

#### 6.7.2.2 Procedure

When the WD is supplied with a trolley for handling the load outside the chamber, carry out the following inspections and tests.

- a) **Stability:** fully load the trolley in accordance with the manufacturer's instructions. Apply a force of 250 N horizontally to the highest point of the load or accessory using the balance according to [6.7.2.1](#). Apply the force successively in at least eight directions at  $45^\circ$  intervals (see [5.28.6](#)).
- b) **Alignment:** visually inspect the trolley for vertical and horizontal alignment with the WD during loading and unloading (see [5.28.2](#)).

- c) Collection of liquid residue: by inspection and operation verify that the trolley is provided with means, which are detachable for cleaning and disinfection, to collect liquid residues from the load and that liquid from the load cannot drip onto the floor (see [5.28.3](#)).
- d) Manoeuvrability: check by inspection.
- e) Retention of load carrier(s): fully load the trolley with load carrier(s) each filled to maximum capacity in accordance with the manufacturer's instructions. Determine by visual inspection whether the load carrier(s) was/were securely retained
  - 1) during loading and unloading;
  - 2) while traversing a gradient at a slope of 1 in 20 (see [5.28.5](#)).
- f) Parking brake: fully load the trolley in accordance with the manufacturer's instructions. Position the trolley on a gradient at a slope of 1 in 20 so that it is free to roll down the slope. Apply the parking brake. Observe whether the trolley remains stationary (see [5.28.7](#)).

## 6.8 Thermometric tests

### 6.8.1 General

Thermometric tests are carried out to verify the attainment of the specified conditions throughout the chamber and load during the operating cycle. In continuous process machines and multi-chamber WD the use of recorders with fixed sensors is impractical for monitoring the temperature of the load and load carrier(s). They should be tested using self-contained data loggers that can be processed through the WD. The use of biological indicators as a substitute for thermometric testing is not acceptable.

### 6.8.2 Load and load carrier(s) temperature test during operating cycle

#### 6.8.2.1 General

The load under test shall consist of a reference load in accordance with ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7 or a performance qualification load of discrete items of the type which the WD is intended to process, or of surrogate devices used to simulate such load items.

The load shall be contained on, or within, load carrier(s) of the type intended for use with the load.

#### 6.8.2.2 Equipment

Temperature recording instrument(s) conforming with the requirements specified in [6.2.2](#).

#### 6.8.2.3 Procedure

Locate the temperature sensors as follows:

- a) on the load carrier at two (2) diagonally opposite corners and in the approximate geometric centre;
- b) at least one (1) on a load item at each level in the load carrier (up to a maximum of three (3) if the load carrier accommodates load items on more than one level);
- c) one (1) on an item in the region known to be slowest to attain the specified operating cycle temperature;
- d) one (1) on an item in the region known to be fastest to attain the specified operating cycle temperature;
- e) one (1) adjacent to the automatic control temperature sensor;
- f) one (1) adjacent to the process recorder or indicator sensor (if fitted) in each chamber or compartment.

These positions should be specified and supported by data from type tests. If these data are not available from the manufacturer, preliminary tests to map the temperature throughout the load will be necessary.

The sensors should be in good thermal contact with the item or installed sensor which they are monitoring and placed, if possible, in or on the part of the item which will be slowest to heat up.

Carry out the test with each type of load carrier. Perform a total of four (4) consecutive tests, the first of which should be at least 60 min since the machine was last used (a "cold start") and the final three (3) with not more than 15 min intervals between cycles (a "hot start").

#### **6.8.2.4 Results**

The test shall be considered satisfactory if the requirements of [5.9.1](#) are met.

### **6.8.3 Chamber wall temperature test**

#### **6.8.3.1 Equipment and materials**

Temperature recording instrument(s) conforming with the requirements specified in [6.2.2](#).

#### **6.8.3.2 Procedure**

Locate the temperature sensors as follows:

- a) one (1) in each corner of the chamber;
- b) one (1) in the centre of the two (2) side walls;
- c) one (1) in the centre of the roof of the chamber;
- d) one (1) adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Use additional locations for sensors on sequential operating cycles, when there is cause to believe that other locations can give lower temperatures e.g. when parts of the outer surface of the chamber are not insulated.

Measure the temperature attained throughout four (4) operating cycles, the first of which should be at least 60 min since the machine was last used (a "cold start") and the final three (3) with not more than 15 min intervals between cycles (a "hot start").

Operate the WD with a load consisting of a reference load in accordance with ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7.

Multi-chamber WD can be tested with each chamber tested consecutively or concurrently. In the latter case, twelve (12) sensors will be required for each chamber.

#### **6.8.3.3 Results**

The test shall be considered satisfactory if the requirements of [5.9.2](#) are met.

### **6.8.4 Temperature tests on tanks**

#### **6.8.4.1 Equipment**

Temperature recording instrument(s) conforming with the requirements specified in [6.2.2](#).

#### **6.8.4.2 Procedure**

Locate the temperature sensors at two (2) diagonally opposite corners of the tank, in the approximate geometric centre of the tank and adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Measure the temperature attained throughout three (3) operating cycles, the first of which shall be at least 60 min since the machine was last used (a "cold start") and the final two (2) with not more than a 15 min

interval between cycles (a “hot start”). Operate the WD empty except for chamber furniture (e.g. load carrier(s)).

WD with more than one tank may be tested with each tank tested consecutively.

This test may be run simultaneously with other operational tests.

#### **6.8.4.3 Results**

The test shall be considered satisfactory if the requirements of [5.3.5](#) are met.

### **6.8.5 Load temperature protection**

#### **6.8.5.1 General**

The WD is fitted with a temperature cut-out to ensure that, in the event of the automatic control failing to control the temperature in the WD, the temperature will not rise to a level which would damage the load in the WD.

#### **6.8.5.2 Equipment**

Temperature recording instrument(s) conforming with the requirements specified in [6.2.2](#).

#### **6.8.5.3 Procedure**

Locate the temperature sensors at two (2) diagonally opposite corners of the load carrier, in the approximate geometric centre of the load carrier and adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Operate the WD empty, except for the load carrier(s), on a normal operating cycle. For multi-cycle machines, test the two (2) cycles having the highest and lowest operating temperatures.

During the stage of the cycle when the maximum temperature is attained, disable the temperature control system in the specified manner, e.g. by removing the temperature sensor connected to the automatic controller.

#### **6.8.5.4 Results**

The test shall be considered satisfactory if the requirements in [5.8.3](#) are met.

### **6.9 Chemical dosing tests**

#### **6.9.1 Dispensed volume**

##### **6.9.1.1 Procedure**

###### **6.9.1.1.1 General**

Use the specified test method (see [5.7.4](#)) or, if no method is specified, use the appropriate method given in [6.9.1.1.2](#) or [6.9.1.1.3](#).

###### **6.9.1.1.2 Volumetric method**

Fill a measuring cylinder of appropriate volume approximately two thirds full with the chemical to be dispensed. Place the suction tube in the measuring cylinder and carry out a normal operating cycle.

At the end of the cycle fill the measuring cylinder accurately to the maximum marked level. Carry out a further operating cycle.

Fill a second measuring cylinder accurately to the maximum marking with the same chemical.

At the end of the operating cycle use the contents of the second measuring cylinder to replenish the first cylinder to the maximum marked level. Record the volume of chemical dispensed from the second measuring cylinder and thus the volume of chemical used for the second operating cycle. Compare this with the nominal volume dispensed.

Run two (2) further operating cycles and repeat the measurements as above.

#### **6.9.1.1.3 Concentration method**

For WD designed to dispense the chemical to produce a measured concentration in the solution within the WD chamber, independently determine the nominal volume to be dispensed.

Take a sample of the water to be used for that stage of the operating cycle and determine the volume of chemical required per litre of water in the chamber by direct measurement (e.g. with an ion selective electrode, spectrophotometrically). The nominal volume can then be calculated by multiplying the value obtained by either the volume determined in accordance with [6.4.3](#) or by separate measurement of the volume retained within the holding tank in the WD.

#### **6.9.1.2 Results**

Check for conformity with [5.7.4](#) and [5.7.5](#).

### **6.9.2 Indication of insufficient process chemical for a cycle**

#### **6.9.2.1 Procedure**

Fill an otherwise empty container with sufficient chemical for more than three (3) but less than five (5) operating cycles. Run the WD on five (5) consecutive cycles. Estimate the volume remaining at the end of each cycle (pre-marked container, dipstick, or mass).

#### **6.9.2.2 Results**

Report whether the WD indicates when there is insufficient chemical remaining to complete a cycle (see [5.7.6](#)).

## **6.10 Tests of cleaning efficacy**

### **6.10.1 General**

Tests of cleaning efficacy shall be performed on the specified cleaning stages, including, where appropriate, pre-wash flushing. Cleaning stages shall be specified according to [4.1](#). It shall be verified and documented that the full cleaning stage does not interfere with analyte detection. During tests of cleaning efficacy, the WD shall be operated without disinfection and drying stages and should not affect the efficacy or safety of the WD process.

The test methods employed for both cleaning type testing and performance qualification testing are specified in ISO 15883-5.

### **6.10.2 Cleaning type test**

The tests for cleaning efficacy shall be carried out in triplicate using the appropriate test method(s) and test soil(s) as specified in ISO 15883-5 by taking into consideration the corresponding category of load.

The test soil used for the load, chamber wall and load carrier(s) may be different. Where different test soils are used the rationale for the choice of test soil shall be documented.

### 6.10.3 Cleaning performance qualification test

Testing is undertaken following satisfactory completion of cleaning type test and the thermometric tests (see [6.8](#)). The tests for cleaning efficacy shall be carried out in triplicate using the appropriate test method(s) as specified in ISO 15883-5:2021, 5.4 by taking into consideration the corresponding category of load. The WD shall be tested using actual loads contaminated by normal use, specified by the user as being representative of loads that it is intended to process.

### 6.10.4 Routine process monitoring

**6.10.4.1** The cleaning performance of WD cycles shall be monitored by routine tests to ensure consistent cleaning performance.

NOTE 1 This will help identify changes due to WD performance, process chemical variation, water quality variation and human error.

The method used for these tests shall be supported by validation data that is based on representative contamination that can remain on medical devices after clinical use (see ISO 15883-5:2021, 4.2.4).

NOTE 2 The frequency of these tests can be determined by local or regional requirements.

**6.10.4.2** Routine process monitoring devices (see ISO 15883-5:2021, 4.2 and 4.3) should include:

- a) representative medical devices soiled by clinical use, or
- b) process challenge devices (PCD) with soiling that have a demonstrated relationship to representative medical devices and their soiling.

**6.10.4.3** The means of evaluation of satisfactory cleaning on these devices should be:

- a) visual examination of residual soil (see ISO 15883-5:2021, 4.4.2);
- b) chemical detection of residual protein (see ISO 15883-5:2021, 4.4.3.2);
- c) detection of other residual analytes if applicable to the medical device (see ISO 15883-5:2021, 4.4.3.3).

### 6.10.5 Tests for process residuals

#### 6.10.5.1 General

The nature of the residues and the level of such residues which can be of concern depend on the process chemicals used during the process and the intended use of the washed and disinfected product.

The sampling method and analytical method shall be capable of determining the presence of the process chemical at concentrations below that specified as potentially harmful, i.e. as the maximum acceptable level.

#### 6.10.5.2 Procedure

Test the efficacy of the rinse process by using the upper limit of the normal dose of the process chemical on a normal operating cycle using a test load of simulated product. Carry out an analysis by the method recommended for the WD on the final rinse water and on the simulated product.

When the cycle includes a neutraliser for the process chemical under study, the volume of neutraliser used shall be the lower limit of the normal dose.

#### 6.10.5.3 Results

Check for conformity with [4.4.1](#) and [4.4.2](#) and report whether the concentration on the simulated product is lower than the specified maximum acceptable level.

Where residual limits are not specified and/or no analytical method is available, biocompatibility risk analysis and/or testing to ISO 10993 series [3] can be used to meet the requirements of [6.10.5](#).

## 6.11 Tests of air quality

### 6.11.1 General

When a WD is fitted with microbial retentive filters, then test the complete installation using the method described in ISO 14644-3.

### 6.11.2 Procedure

Introduce a challenge aerosol of inert particles of the type produced by a dispersed oil particle generator into the air upstream of the filter. Scan the downstream face of the filter and its housing for leakage using a photometer.

### 6.11.3 Results

The test shall be considered satisfactory if the reading on the photometer is steady and repeatable and does not exceed 0,01 % of the upstream reading (see [5.26](#)).

## 6.12 Test of load dryness

### 6.12.1 General

WD designed to dry specified loads shall be tested using the test methods specified in [6.12.3](#) and [6.12.4](#).

The anhydrous copper (II) sulfate paper test method shall be performed when the WD operating cycle includes a drying stage.

### 6.12.2 Materials

6.12.2.1 Anhydrous copper (II) sulfate paper.

6.12.2.2 Compressed air.

6.12.2.3 Test load as specified in ISO 15883-2, ISO 15883-3, ISO 15883-4, ISO 15883-6, or ISO 15883-7.

### 6.12.3 Exterior surface drying

#### 6.12.3.1 Procedure

Carry out a normal operating cycle from a cold start i.e. the WD shall have been used within the previous hour.

Immediately, at the end of the recommended drying period, use a piece of anhydrous copper (II) sulfate paper to test the presence of moisture on the exterior surfaces of the load.

When removing the load from the WD, and as the individual load items are being inspected, observe and record any water being discharged.

Examine the paper for colour change (i.e. anhydrous copper (II) sulfate paper from white or light blue to deep blue) as evidence of residual water.

Place a piece of anhydrous copper (II) sulfate paper in any crevice or lumen and between the control knobs on load items where water can linger (e.g. valve housing) and subsequently check the paper for blue spots.

This test may be used for routine testing but in this case the load items used are required to be processed before patient use.

NOTE The test is intended to be performed in the worst case scenario with the most challenging load in the WD.

### 6.12.3.2 Result/acceptance criteria

Record if residual water was observed or not.

There shall be no blue spots on the anhydrous copper (II) sulfate paper.

### 6.12.4 Lumen load drying

#### 6.12.4.1 Procedure

At the end of the drying stage, the lumen test load items or surrogate(s) shall be removed from the WD. Direct the distal end of the lumen test load item towards a horizontal piece of anhydrous copper (II) sulfate paper at a distance of 50 mm to 100 mm and flush medical grade air at a positive pressure up to 120 kPa through each channel system. The full length of each lumen test load item shall be tested.

NOTE 1 For type testing compressed air is sufficient.

NOTE 2 The sensitivity of the test can be increased by pre-wetting the paper with > 99,97 % isopropanol.

#### 6.12.4.2 Result/acceptance criteria

Record if residual water was observed or not.

There shall be no blue spots on the anhydrous copper (II) sulfate paper.

### 6.13 Test of automatic control

#### 6.13.1 General

The automatic control test is designed to demonstrate that the operating cycle functions correctly as shown by the values of the cycle variables indicated and recorded by the instruments fitted to the WD.

The temperature sensors for thermometric testing shall be connected to the chamber during this test. If a sensor is placed adjacent to each of the sensors connected to the installed temperature measuring instruments the calibration of these instruments should be checked during periods of stable temperature in the automatic control test.

#### 6.13.2 Procedure

Place the test load appropriate to the type of WD, contained within the load carrier(s) normally used, in the chamber.

For WD equipped with multiple operating cycle capability, select the operating cycle to be tested. Start the cycle.

Ensure that a process record is made by the recording instrument fitted to the WD. If the WD does not have a recorder, observe and record the elapsed time, indicated chamber temperatures and pressures at all significant points of the operating cycle, for example the beginning and ending of each stage, and the maximum values during the holding time.

At the approximate mid-point of the cleaning and disinfection holding time, record the elapsed time and the indicated chamber temperature.

### 6.13.3 Results

The test shall be considered satisfactory if the following characteristics are observed:

- a) a visual display indicating “cycle complete” occurs [see [5.12.8 d\)](#) and [5.12.9 b\)](#)];
- b) during the whole of the operating cycle the values of the cycle variables as indicated by the instruments on the WD or shown on the batch process record are within the limits specified (see [5.19.5](#));
- c) during the cleaning and disinfection stages:
  - 1) the indicated and recorded chamber temperatures are within the range specified (see [4.3.1.1](#) and [4.3.2.1](#));
  - 2) the time for which each disinfection temperature was maintained was not less than that specified (see [4.3.1.1](#) and [4.3.2.1](#));

NOTE Chemical disinfection involves exposure of load surfaces to the specified conditions of the chemical disinfectant concentration and temperature for the required contact time.

- d) the door(s) cannot be opened until the cycle is complete (see [5.4.1.4](#));
- e) the person conducting the test does not observe any mechanical or other anomaly.

Repeat the test three (3) times to ensure that the automatic controller consistently produces operating cycles controlled within the specified limits.

## 7 Documentation

All documentation necessary for the safe and effective installation, operation, maintenance and testing of the equipment shall be supplied in one of the official languages of the countries in which it is to be installed or as agreed with the purchaser.

NOTE Regional or national regulations addressing the use of languages can apply (see [Clause 10 l](#)).

## 8 Information to be supplied

### 8.1 General

The following information shall be provided:

- a) Any pre-treatment of the item to be processed in the WD necessary to achieve the required performance standard shall be stated.

NOTE The nature of the item to be processed can require additional actions such as dismantling for separate processing, the pre-cleaning of difficult surfaces (inaccessible sites) by a manual process, etc., prior to the item being processed by the WD. Such pre-cleaning can be necessary to reduce the initial bioburden and/or contamination.

- b) For each operating cycle that can be used the following parameters shall be described:
  - 1) the specific purpose for which the WD is intended, including any restrictions;
  - 2) the type of products which the process is designed to clean/disinfect, this information shall be based on type testing on specific products and/or product families;
  - 3) the washer-disinfector accessories, including load carrier(s) that shall be used;
  - 4) the process chemicals;
  - 5) the values, including the ranges of the process variables of the processes, e.g. time, temperature, amount of water, amount of process chemicals, cleaning and disinfecting time/temperature (see [4.1.4](#));