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Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

Laveurs désinfecteurs —

Partie 1: Exigences générales, termes et définitions et essais

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 15883-1 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in collaboration with Technical Committee ISO/TC 198, *Sterilization of health care products*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

ISO 15883 consists of the following parts, under the general title *Washer-disinfectors*:

— *Part 1: General requirements, terms and definitions and tests*

— *Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.*

— *Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers*

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

— *Part 5: Test soils and methods for demonstrating cleaning efficacy* [Technical Specification]

Introduction

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

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

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

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

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

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

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

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

a) it should be noted that, until verifiable European criteria are adopted, existing national regulations concerning the use and/or the characteristics of the washer-disinfector remain in force;

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

Washer-disinfectors —

Part 1: General requirements, terms and definitions and tests

1 Scope

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

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

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

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

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

NOTE If it is considered that prion protein can be present, particular care is needed in the choice of disinfectants and cleaning agents to ensure that the chemicals used do not react with the prion protein in a manner that may inhibit its removal or inactivation.

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

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

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

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

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

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

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

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

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

United States Pharmacopeia, USP Pharmacopeia, Rockville, USA

3 Terms and definitions

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

3.1
A_0
equivalent time in seconds at 80 °C, delivered by the disinfection process, with reference to a microorganism with a z value of 10 K

NOTE See Annex B.

3.2
automatic controller
device that, in response to pre-determined cycle variables, operates the apparatus sequentially through the required stages of the process or processes

3.3
bedpan washer-disinfector
washer-disinfector intended to be used for the emptying, flushing, cleaning and thermal disinfecting of human waste containers

3.4
bioburden
population of viable microorganisms on a product and/or its container

3.5
calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standard

[EN 285:1996, definition 3.5]

3.6
calorifier
closed vessel, in which water is indirectly heated, by the flow of heated fluid through a heat exchanger, under a pressure greater than atmospheric

3.7
chamber
that part of the washer-disinfector in which the load is processed

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

3.8
chemical disinfection
disinfection achieved by the action of one or more chemicals the primary purpose of which is to be microbicidal

3.9
cleaning
removal of contamination from an item to the extent necessary for its further processing and its intended subsequent use

3.10
continuous process machine
machine which automatically transports the load through each stage of the operating cycle

3.11
critical process variables
those process variables for which the values during an operating cycle have been identified by the manufacturer as sufficient to ensure that the cycle meets the performance defined during validation

3.12
cycle complete
indication that the washing and disinfection cycle has been satisfactorily completed and that the disinfected load is ready for removal from the chamber

3.13
cycle control recorder
a device which records the values of one or more control variables as seen by the automatic controller

3.14
D **value**
exposure time required under a defined set of conditions to cause a 1-logarithm or 90 % reduction in the population of a particular microorganism

3.15
dead volume
volume of pipework which is not purged by the usual flow of liquids during the operating cycle

3.16
disinfection
reduction of the number of viable microorganisms on a product to a level previously specified as appropriate for its intended further handling or use

3.17
disinfection temperature
minimum temperature of the disinfection temperature band

3.18
disinfection temperature band
range of temperatures, expressed as the disinfection temperature (3.17) and the maximum allowable temperature which may prevail throughout the load during the disinfection time

3.19
disinfection time
period for which the critical process variable(s) (e.g. temperature of the load, disinfectant concentration in the chamber) are maintained at or above that specified for disinfection

3.20
door
device provided as a means of closing and sealing the chamber

3.21
double-ended washer-disinfector
washer-disinfector with separate doors for loading and unloading

3.22
endoscope washer-disinfector
washer-disinfector intended to clean and disinfect loads containing flexible endoscopes

3.23
fail safe
attribute of washer-disinfector design, or its associated services, that ensures that a single fault condition will not give rise to a safety hazard

3.24
fault
recognition by the automatic controller that at least one of the pre-set process variables for the washer-disinfector cycle have not been attained

3.25
fluid
liquid, gas or vapour

3.26
flushing
removal of gross contamination and/or the contents of a load item, but not necessarily contamination adhering to the surface of the load item, by displacement with water

3.27
free draining
allowing the unimpeded flow of liquids under the influence of gravity towards the discharge point

3.28
holding time
period during which the critical process variables are maintained at or above the values specified

3.29
human waste
excretions and body fluids including faeces, urine, blood, pus, vomit and mucus

3.30
human waste container
re-usable vessel for holding and transporting human waste

3.31
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2001, definition 2.20]

3.32
instrument washer-disinfector
washer-disinfector intended to clean and disinfect loads containing surgical instruments, anaesthetic accessories, bowls, dishes, receivers, utensils, glassware and similar items

3.33
load
collective term used to describe all the goods, equipment and materials that are put into a washer-disinfector at any one time for the purpose of cleaning and disinfecting it by an operating cycle

3.34
loading door
door in a double-ended washer-disinfector through which the load is put into the washer-disinfector prior to processing

3.35
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or relative article, intended by the manufacturer to be used, alone or in combination, for human beings for one more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment, or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury;

— investigation, replacement, modification or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

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

[ISO 13485:2003, definition 3.7]

3.36
microbial reduction factor
extent to which the bioburden is reduced in tenfold increments expressed as logarithms (base 10)

3.37
monitoring
measurement of physical variables and comparison of the values obtained with the values specified for the process

3.38
normal operation
operation of the washer-disinfector in accordance with the manufacturer's instructions and with all process parameters within the limits specified by the manufacturer

3.39
operating cycle
complete set of stages that is carried out in the sequence as regulated by the automatic controller

3.40
operating pressure
gauge pressure at which a vessel is operated during normal use

3.41
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO/TS 11139:2001, definition 2.24]

3.42
override
system by which the operating cycle can be interrupted or modified as necessary

3.43
performance qualification
PQ
process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification

[ISO/TS 11139:2001, definition 2.26]

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

3.44
process chemical
formulation of chemical compounds intended for use in a washer-disinfector

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

3.45
process variable
physical and chemical properties that influence the efficacy of all stages of the process

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

3.46
process verification recorder
device that, independently of the automatic controller, records values obtained for some, or all, of the control variables

3.47
recorder
system fitted to the washer-disinfector, or connected to the washer-disinfector, producing a permanent record of information graphically, digitally or electronically

3.48
re-qualification
repeat of part or all of the validation test requirements for the purpose of confirming process reliability

3.49
rinsing
removal of process residues by displacement and dilution with water

3.50
routine test
periodic checking and testing carried out to establish that the operational performance of the washer-disinfector remains within the limits established during validation

3.51
steam generator
vessel designed to contain water and a heating system (e.g. a steam coil or a fully immersed electric element) which is used to heat water to its vapour state

3.52
tank
process vessel, integral to the washer-disinfector, designed to hold fluids that are used during processing

3.53
test microorganism
microbial strain from a recognised culture collection used in microbiological testing of the performance of a washer-disinfector

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

3.54
test soil
formulation used to test the efficacy of cleaning in a washer-disinfector

3.55
thermal disinfection
disinfection achieved by the action of moist heat

3.56
type test
test programme to verify conformity of a washer-disinfector type to this standard and establish data for reference in subsequent tests

3.57
unloading door
door in a double-ended (3.21) washer-disinfector through which the load is removed after an operating cycle

3.58
validation
documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[ISO/TS 11139:2001, definition 2.50]

3.59
verification
confirmation through the provision of objective evidence, that specified requirements have been fulfilled

[ISO 9000:2005, definition 3.8.4]

3.60
viable microorganism
microorganisms, including viruses, which are capable of multiplication under specified culture conditions

3.61
warning pipe
secondary overflow pipe so fitted that its outlet, whether inside or outside the machine, is in a conspicuous position to indicate an overflow condition

3.62
washer-disinfector
WD
machine intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice

3.63
washing
removal of adherent contamination from surfaces to be cleaned by means of an aqueous medium, with or without process chemicals, as necessary

3.64
works test
series of tests performed prior to delivery to demonstrate compliance of each washer-disinfector with its specification

3.65
z **value**
change in temperature in kelvins (K) required to achieve a tenfold change in the rate of microbial inactivation by a moist heat disinfection process

4 Performance requirements

4.1 General

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

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

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

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

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

a) cleaning, which may include several stages;

b) disinfecting;

c) rinsing;

d) drying (when appropriate).

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

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

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

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

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

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

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

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

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

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

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

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

4.2 Cleaning

4.2.1 General

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

The test method for type testing and operational testing (6.10.2) shall employ one of the nationally published tests soils and methods as described in ISO/TS 15883-5 (see also References [24] to [39]).

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

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

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

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

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

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

4.2.2 Flushing stage

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

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

4.2.3 Washing stage

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

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

4.3 Disinfection

4.3.1 Thermal disinfection

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

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

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

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

4.3.2 Chemical disinfection

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

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

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

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

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

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

4.3.3 Thermal and chemical disinfection

4.3.3.1 The temperature on all surfaces of the load and load carrier shall be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.2).

4.3.3.2 The temperatures recorded on the surface of the chamber wall shall be within −0 °C and +5 °C of the disinfection temperature throughout the time specified for disinfection when this has been specified as a time/temperature relationship (see 6.8.3).

4.4 Rinsing

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

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

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

4.5 Drying

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

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

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

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

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

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

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

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

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

4.6 Process chemicals

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

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

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

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

5 Mechanical and process requirements

5.1 Materials, design and manufacture/construction

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

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

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

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

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

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

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

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

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

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

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

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

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

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

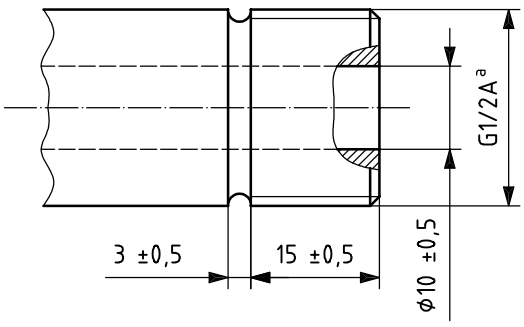
5.1.8 The chamber shall not leak when tested in accordance with 6.5.3.

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

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

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

Dimensions in millimetres



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

Figure 1 — Entry port for temperature sensor leads

5.1.11 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 connecting sleeve shall have an internal diameter of (10 ± 0,5) mm, an external male thread conforming to ISO 228-1 extending for a length of (15 ± 0,5) mm with a clear distance of (3 ± 0,5) mm before any increase in diameter of the sleeve (see Figure 1).

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

The connecting sleeve shall be positioned so that liquid will drain from it under the influence of gravity.

5.2 Safety

The WD shall comply with the requirements of IEC 61010-2-045.

5.3 Calorifiers and tanks

5.3.1 Disinfection of systems within the WD

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

This shall be achieved by either:

a) ensuring that all parts of the WD that recirculate fluids to the load or chamber are purged and disinfected during the normal operating cycle, or

b) by the provision of a separate machine purging and disinfection cycle.

5.3.1.2 The manufacturer shall inform the user of the requirements for the use of a purging and disinfection cycle prior to use when the WD has not been used for a period of 24 h or more [see 8.3 b)].

Disinfection during the purging and disinfection cycle shall be by thermal disinfection for WDs in which the load is subjected to thermal disinfection and is the preferred method for WDs employing chemical disinfection of the load.

5.3.2 Tanks

5.3.2.1 Tanks for storing process water within the WD shall be:

a) free-draining;

b) located such that they are cleanable 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 warning pipe or equivalent means to indicate to the operator that a tank is overflowing.

5.3.2.2 When the water supply is contaminated with gross particulate material (> 500 µm) the water storage tank shall be fitted with a removable and cleanable filtration device.

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

5.3.2.4 When heat sources are installed, they shall be removable for replacement and removable or accessible for cleaning.

5.3.2.5 In order to ensure freedom from microbial contamination, 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 the following conditions:

a) the water in the tank is kept constantly at a minimum of 65 °C, or

NOTE In order to maintain a minimum temperature of 65 °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 65 °C.

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

The minimum acceptable quality for the chemical purity of rinse water, and additional requirements for microbial purity, are specified in subsequent parts of ISO 15883.

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 by the purchaser [see 10 o)].

Machines can be fitted with either one door, which serves for both loading and unloading, or two doors, being of the “pass-through” type in which one door is used for loading and the other for unloading. WDs without doors are also possible (see 5.4.5).

5.4.1.2 The door-seal shall prevent fluid 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 cleaning 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 (steam, compressed air, circulating water, etc.) to the chamber are specified in IEC 61010-2-045.

When tested in accordance with 6.5.3, 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 manufacturer 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.

Compliance 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 machines in which access to the load is restricted by means of locked doors this shall require the use of a special key, code or tool to release the door lock and gain access to the load.

For a continuous process machine, it might not be necessary to open a door to gain access to the load (see 5.4.4).

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 61010-2-045.

5.4.1.8 It shall not be possible for the operator to start the process if the doors are not locked. Compliance 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 61010-2-045).

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 automatic 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. 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 doors fitted between consecutive sections of a multi-section machine, and access ports fitted to the outside of the machine, can be opened and closed by an operator without the use of a tool, means shall be provided which will prevent opening if this would create a deleterious effect on the load or the environment in which the WD is located.

5.4.5 Continuous process WDs without doors

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

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

5.4.5.3 WDs without doors shall have means to prevent the escape of fluid (liquids, aerosols and vapours) from the WD during a process cycle.

5.4.5.4 For WDs in which access to the load is not restricted by means of doors, the method of precluding access during an operational 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 General

5.5.1.1 The pipework, pumps, valves and fittings shall be constructed, installed and/or operated so that any residual liquid will flow towards a drain discharge point (see 6.5.5).

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 re-contaminate the disinfected load. Also, residual fluids can lead to corrosion.

5.5.1.2 When tested in accordance with 6.5.1, the dead volume shall not exceed the volume stated by the manufacturer [see 8.3 g)]. In addition, the recommended method of cleaning all injection lines and valves shall be stated [see 8.3 g)].

The pipework should be so constructed that the dead volume is minimized.

5.5.1.3 For small WDs intended to be placed on a work surface (i.e. table top machines) the requirements of 5.5.1.1, 5.5.1.2 and 5.5.2 do not apply.

5.5.2 Control valves

Unless otherwise specified in subsequent parts of this standard, for each valve connected to the chamber, the following rules of application shall be laid down:

a) It shall not be used in applications where the temperatures and pressures to which it will be exposed during operation in accordance with the manufacturer's instructions can exceed the maximum stated by the manufacturer of the valve. It is good practice to ensure that normal service conditions do not exceed 80 % of the specified maximum values.

b) It shall be removed by fittings designed for disconnection without removing connecting pipes, although, if necessary, it shall be possible to displace such pipes without removing them.

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 when loaded in accordance with the manufacturer's instructions.

5.6.2 Nozzles shall be protected from blockage by the passage of particles, e.g. by the provision of a filter upstream of the nozzle which will remove particles of a size which could block the nozzles.

All nozzles should be designed to minimize the possibility of blockage.

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.

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.

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

Removable nozzles shall have a means of identifying that they 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 by the WD manufacturer. The method to be used shall be specified in the instructions for use [see 8.3 b)].

5.6.6 Fixed irrigation nozzles shall be designed and constructed to provide a similar flow of water from all nozzles of the same type intended for the same application.

5.6.7 It shall be possible to check that fixed nozzles intended to provide fluids for the irrigation of the internal channels of hollow instruments 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. The number of dosing systems to be provided, within the maximum available number specified by the WD manufacturer, shall be agreed with the user [see 10 r)].

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 a special key, code or tool.

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) in the process cycle 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 operational 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.

The WD manufacturer shall specify the test method to be used to demonstrate compliance.

5.7.5 The manufacturer shall specify the accuracy and reproducibility of the control of volume admitted for each of the dosing systems provided.

Compliance shall be tested in accordance with 6.9 or by a method of demonstrated equivalence specified by the WD manufacturer.

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.

5.8 Load temperature protection

5.8.1 WDs intended to process items, which may 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 WDs 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 6.5.6. A chamber designed to work at atmospheric pressure shall not exceed atmospheric pressure by more than 200 hPa (200 mbar).

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) the temperatures recorded on the surface of the load and load carrier are within − 0 °C and + 5 °C of the disinfection temperature throughout the holding period for the disinfection stage;

b) the temperatures recorded on the surface of the load and load carrier are within ± 5 °C of the set temperature for the relevant stage throughout the holding period for each of the other stages;

c) the temperature profile obtained for the temperature controlled stages of the operating cycle shall be consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.2.3);

d) the holding time, as determined from the measured temperatures on the surface of the load items, is not less than that specified for the disinfection stage (or the specified A_0 value has been obtained);

e) during the holding time the measured temperatures on the surface of the load and load carriers are within the disinfection temperature band specified for the operating cycle (or the specified A_0 value has been obtained);

f) the temperatures shown on the chamber temperature indicator and/or recorder are within ± 2 °C of the temperature measured at the automatic control sensor;

g) the temperature measured on the surface of each load item does not fluctuate by more than ± 2 °C and does not differ from that in other load items by more than 4 °C;

h) at the end of the 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) the temperatures recorded on the surface of the chamber throughout the holding period for the disinfection stage are within − 0 °C and + 5 °C of the disinfection temperature;

b) the temperatures recorded on the surface of the chamber throughout the holding period for each of the stages, other than the disinfection stage (see above) are within ± 5 °C of the set temperature for the relevant stage;

c) the temperature indicated/recorded by the WD instruments are within ± 2 °C of that recorded by the test instrument from the sensor adjacent to the reference sensor throughout the holding period for the disinfection stage;

d) the temperature profile obtained for the temperature controlled stages of the operating cycle are consistent within ± 2,5 °C for the last three of four test cycles (see 6.8.3.2).

5.10 Switches, gauges and indicating devices

5.10.1 The operating cycle shall be started by means of a single switch. This switch can be combined with the indicators shown in IEC 60073.

5.10.2 Each switch, gauge or indicating device intended to be used by the operator shall be marked with an appropriate symbol and/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 and/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.

WDs can be fitted with either, or both, of two separate recording systems: a “cycle control” recorder which records the values of control variables as seen by the controller, or a “process verification” recorder which, independently of the controller and its sensors, records the values attained to some or all of the critical variables which determine the adequacy of the process.

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 thermal disinfection:

   — the WD shall be equipped with a temperature indicator, independent from the controller, to allow the operator to verify attainment of the programmed disinfection temperature (This can be used when, because of the nature and intended use of the load, the risk arising from use of the product after an unsatisfactory disinfection process is low.);

b) verification by process record, independent from the controller, of the attainment of thermal disinfection conditions:

   — the WD shall be equipped with a temperature recorder, with sensors and signal processing independent from the controller, to record the attainment of the programmed disinfection conditions (This can be used when, because of the nature and intended use of the load, it is necessary to provide confirmatory evidence that the disinfection process has taken place within the limits established during validation.);

   — this provides no verification of the adequacy of the cleaning process; cleanliness of the load should be established by inspection of all load items;

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

   — the WD shall be equipped with a multi-channel recorder, with sensors and signal processing independent from the controller, to record the process variables which were determined during validation studies to be critical to the satisfactory outcome of the cleaning and disinfection processes (see also 5.17.2.7 and 5.17.2.8). (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 processes have taken place within the limits established during validation. This can include WDs for products which will be used without further processing and where the risks arising from an unsatisfactory cleaning and/or disinfection process are unacceptable.)

This verification of the cleaning process provides assurance of cleaning for those items which 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 part of ISO 15883 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”, “Drying cabinet 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.

Removal of the connected sensor may be necessary.

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 disinfected throughout the load and chamber will attain the disinfection temperature for the required time.

For a method of testing, see the appropriate part of ISO 15883.

Sensing points additional to those specified can 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 cycle.

Usually sensors are located in the water admitted to, in, or leaving the chamber.

5.12.8 The following indicators shall be located at the loading end of the WD:

a) “in-process” indicator;

b) “fault” indicator;

c) hours run meter or cycle counter that cannot be re-set by the user;

d) “cycle complete” indicator;

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 cycle.

Cycle complete is not applicable to a continuous process machine.

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 On double-ended WDs, the following instruments and indicators shall be located at the unloading end:

a) “in-process” indicator;

b) a “cycle complete” indicator;

c) a “fault” indicator.

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

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

5.12.10 Failure of any sensor in a system controlling disinfection time or temperature 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 by the WD manufacturer to ensure that the conditions sensed are representative of the process conditions that are to be controlled e.g. flow through lumen instruments, spray pressure, foam limitation.

5.13 Temperature indicating systems

5.13.1 Temperature sensors shall be either platinum resistance types complying with Class B of IEC 60751 or thermocouples complying with one of the international tables specified in Tolerance Class 2 of IEC 60584-1:1995 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;

d) have an accuracy of at least ±1 °C over the scale range 10 °C to 99 °C;

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 a special key, code or tool.

NOTE 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 kilopascals or bar;

c) have an accuracy of at least ± 5 kPa (0,05 bar);

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 (0,2 bar);

f) for digital instruments have a resolution of at least 1 kPa (0,01 bar);

g) be adjusted to an accuracy of at least ± 5 kPa (0,05 bar) 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 a special key, code or tool.

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.

When graduated in bar, the instrument should be labelled to indicate whether this measurement is absolute or gauge pressure.

5.15 Timing equipment

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

5.15.2 Time indicators, including chart recorders, shall:

a) be graduated in seconds or minutes;

b) have an accuracy of at least ± 2,5 % for periods up to 5 min and for periods above 5 min of at least ± 1 %;

c) have means to adjust *in situ* by means of a special key, code or tool.

5.16 Operating cycle indicating equipment

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

5.16.2 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.

5.17 Recording instruments (if fitted)

5.17.1 Requirements for 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.

5.17.2 Requirements for process verification recorders

5.17.2.1 When process verification recording is required, unless already specified in a subsequent part of ISO 15883, this shall be in the information supplied by the purchaser to the manufacturer.

5.17.2.2 The sensors connected to the process verification recorder 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.

5.17.2.3 When a microprocessor based system is used any signal amplifier and A to D (Analogue to Digital) converter shall be separate from those used by the controller.

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

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

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

5.17.2.7 When full 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 and air in each chamber at each stage in the operating cycle;

b) the volume of each process chemical admitted, and the time at which it was admitted, at each stage in the operating cycle;

c) the temperature of water in each heated storage tank;

d) the pressure and/or flow of water/aqueous solutions supplied to each chamber during washing and rinsing stages;

e) the electrical conductivity of the final rinse water.

5.17.2.8 The maximum expected value of the variable to be measured shall not exceed two thirds of the full scale value of the measuring instrument. The full scale value of the measuring instrument shall not exceed the maximum expected value by more than 150 %.

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

a) Temperature

- accuracy: ± 1 % over the range 0 °C to 100 °C;
- resolution: 1 °C or better;
- sampling rate: at least every 5 s.

b) Pressure

— accuracy: ± 2,5 % over the range 100 kPa to 500 kPa;

— resolution: 5 kPa or better;

— sampling rate: at least every 5 s.

c) Conductivity

— accuracy: ± 5 % of reading or ± 0,1 µS/cm whichever is greater;

— resolution: 1 % of reading or 0,1 µS/cm whichever is greater;

— sampling rate: at least every 5 s;

— temperature compensation 0 °C to 95 °C.

d) pH

— accuracy: 0,5 pH units;

— resolution: 0,1 pH units;

— sampling rate: at least every 5 s;

— temperature compensation: 0 °C to 95 °C.

e) Volume/flow

— accuracy: ± 5 % of full scale;

— resolution: ± 1 % of full scale;

— sampling rate: at least every 5 s;

— temperature compensation: 0 °C to 95 °C.

5.17.2.9 Either analogue or digital recorder shall be used.

5.17.2.10 The recorder shall produce a permanent record.

The record produced should remain legible for the duration of record storage required by the purchaser's regulatory authority, when stored under ambient conditions. Thermal paper records are unlikely to meet this requirement.

5.17.2.11 The printing of data shall be sufficient to ensure that any deviation outside the permitted tolerances can be identified.

5.17.2.12 For calibration purposes, means shall be provided to adjust the recorder *in situ* by the use of a special key, code or tool.

5.17.2.13 Unless otherwise specified by the purchaser, for double-ended WDs the printed record should be produced on the unloading side of the WD.

5.18 Control systems

5.18.1 The WD shall be provided with an automatic controller.

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

5.18.3 The automatic controller shall check the attainment or otherwise of the pre-set cycle variables, within pre-determined limits, essential to the efficacy of the operating cycle.

5.18.4 The manufacturer shall specify the values for each cycle variable programmed into the automatic controller such that the performance requirements in Clause 4 are met.

5.18.5 The automatic controller shall ensure that within the limits specified by the manufacturer the operating cycle is reproducible during each subsequent cycle. It shall be possible to maintain continuously the temperature within the specified disinfection temperature band for the specified time (see 6.13).

5.18.6 It shall not be possible to adjust the pre-set variables during the progress of an operating cycle.

5.18.7 Analogue recording instruments shall not be used for a control function unless it can be demonstrated that the control function does not adversely affect the accuracy of the instrument.

5.18.8 Access to control devices, including access for the purpose of setting the cycle variables, which can be operated without dismantling the control or moving it from its fixed position on the machine shall only be by means of a special key, code or tool.

5.18.9 When WDs are programmed for a number of operating cycles, the required cycle shall be selected by key, code or switch.

5.18.10 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 a special key, code or tool different from the one specified above.

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

5.18.12 Any control which is pre-set, but adjustable, shall either be located behind a lockable panel or require the use of a special key, code or tool for its adjustment.

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

5.18.14 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 fail-safe in the event of failure of any service, i.e. air steam, electricity, water or drainage.

It is good practice to ensure that incandescent indicator lamps, i.e. excluding light-emitting diodes, are operated at not more than 80 % of their maximum rating.

5.19 Override of automatic control

5.19.1 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.

5.19.2 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 a special key, code or tool, different from those specified in 5.18.8, 5.18.12 and 5.19.1 c);

b) not be dependent on a fault having occurred.

When using the special key, code or tool specified in item a) above, it shall be possible for a trained or authorized person to view the WD gauges simultaneously.

5.20 Microprocessor control systems

If 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 processor 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 variable 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 life 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 processor shall monitor all sensors, at an interval not greater than 2 s intervals.

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).

5.21 Access to software

When required by the purchaser the complete programme and software, including source code, for machines controlled by the microprocessor shall be lodged with an independent body (such as a bank or other secure repository), so that in the event of the WD manufacturer ceasing to trade or failing to appoint successors, the purchaser or their agent shall have access to the programme and software.

5.22 Fault indication systems

5.22.1 If the values of the cycle variables are outside the limits specified by the manufacturer (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 washing/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 a special key, code or tool. A visual display of fault shall continue at least until the door-locking mechanism is released by the use of a special key, code or tool.

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

5.22.4 For double-ended WDs, after a fault has occurred, any load, which 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 by the WD manufacturer. When necessary, means shall be provided to monitor the attainment of this water quality either periodically or continually for each cycle.

NOTE The quality of water can include consideration of chemical purity, hardness, temperature, supply pressure, microbial contamination, etc.

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

5.23.2 The WD shall be designed to operate either:

a) with potable water supplied directly to the WD, or

b) with potable water supplied to the water treatment equipment supplying the WD.

Water treatment equipment can include, e.g. a softener, de-ionizer or reverse osmosis plant, as necessary.

NOTE Many of the attributes of the water supplied to the WD can affect the efficacy and or efficiency of the process. These include hardness, pH, microbial purity as well as various reactive anions and cations.

Specific requirements for particular applications are specified in subsequent parts of ISO 15883.

5.23.3 The WD manufacturer shall request from the user details of the available water supply and advise the user of necessary water treatment. In the absence of reliable information from the user, the quality of the water available shall be tested in accordance with 6.4.

5.24 Venting and drainage systems

5.24.1 The WD shall be vented either:

a) directly to the atmosphere external to the building, or

b) indirectly into the drainage system via a condenser, or

c) into the working area.

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

If specified by the purchaser, ductwork can be supplied [see 6.5.6 and 10 q)].

In case of noxious discharges, attention is drawn to the requirements of IEC 61010-2-45.

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 6.5.6.

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, e.g. the connection should be of the spigot type with the connecting ductwork inside the spigot up stand on the WD.

5.24.5 Details of the ventilation discharge requirements shall be provided which include the following:

a) air volume;

b) system pressure drop;

c) maximum temperature and maximum relative humidity at that temperature.

5.24.6 Means shall be provided to ensure that any condensate draining from the ductwork will not contact the load (see 6.5.7). When tested in accordance with 6.5.7 all surfaces of all test pieces 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 the following:

a) a water seal (usually of a depth no less than 50 mm);

NOTE Local regulations applicable to the water seal can exist.

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

NOTE 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 cycle and it shall not be possible to open the door without the use of a special key, code or tool.

NOTE Blocked drain protection is intended to prevent spillage and minimize the risk of (cross) infection.

This test might 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 air filters intended to ensure that air free from microbial contamination is used for drying the load 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 and/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 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 WD manufacturer shall state the extent to which the load carrier may be withdrawn and remain stable.

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.

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

5.27.3 The load carrier shall be constructed from durable, corrosion-resistant materials and shall withstand, without damage, the environment within the chamber.

5.27.4 The load carrier shall prevent neither the attainment of the pre-set cycle variables nor the free drainage of water from the load and the penetration of water and/or steam into the load.

5.27.5 The load carrier(s) shall be designed so that they cannot be mis-positioned in a manner which will prevent compliance with the requirements of 5.27.4.

5.27.6 Load carriers connected to the process fluid circulation system shall be designed and constructed so that they cannot be mis-aligned in the WD (see 6.7.1).

5.27.7 The load carrier shall be designed and constructed so that it does not impair cleaning and disinfection of the load.

5.27.8 The load carrier intended to accommodate the item(s) shall be designed in such a manner that the contact between the different surfaces of the same item or between two items is reduced to the minimum necessary.

If one or more phases of the processing of the device are conducted by immersion, the basket intended for accommodating this device shall be designed in such a manner that the whole of the device is always immersed at the time of these phases.

If one or more phases of the processing of the device are conducted by spraying, the contact surfaces between the device and the basket shall be reduced to the minimum necessary.

5.28 Trolleys

5.28.1 If trolleys are used in conjunction with the WD to move loads and/or load carriers, 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 [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 carriers 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 WDs shall be designed and constructed to facilitate cleaning and disinfection of the trolley between uses.

5.29 Environment

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.

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 compliance with the specified requirements of this part of ISO 15883. They may be used in type tests, works tests, and in validation and re-qualification tests, or in routine tests. Other tests and methods providing equivalent assurance may be used by the manufacturer as the basis of claiming compliance with this part of ISO 15883. In any case of dispute, the reference tests given in this part of ISO 15883 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 WDs, as supplied, with this part of ISO 15883

The manufacturer shall supply documentary evidence that the WD complies with the requirements of both this part of ISO 15883 and subsequent relevant parts of ISO 15883.

The manufacturer of the WD shall carry out such testing on cleaning efficacy and disinfection of specific loads as may be required to substantiate any performance claims made by the manufacturer of the WD.

6.1.3 Conformity of WD, as installed, with this part of ISO 15883

6.1.3.1 Validation

6.1.3.1.1 For WDs, 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 comply with the requirements of this part of ISO 15883.

The documentary evidence can 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 WDs claiming compliance with this part of ISO 15883.

6.1.3.1.3 If the WD has different cycles, the tests shall be carried out for each cycle type.

6.1.3.1.4 In the case where cycles using the same load configuration only differ by the length of the different phases, 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 61010-2-045).

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 part of ISO 15883 apply except insofar as the test methods and requirements are modified by the requirements of subsequent parts of ISO 15883. When no relevant subsequent part exists all relevant parts of the test programmes in this part of ISO 15883 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:

— cleaning efficacy;

— disinfection conditions throughout the chamber, load carrier and load;

— drying efficacy;

— freedom from process residues.

6.1.3.4.5 Each cleaning and disinfection process 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.

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

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

a) a specified disinfection temperature and a minimum time for which the surfaces to be disinfected will be subjected to this 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 Certification of validation

Installation qualification, operational qualification and performance qualification reports shall be prepared and signed by persons designated as responsible for preparing, reviewing and accepting the reports.

6.1.5 Re-qualification

Re-qualification 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 a review of records of routine tests of WD performance indicates unacceptable deviation(s) from data determined during the initial validation;

c) if WD performance is unacceptable;

d) if process conditions (e.g. process chemicals) are changed;

e) at defined intervals.

The defined interval can be determined by regulatory authorities or by risk analysis. Normal practice would be for re-qualification to be carried out annually.

6.1.6 Process control and monitoring

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.

WDs shall be tested periodically in accordance with a documented schedule to demonstrate the continued reproducibility of the validated process 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 Test equipment

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 part of ISO 15883.

6.2.1.2 Temperature sensors shall be either platinum resistance elements and comply with IEC 60751:1983, Class A, or shall be thermocouples and shall comply with the relevant international table specified in IEC 60584-1:1995; 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, etc.

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 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 Thermometric recording instruments

6.2.2.1 One or more thermometric recording instrument(s) shall be used in conjunction with the temperature sensors to record the temperatures measured in the locations specified in the tests described in this part of ISO 15883. They may also be used to verify the readings obtained from instruments fitted to the WD.

6.2.2.2 The thermometric 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 analogical 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 instrument manufacturer's instructions by a validated method using a working or reference standard that is traceable to a national standard.

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

6.3 Tests on doors, interlocks and fault indications

6.3.1 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 a cycle with each door left unlocked in turn and with both doors unlocked.

6.3.1.2 On machines 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 machines 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 cycle, shall be tested in a similar manner.

6.3.1.4 Check for compliance with 5.4.1.8 by establishing whether it was possible to initiate a cycle with one or more doors open.

6.3.2 Door locking during 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 of the doors. 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 WDs

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

Between 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 satisfactory operating cycle:

— during unloading observe whether the loading door remains locked when the unloading door is unlocked;

— during unloading and loading observe when the indication “cycle complete” is cancelled.

6.3.3.2 Report:

a) whether it was possible:

   — to open either the unloading door after initiation of a cycle before the cycle had been completed satisfactorily (see 5.4.3.1);

   — for both doors to be open simultaneously (see 5.4.3.3);

   — for an operator at one end to operate the door at the other end (see 5.4.3.3);

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.

6.3.5.2 Procedure

Carry out the testing of each sensor as follows:

— start an operating cycle;

— during, or before, the stage of the cycle at which the sensor is intended to provide data used to determine the control of the cycle, disable the sensor.

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 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 5.18.14).

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 a 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 a special key, code or tool (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 WDs 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 WDs 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 subsequent parts of ISO 15883, or required by the WD manufacturer (see 5.23.3), the tests described in 6.4.2 to 6.4.4 shall be applied.

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

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 determinands 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:

— conductivity;

— pH;

— oxidizable substances [determined by the European Pharmacopoeia (EP) method or as redox potential determined by the United States Pharmacopoeia (USP) method];

— total hardness (salts of Ca^{2+}, Mg^{2+}, Sr^{2+} expressed as mmol $CaCO_3$);

— total dissolved solids (TDS) determined as evaporative residue;

— inorganic phosphate [P_i] and inorganic silicate [SiO_2], determined as the molybdate reactive species;

— chloride [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 other parts of ISO 15883, 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 Pharmacopeia (EP) or United States Pharmacopeia (USP).

6.4.2.4 Tests for microbial quality

Make a total viable count by membrane filtration of not less than 100 ml final rinse water sample. Place the filter on R_2A-medium in accordance with Annex D, or other suitable low nutrient medium and incubate at 28 °C to 32 °C for a minimum of 5 days to determine the aerobic mesophillic viable count.

Other methods, including rapid methods such as ATP bioluminescence, 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 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:

— conductivity;

— pH;

— oxidizable substances [determined by the European Pharmacopoeia (EP) method or as redox potential determined by the United States Pharmacopoeia (USP) method];

— total hardness (salts of Ca^{2+}, Mg^{2+}, Sr^{2+} expressed as mmol $CaCO_3$);

— total dissolved solids (TDS) determined as evaporative residue.

6.4.4 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 accuracy of the vessels shall be equal to, or better than, 1 % of the volume to be measured, as specified by the manufacturer.

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.

6.5 Tests on pipework

6.5.1 Estimation of dead volume of pipework

6.5.1.1 General

The test is intended to verify the volume stated by the manufacturer. The test shall be carried out after the checks for free drainage specified in 6.5.4 have been completed and found to be satisfactory.

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 6.4.4). Measure the volume of water discharged and the dead volume, estimated as the volume retained, calculated from the difference between the two values.

When the WD has two or more pipework systems which are entirely separate e.g. for flushing water, wash water, rinse water, chemical disinfectant solution, 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 maximum retained volume stated by the manufacturer (see 5.5.1.3).

6.5.2 Free draining of chamber and load carriers

At the end of a normal operating cycle inspect the chamber and load carriers for evidence of pools of retained water.

6.5.3 Chamber leak tightness

Fill the chamber containing a load carrier and a test load equal to the maximum volume that could be accommodated with a volume of water equivalent to the maximum volume of water used for any stage of the cycle.

Inspect the WD for leakage.

6.5.4 Free draining (tanks, chamber, load carriers)

6.5.4.1 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.

6.5.4.2 Free draining of chamber and load carriers

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

6.5.4.3 Free draining of tanks

Fill all tanks and reservoirs for water and aqueous solutions with water to the maximum level required for normal operation and then allow them to drain. Inspect the tanks for evidence of pools of retained water.

6.5.5 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.

6.5.6 Venting

6.5.6.1 Equipment

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

6.5.6.2 Procedure

Close and seal the chamber of the WD in the manner specified by the manufacturer 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.

6.5.6.3 Results

Check for compliance with 5.8.4 and 5.24.2.

6.5.7 Load contamination from ductwork of the WD

6.5.7.1 Equipment and materials

The equipment and materials shall consist of:

— 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;

— stopwatch;

— load carrier and full load for the WD;

— paper towels.

6.5.7.2 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 ± 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 ± 5) s.

Refill the vessel with (200 ± 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 carriers which the WD is designed to process.

6.5.7.3 Results

Report whether the results comply with 5.24.6, i.e. there is no visible water on the load or load carriers.

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 test instrument.

The test instrument shall be in a known state of calibration in accordance with ISO 10012-1, traceable to a relevant national standard for the level of accuracy specified in this part of ISO 15883.

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 operational cycle, or at two or more values in the range of values over which readings will be made during an operational cycle, as specified by the manufacturer. Compare the readings obtained from the test instrument and the WD system.

6.6.2 Legibility

Determine the legibility of all indicators and gauges 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 ± 100) lx at a distance of $0,25^{+0,05}_{0}$ m and at a distance of $1,0^{\ 0}_{-0,05}$ m to determine whether the reading is legible.

6.7 Tests on load carriers

6.7.1 Load carriers used within the chamber

6.7.1.1 Equipment

Spring balance calibrated in kilograms with a range including 0 kg to 30 kg and with an accuracy of ± 1 kg over the range 0 kg to 30 kg attached to the load carrier 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 and/or transferring the load into and/or out of the chamber and operate it in the manner specified by the manufacturer. During loading and after cycle completion carry out an inspection to see if the requirements of 5.27 are met. This shall include establishing that:

   — the load remained wholly supported and retained within the usable chamber space for the duration of the operating cycle;

   — the load carrier was retained in the chamber by a mechanism which was only released when the transfer system was in place;

   — the load carrier remained stable when withdrawn for a distance specified by the manufacturer, and was fitted with a retaining device, which had to be released if the load was to be withdrawn further;

   — the load carrier could not be mis-positioned in a manner which would prevent the free drainage of water and the penetration of water and/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

Spring balance calibrated in kilograms with a range including 0 kg to 30 kg and with an accuracy of ± 1 kg over the range 0 kg to 30 kg attached to the load carrier 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° 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, 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 carriers: fully load the trolley with load carriers each filled to maximum capacity in accordance with the manufacturer's instructions. By visual inspection determine whether the load carriers were securely retained:

— during loading and unloading;

— 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 WDs and multi-chamber WDs the use of recorders with fixed sensors is impractical for monitoring the temperature of the load and load carriers. 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 temperature test

6.8.2.1 General

During thermometric tests for thermal disinfection, in order to avoid pre-heating the load, the washing stages shall be disabled or the controlled temperature at the start of the disinfection stage reduced to be at or below the lowest temperature specified for the washing stage.

NOTE This creates the "worst case" conditions with which the disinfection stage can be expected to cope and ensures that disinfection conditions will be attained in the event of a failure of the washing stage.

The disinfection stage may be combined with the washing stage or the rinsing stage in some WDs (see also 4.1.3).

The load under test shall consist of a reference load (see subsequent parts of ISO 15883) 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 carriers of the type intended for use with the load.

6.8.2.2 Equipment

Temperature recorder complying 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 diagonally opposite corners and in the approximate geometric centre;

b) on items in the load with at least one on an item at each level in the load carrier (up to a maximum of three if the load carrier accommodates load items on more than one level);

c) one on an item in the region known to be slowest to attain the disinfection temperature;

d) one on an item in the region known to be fastest to attain the disinfection temperature;

e) one adjacent to the automatic control temperature sensor;

f) one adjacent to the process recorder or indicator sensor (if fitted) in each chamber or compartment.

These positions should be specified by the manufacturer 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 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 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 recorder complying with the requirements specified in 6.2.2.

6.8.3.2 Procedure

Locate the temperature sensors as follows:

a) one in each corner of the chamber;

b) one in the centre of the two side walls;

c) one in the centre of the roof of the chamber;

d) one adjacent to the temperature sensor used as the reference sensor for chamber temperature.

Use additional locations for sensors on sequential 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 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 with not more than 15 min intervals between cycles (a “hot start").

Operate the WD with a load consisting of a reference load (see subsequent parts of ISO 15883).

Multi-chamber WDs can be tested with each chamber tested consecutively or concurrently. In the latter case, 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 recorder complying with the requirements specified in 6.2.2.

6.8.4.2 Procedure

Locate the temperature sensors at two 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 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 with not more than a 15 min interval between cycles (a “hot start"). Operate the WD empty except for chamber furniture (e.g. load carriers).

WDs 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 5.3.2.5 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 recorder complying with the requirements specified in 6.2.2.

Three independent data loggers and a temperature recorder having at least one sensor can be used as an alternative.

6.8.5.3 Procedure

Locate the temperature sensors at two 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, on a normal operating cycle. For multi-cycle machines, test the two 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 manner specified by the manufacturer, 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 test method specified by the manufacturer (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 cycle use the contents of the second measuring cylinder to replenish the first cylinder to the maximum marked level. Note 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 a further operating cycle and repeat the measurements as above.

6.9.1.1.3 Concentration method

For WDs 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 6.4.4 or by separate measurement of the volume retained within the holding tank in the WD.

6.9.1.2 Results

Check for compliance 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 but less than five operational cycles. Run the WD on five 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

During tests of cleaning efficacy, the cycle shall be run without a disinfection stage. The drying stage may also be omitted if this is necessary to facilitate the detection of residual contamination or test soil.

6.10.2 Cleaning efficacy test 1

6.10.2.1 General

The tests for cleaning efficacy shall be carried out using the appropriate test method(s) and test soil(s) as described in ISO/TS 15883-5 by taking into consideration the corresponding category of load. (See also References [24] to [39].)

The attention of users is drawn to local regulations that can require the use of particular test soils and test methods.

The attention of manufacturers is drawn to the user's choice of test soil(s) and method(s) for operational testing; this can indicate a need to carry out similar testing before the WD is supplied.

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

6.10.2.2 Procedure

Contaminate the test load, chamber walls and load carrier with the test soil as described in the relevant test method of ISO/TS 15883-5.

Operate a normal wash cycle for the load type under test.

After completion of the wash cycle, examine the test load, chamber walls and load carrier for the presence of residual test soil using the method described in the relevant test method of ISO/TS 15883-5.

6.10.2.3 Results

The test result shall be regarded as satisfactory if it meets the criteria given in the relevant test method of ISO/TS 15883-5.

6.10.3 Cleaning efficacy test 2

6.10.3.1 General

This test is undertaken following satisfactory completion of cleaning efficacy test 1 and the thermometric tests (see 6.8). 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.

6.10.3.2 Procedure

Operate no less than three cycles using actual loads contaminated by normal use of the type that it is intended to process.

Visually assess the cleanliness of the processed items.

When the items are visually clean, one of the methods given in Annex C shall be used to detect the presence of residual proteinaceous contamination.

When other methods will be used routinely for assessing the acceptability of items processed through the WD, the test method to be used shall be agreed between the user and the manufacturer.

NOTE Other types of contamination e.g. non-proteinaceous can require other test methods.

6.10.3.3 Results

Report the composition of the test load, the method(s) used to assess the cleanliness of the load and whether all parts of the load were found to be free from residual contamination by the test method used.

6.10.4 Tests for process residuals

6.10.4.1 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 process chemicals used during the process (detergents, rinse aids, etc.) may not be completely removed by the rinsing process.

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.

6.10.4.2 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 by the manufacturer 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.

6.10.4.3 Results

Check for compliance 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 testing to ISO 10993 can be used to meet the requirements of 6.10.4.

6.11 Tests of air quality

6.11.1 Procedure

Test the complete installation using the method described in ISO 14644-3. 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.

6.11.2 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 Load dryness test

6.12.1 General

The following test shall be carried out when the operating cycle includes a drying stage.

6.12.2 Procedure

Fully load the WD with a test load as specified in the relevant subsequent part of ISO 15883.

Carry out a normal operating cycle from a cold start, i.e. the WD shall not have been used within the previous hour. Within 5 min of the end of the operating cycle, place a sheet of coloured (e.g. blue or green) crepe paper on a flat surface and place the load on it. When removing the load from the WD, and as the individual load items are placed onto the crepe paper, observe and record any water being discharged. Examine the crepe paper for dampness shown by dark spots on the paper which shall be regarded as evidence of residual water.

When the test load includes items with a lumen these items shall be examined for internal retained moisture by blowing through with dry compressed air and aiming the discharge at a mirror. Misting of the mirror or the expulsion of visible drops of moisture shall be regarded as evidence of residual water.

6.12.3 Results

Report whether or not any residual water was found (see 4.5.2).

6.13 Automatic control test

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 may 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 normally used, in the chamber.

For WDs equipped with multiple 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 note 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 or sub-stage, and the maximum values during the holding time.

At the approximate mid-point of the disinfection hold time, note 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 operational 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 5.18.5);

c) during the disinfection stage:

1) the indicated and recorded chamber temperatures are within the range specified (see 4.3.1.1);

2) the time for which the disinfection temperature was maintained was not less than that specified (see 4.3.1.1);

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 times to ensure that the automatic controller consistently produces operating cycles controlled within the limits specified by the manufacturer.

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.

Attention is drawn to regional or national regulations addressing the use of languages.

8 Information to be supplied by the manufacturer

8.1 General

The manufacturer of the WD shall provide the following information:

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

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 by the manufacturer:

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 validation studies on specific products and/or product families;

3) the accessories that shall be used;

4) the process chemicals;

5) the values of the cycle variables of the processes e.g. time, temperature, amount of water, amount of process chemicals, disinfecting time/temperature;

6) the maximum rate of change of process variables e.g. pressure, temperature (see 4.1.4).

c) The conditions necessary to meet the performance requirements for each stage of the process and for each operating cycle shall be stated by the manufacturer.

d) For WDs in serial production, the manufacturer shall state the standard service time required to carry out all routine maintenance tasks and the intervals at which these shall be carried out.

8.2 Before delivery of the WD and for installation

In order to enable the purchaser to prepare for installation, and then correctly to install and operate the WD and to perform routine maintenance and testing (see also Clause 10), before delivery of the WD and for installation, the WD manufacturer shall provide the purchaser with the following information:

a) installation instructions, including the overall dimensions and overall mass of the WD, the floor loading at each support when the WD is filled with water, the clearance required for access and the masses of the principal heavy components;

b) details of the services required (i.e. steam, water, gases, electricity, compressed air, drainage and ventilation), including the maximum demand and the minimum and maximum values for the correct functioning of the WD,and that shall include for each validated process, for each water connection:

   — the volume of water used per cycle and for each process stage, with tolerances;

   — the maximum flow of water and condensed steam to the drain and the maximum temperature of effluent that may be discharged from the machine during normal operation and in a single fault condition;

   — the maximum hardness value, the range of pH and the conductivity of the water;

c) maximum total heat in watts transmitted to the surrounding air when the WD is operated in an ambient temperature of (23 ± 2) °C in still air;

d) maximum heat in watts transmitted from the fascia when the WD is operated in an ambient temperature of (23 ± 2) °C in the working area;

e) mean and peak sound power levels generated by the WD, expressed as an A-weighted sound power level (see IEC 61010-2-45);

f) type of doors and information on the necessary space required for the movement of the door(s);

g) suitable process chemicals for each stage of the process where these are required;

h) details of any supplied materials or necessary materials (detergents, chemical disinfectants, etc.) which are to be used for the correct functioning of the WD and which are subject to control under national guidelines for the safe handling of chemicals or have environmental limits set; the chemical constituents (active ingredients) shall be listed and any national guidance on exposure limits [e.g. the time weighted average (TWA) and 10 min short-term exposure levels (STEL)] shall be provided;

i) details of the independent body where complete programme and “software” are lodged, when this is required by the purchaser (see 5.21);

j) maximum deviation from a plane horizontal surface that can be accommodated (see 5.1.4);

k) declaration with which parts of ISO 15883 the WD complies.

8.3 At delivery of the WD

At delivery of the WD, the manufacturer shall provide the purchaser with at least the following information:

a) operating instructions and short form of manual; the short form manual should be available in waterproof material;

b) user instructions with at least:

   — range of application;

   — type of load;

   — load configuration;

   — correct loading procedure;

   — total chamber volume;

   — design pressure, allowable working pressure and allowable temperature;

   — description of the available operating (cleaning and disinfection) cycles;

   — description of controls and indicating devices;

   — description and setting of safety devices;

   — instructions for malfunctions;

   — instructions for purging and disinfecting the WD;

   — instructions for cleaning the panelling;

   — instructions for checking that spray nozzles are not blocked;

   — instructions for checking that spray arms are free to move;

   — instructions for checking the flow through nozzles for irrigation of hollow instruments;

c) dimensions of the usable space of the chamber;

d) loading capacity;

e) description of the WD operating cycle or cycles which should include:

   — a diagram showing the sequence of operation of all components;

   — the process variable used to control each stage, e.g. time, attainment of temperature,

   — details of the maximum operating temperature and time for each stage;

f) information on process security details (e.g. door interlocking mechanism) (see 5.4.3);

g) maintenance manual which should include:

   — maintenance tests and the frequency that they should be carried out;

   — electrical diagrams and circuits;

   — hydraulic plans and circuits;

— the dead volume of pipework;

— the recommended method of cleaning all injection lines and valves;

— actions required to produce test conditions specified in Clause 6;

— a complete spare parts list;

— a list of the special tools necessary for maintaining and testing;

— type of guarantee offered;

— list of service stations;

— guidance on tracing and rectifying causes of malfunction;

h) documented evidence of compliance with this part of ISO 15883;

i) the facsimile of the marking on the vessel (see Clause 9).

9 Marking, labelling and packaging

9.1 Marking and labelling

The WD shall be externally marked in accordance with the requirements of IEC 61010-2-045. In addition, there shall be indication of:

a) the year of manufacture;

b) the lowest and highest pressure of water and steam (total pressure);

c) the lowest and highest water temperature (for each type of water).

9.2 Packaging

The WD, unless intended for assembly on site by the WD manufacturer, shall be packed for delivery in durable, dust-proof packaging designed and constructed to protect the WD against vibration, mechanical shock and the ingress of dust and moisture during transport and storage to the extent necessary to ensure that its operational capability is not impaired.

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

In order to ensure that equipment supplied will meet the purchaser's requirements, it is recommended that the following information should be requested from the purchaser (regional or national regulations can also address these requirements):

a) any statutory or other regulations, in particular, local water regulations, to which the WD is required to conform, other than those stated in the foreword to this part of ISO 15883;

b) the name of each regulatory authority responsible for formulating the regulations referred to in item a);

c) the type of goods to be disinfected (see subsequent parts of ISO 15833 as relevant), the maximum acceptable processing temperature for thermolabile products, any particular requirements for water quality (e.g. freedom from bacterial endotoxins) and the class(es) of chemicals which can be used with the devices;

d) the maximum capacity per operating cycle for each load type that can be processed (see subsequent parts of ISO 15833 as relevant);

e) the required type and size (internal dimensions) of WD;

f) whether inspection of pressure vessels is to be carried out by the manufacturer only and not by the Inspecting Authority;

g) the required location of any emergency stop buttons or switches;

h) the type of recorder(s) to be fitted, if any;

i) the environmental temperatures to be expected for the working area and for the maintenance area;

j) the load supporting and handling equipment required;

k) details of the operating cycle(s) required that do not correspond to any of the operating cycles specified in subsequent parts of ISO 15883, as relevant;

l) the language for documentation (see Clause 7);

m) location, including any restriction in the overall size of the machine that can be installed or any restriction on access for maintenance;

n) electrical terminals required for dosing systems;

o) location of loading and unloading doors;

p) ductwork to be supplied;

q) services available;

r) the number of dosing systems required and the number of additional dosing systems for which provision should be made to allow for their later addition;

s) the quality of the water supplied;

t) the test method(s) and soil(s) to be used for operational qualification of cleaning efficacy;

u) whether software security provision is required.

Annex A
(informative)

Test programme

The interrelationship of test programmes is described in Figure A.1.

<table>
<tr><th colspan="2">Production of WDs</th></tr>
<tr><th colspan="2">Serial production</th><th>Individual production</th></tr>
<tr><td colspan="2">Type test / works test</td><td>Works test[a]</td></tr>
<tr><td rowspan="3">VALIDATION</td><td colspan="2">Installation qualification</td></tr>
<tr><td colspan="2">Operational qualification</td></tr>
<tr><td colspan="2">Performance qualification</td></tr>
<tr><td colspan="3">Routine tests / annual re-qualification.</td></tr>
<tr><td colspan="3">[a] The type tests are for machines in serial production with individual machines subjected to works tests prior to delivery. For machines which are not in serial production, the range of tests usually carried out as type tests should be undertaken as works tests on each machine prior to delivery.</td></tr>
</table>

Figure A.1 — Interrelationship of test programmes

Table A.1 summarizes the recommended test programmes applicable to most WDs. Subsequent parts of the standard specify which of these tests are not applicable to specific types of WD and also specify additional tests when necessary.

The calibration required during operational and routine testing of instruments installed on the WD may be limited to verification of calibration at the value(s) of interest for the particular instrument, e.g. the disinfection temperature.

Table A.1 — Summary of test programmes for WDs

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
1 Cleaning efficacy							
1.1 Chamber	4.2.1.1	6.10.2	X	B	X	B	B
1.2 Load carrier	5.1.10	6.10.2	X	B	X	B	B
1.3 Load	4.2.1.1	6.10.2	X	B	X	B	X(Q)
		6.10.3 (visual)	B	B	B	X	X(D)
		6.10.3 (Annex C)			O	X	O
2 Thermometric							
2.1 Thermal disinfection							
— Chamber walls	4.3.1.2, 4.3.1.3, 4.3.3.2 and 5.9.2	6.8.3	X	X	O	X	O
— Load carrier	4.3.1.1, 4.3.1.3	6.8.2	X	X	X	B	O
— Final rinse water tank	5.3.2.5	6.8.4	X	B	X	B	O
— Load	4.3.1.1, 4.3.1.3, 4.3.3.1, 5.9.1	6.8.2	X	X	X	X	X(Q)
2.2 Temperature control							
— Rate of rise	4.1.4	6.8.2	X	B	X	B	X(Q)
— Flushing stage	4.2.2	6.8.2	X	B	X	B	X(Q)
— Washing stage	4.2.3	6.8.2	X	B	X	B	X(Q)
2.3 Over-temperature cut-out	5.8.3	6.8.5	X	X	X	B	B
2.4 Chemical disinfection[a]							
— Chamber walls and load carrier	4.3.2	6.8.2	X	X	B	X	O
— Calorifier and tanks	4.3.3	6.8.3					
— Load	5.3.2.3	6.8.4	X	X	B	X	X(Q)
	4.3.2, 4.3.3	6.8.3	X	X	B	X	X(Q)
3 Load dryness	4.5.1, 4.5.2	6.12	X	X	O	X	O
4 Fluid emission							
— Chamber leak proof	5.1.7, 5.1.8	6.5.3	X	X	X	B	B

Table A.1 *(continued)*

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
5 Doors and interlocks							
5.1 Cycle start	5.4.1.8	6.3.1	X	X	X	B	X(Q)
5.2 Loading/unloading	5.4.3.1	6.3.4	X	X	X	B	X(Q)
	5.4.3.3	6.3.3	X	X	X	B	X(Q)
	5.4.1.4	6.3.4	X	X	X	B	X(Q)
		6.3.7					
5.3 On fault condition	5.4.1.5	6.3.5	X	B	X	B	O
	5.22	6.3.6	X	B	X	B	O
— Door interlock	5.4.3.2	6.3.7	X	B	X	B	O
6 Process residuals	4.4.1, 4.4.2	6.10.4	X	B	B	X	B
7 Chemical dosing							
7.1 Accuracy and repeatability	5.7.5	6.9.1	X	X	X	B	X(Q)
7.2 Low level indicator	5.7.6	6.9.2	X	X	X	B	X(Q)
8 Water quality	4.4.1	6.4.2	X	B	X[b]	B	O
8.1 Rinse water	4.4.2, 4.4.3	6.4.2	X	B	X	B	O
	4.2.1.2	6.4.3	X	B	B	B	B
8.2 Prior to OQ and PQ	8.2 b)	6.4.3	X	B	O	B	B
8.3 Volume per stage	8.2 b)	6.4.4					
9 Air quality	4.5.3, 4.5.4	6.11	X	X	X	B	O
10 Pipework							
10.1 Dead volume	5.5.1.3	6.5.1	X	B	O	B	B
10.2 Free draining	4.1.7	6.5.2	X	B	O	B	B
	5.1.10	6.5.2	X	B	O	B	B
	5.3.1.1 a)	6.5.4	X	B	O	B	B
	5.5.1.2	6.5.4	X	O	O	B	B
		6.5.5	X	B	X	B	B
10.3 Venting system	5.24.2	6.5.6	X	B	O	B	B
	5.8.4, 5.24.6	6.5.6	X	B	B	B	B
11 Instrumentation							
11.1 Legibility	5.12.3	6.6.2	X	B	B	B	B
11.2 Calibration	5.11	6.6.1	X	X	V	B	v(Q)
	5.14		X	X	V	B	v(Q)
	5.15						
12 Load carriers – internal							
12.1 Stability	5.27.1 a), b)	6.7.1	X	B	B	B	B
12.2 Alignment	5.27.4	6.7.1	X	B	B	B	B
	5.1.10	6.7.1	X	B	B	X	B
12.3 Fitting	5.27.5	6.7.1	X	B	B	B	B
12.4 Force to move	5.27.1 b)	6.7.1	X	B	B	B	B

Table A.1 *(continued)*

Brief description of test	Requirements subclause	Test subclause	Type test	Works test	Operational qualification	Performance qualification	Routine test
13 Trollets							
13.1 Alignment	5.28.2	6.7.2	X	B	B	B	B
14 Operating cycle							
14.1 Spray system	5.6	6.10	X	X	X	X	X
	5.6.4	verified by 1, 2.1 and 2.2 of Table A.1	X	B	B	B	B
14.2 Reproducibility	5.9.1 c)	6.8.2	X	X	X	O	O
	5.9.2 d)	6.8.3	X	X	X	O	O
14.3 Fault indication	5.22.1	6.3.5	X	X	X	B	O
	5.22.1	6.3.6	X	B	B	B	B
	5.4.1.5	6.3.8	X	B	B	B	B

X recommended

B not recommended

O optional test which can be requested by the purchaser or user

v verification of calibration at the value(s) of interest for the particular instrument e.g. the disinfection temperature

Q quarterly test interval, W weekly test interval, D daily test interval

The tests included in this table assume that all necessary installation qualification checks and tests (see 6.1.3.2) have been completed satisfactorily.

Optional tests may be carried out at discretion or may be required by local regulation.

Test intervals suggested are given for guidance only. Individual programmes of routine tests should be defined on the basis of a risk analysis, taking into account the conditions and reliability of the WD, the extent of independent monitoring of each cycle and the use to which the WD is put.

[a] Applied only to WDs employing chemical disinfection with controlled temperatures.

[b] No need to be repeated when reliable data are already available; the data may be provided by the user.

Annex B
(informative)

A_0 concept — Comparative lethality of moist heat processes

B.1 General

There are several, well-established, time–temperature relationships for moist heat disinfection which are regarded as equally acceptable. Clearly temperatures other than those chosen, when maintained for an appropriate time, will also be capable of producing a disinfected product.

For a moist heat disinfection process, a particular time at a particular temperature can be expected to have a predictable lethal effect against a standardized population of organisms. If particularly resistant organisms are chosen and it is assumed that they are present in numbers in excess of that likely to be encountered in real product, then it is possible to define standard exposure conditions which will always yield a disinfected product in a correctly operated WD. Actual exposures can then be related to these standard exposure conditions.

Levels of disinfection can be specified by regional or national authorities.

Definition of moist heat disinfection processes may be achieved by means of the A_0 method which uses a knowledge of the lethality of the particular process at different temperatures to assess the overall lethality of the cycle and express this as the equivalent exposure time at a specified temperature.

"A" is defined as the equivalent time in seconds at 80 °C to produce a given disinfection effect.

When the z value is 10 °C, the term A_0 is used.

The A_0 value of a moist heat disinfection process is the equivalent time in seconds at a temperature of 80 °C delivered by that process to the product with reference to microorganisms possessing a z value of 10 °C.

B.2 A value expressed mathematically

The A value expresses heat treatment in terms of the equivalent effect of a stated time at some stated temperature for a particular z value, i.e. the A value is the equivalent time in seconds at 80 °C for an organism of specified z value.

$$A_0 = \sum 10^{\left[(T-80)/z\right]} \times \Delta t \qquad \text{(B.1)}$$

where

A_0 is the A value when z is 10 °C;

t is the chosen time interval, in seconds;

T is the temperature in the load, in degrees Celsius.

In calculating A_0 values, a lower temperature limit for the integration is set at 65 °C since for temperatures below 65 °C, the z value and D value of thermophilic organisms may change dramatically and below 55 °C there are a number of organisms which will actively replicate.

B.3 “Disinfected”

In order to utilize the A_0 method, it is first necessary to decide on the extent of treatment which will be necessary to provide the required level of assurance that the product has been disinfected.

The definition given in this part of ISO 15883 recognizes that the extent of treatment will depend on the extent and type of contaminating microorganisms which are likely to be present and the intended subsequent use or treatment for the disinfected item.

The appropriate standard defines the minimum acceptable A_0 values for different types of WD but these may need to be modified by the user in the light of particular operational circumstances.

The use of A_0 of 60 is recognized as being the usually acceptable minimum for products which are intended to come into contact with intact skin and are unlikely to contain high numbers of heat-resistant pathogenic organisms. It is emphasized that this requires a low pre-disinfection bioburden and the absence of heat-resistant microorganisms capable of causing serious human disease.

An A_0 of 600 may be achieved by 10 min (600 s) at 80 °C, or by 1 min at 90 °C, or by 100 min at 70 °C and so on. The combination of time and temperature to be used to achieve the A_0 of 600 may be decided by the user in the light of operational requirements. A_0 values higher than 600 will be required for other applications and suitable minima for particular applications are specified in subsequent parts of ISO 15883.

The total A_0 value of a process takes account of the heating up and cooling down phases of the cycle and can be calculated by integration of lethal rates with respect to time at discrete intervals. For heat-sensitive products, it is desirable to minimize the heat treatment given to the product and reduce the energy input to a level which, while providing adequate assurance of disinfection, will minimize the degradation of the product.

There are a number of pre-requisites which should be considered before the use of the A_0 method is appropriate. These include:

a) the efficacy of the disinfection process under consideration is dependent only on temperature i.e. there is adequate assurance that all parts of the load are subjected to moist heat at a temperature at or above the control (reference) temperature;

b) the WD to be used has cycle control which is adequate to ensure that production cycles consistently reproduce the conditions established during validation (A_0 monitoring of a process cannot be used to justify the use of a WD which demonstrates excessive temperature variation within the load, poor reproducibility from cycle to cycle, etc.);

c) temperature profile studies have been conducted to establish the uniformity of conditions throughout the load and to identify the location of those parts of the load which are slowest to heat up and fastest to cool down;

d) the loading composition and pattern of production cycles are controlled within the limits established during validation to ensure that the results obtained remain valid;

e) the items to be disinfected are of a type and from a source where the nature and extent of the microbial contamination may reasonably be assumed to be within the limits previously assumed or determined in calculating the required cycle lethality.

Similar concepts are used in the F_0 for steam sterilization and also for dry heat sterilization processes and for depyrogenation by exposure to dry heat.

B.4 Control of microbial contamination in rinse water stored in the WD

It is a requirement of this part of ISO 15883 that rinse water stored within the WD is maintained at no less than 65 °C or disinfected in the process prior to use. Thermal disinfection may be achieved by the exposure of the rinse water to sufficient heat during the operating cycle. This may be checked by determining the A_0 value for

the heat treatment received by the rinse water. If the test recorder is not capable of calculating A_0, the following procedure may be used:

a) from the measured temperatures, identify the point during the heat-up time at which the water temperature first reaches 65 °C; note the temperature T (°C) at subsequent ten second intervals until the end of the holding time;

b) for each measurement, calculate the incremental ΔA_0 from the following equation:

$$\Delta A_0 = 10^{\left[(T-80)/10\right]} \times 10 \qquad \text{(B.2)}$$

where T is the lowest temperature of the water for each ten second time interval (Δt = 10 s), in degrees Celsius

c) the A_0 value is the sum of all ΔA_0.

The test should be considered satisfactory if the A_0 for the water is not less than the specified value given in the relevant part of ISO 15883 (e.g. 600 s for a surgical instrument WD).

B.5 Disinfection of load

The A_0 value delivered by a process may be estimated from the lowest temperature–time curve registered from the load. The process is satisfactory if the registered A_0 value is within the minimum and maximum limits established during validation.

B.6 Microbial challenge studies

Biological challenges may be used during process development in order to demonstrate the process lethality provided by the disinfection cycle.

Defined inoculated carriers used for this purpose act as bioburden models and can be used in obtaining data to calculate A_0 values delivered by the cycle or to supplement physical temperature measurement (e.g. from thermocouples).

NOTE A defined inoculated carrier is one that has a known population of a specific organism with known D value and z value.

The number of organisms to be used in the inoculated carrier can be calculated from the following formula:

$$D_{\text{prd}}\left(\log_{10} N_{\text{prd}} + 6\right) = D_{\text{bi}}\left(\log_{10} N_{\text{bi}} + 1\right) \qquad \text{(B.3)}$$

where

D_{prd} is the resistance (D value) of the most resistant organisms in the product bioburden;

N_{prd} is the number of organisms on the product to be disinfected;

D_{bi} is the resistance (D value) of the inoculated carrier organisms;

N_{bi} is the number of organisms on the inoculated carrier.

For disinfection, the temperature dependence of the process is described by the z value, i.e. the change in temperature required to give a tenfold change in the rate of microbial kill. Increasing or decreasing the temperature of the process requires a corresponding decrease or increase in exposure time to maintain the same cycle lethality or A_0 value.

Table B.1 — A_0 values for a range of time–temperature conditions

Holding time		Temperature	A_0 value
min	s	°C	
1	—	80	60
—	6	90	60
10	—	80	600
100	—	70	600
1	—	90	600
1	—	93	1 200

Annex C
(normative)

Test methods for the detection and assessment of residual proteinaceous contamination

C.1 Ninhydrin method for the detection of residual proteinaceous contamination

C.1.1 General

Much of the contamination which occurs on reusable medical devices is, in whole or part, proteinaceous in nature. The method described provides a pass/fail test with a high level of sensitivity for proteins and amino acids. For references see [19] and [34].

NOTE The sensitivity of the test is sufficient to detect glycine at a concentration of 2 mg/m^2.

C.1.2 Equipment and materials

— cotton swabs (plastic handles);

— 2 % ninhydrin in 70 % isopropanol;

— distilled water;

— oven (110 °C).

C.1.3 Procedure

Moisten the swab with sterile distilled water and use it to swab the surface of the instrument(s) to be tested. Ensure that the area to be swabbed is not less than 5 cm^2 and not more than 50 cm^2.

After swabbing the instrument, examine the swab. Any discolouration indicates that the instrument was not clean and there is no need to proceed further.

Place a drop (approximately 0,05 ml) of the ninhydrin reagent on the swab and allow to air dry for approximately 5 min. If a purple coloration develops, residual protein/amino acids have been detected and no further action is needed.

If no colour has developed, transfer the swab to the oven and heat at 100 °C to 110 °C for 30 min and re-examine the swab for purple colouration.

Run a positive and negative control for each series of tests carried out.

C.1.4 Acceptance criteria

When tested in accordance with C.1.3:

— there shall be no discoloration of the swab prior to the application of the ninhydrin reagent;

— there shall be no visible purple discoloration of the swab after application of the ninhydrin reagent.

C.1.5 Safety aspects

The information provided by the manufacturer of chemicals, for example in the safety data sheet, shall be applied and the appropriate personal protective equipment worn.

C.2 OPA method for the assessment of residual proteinaceous contamination

C.2.1 General

The modified ortho-phthalic dialdehyde (OPA) method is a quantitative method for the determination of the free primary amino groups of the proteins. OPA, in the presence of *N*,*N*-dimethyl-2-mercapto-ethyl-ammonium chloride with an α- and ε-amino group, forms a stable fluorescent alkylthio-2-alkylisoindol which is detected spectrophotometrically at 340 nm. For references see [20] and [21].

C.2.2 Equipment and materials

The equipment and material shall consist of the following:

— spectrophotometer UV/VIS;

— 1 ml quartz cuvettes;

— caps for cuvettes

— sodium dodecylsulphate (SDS);

— *o*-phthalic dialdehyde;

— *N,N*-dimethyl-2-mercapto-ethylammonium-chloride;

— 0,1 M disodium tetraborate buffer;

— methanol;

— polyethylene bag, polyethylene, polypropylene or glass tube;

— beaker;

— syringe;

— silicone tubing.

C.2.3 Procedure

For sampling, wash the instrument surface to be tested with a small volume (5 ml) of 1 % SDS over a period of 30 min. For testing the whole (outer) surface, place the instrument in a polyethylene bag and after addition of 5 ml SDS, seal and vigorously pass it from one hand to the other several times to ensure that the SDS solution was able to access all surfaces.

For testing inner surfaces such as channels of minimal invasive surgical instruments, clamp the instruments to a stand with the distal end standing on the base of a beaker. Connect a disposable syringe to the other end of the instruments channel using pieces of silicone tubing. After placing 5 ml 1 % SDS in each beaker, flush each lumen several times by drawing up and emptying the syringe.

For the preparation of the OPA reagent solution, dissolve 40 mg *o*-phthalic dialdehyde in 1 ml methanol, then add 50 ml 0,1 M disodium tetraborate buffer (pH 9,3), 100 mg *N,N*-dimethyl-2-mercaptoethylammonium chloride and 1,25 ml of an aqueous 20 % (mass fraction) SDS solution.

With a single beam spectrophotometer, perform a zero adjustment with 1 ml OPA reagent solution in the quartz cuvette before each measurement. If a double beam spectrophotometer is used, place a cuvette with OPA reagent solution in the second beam as a zero reference through the test.

For protein determination add 100 µl of the 1 % SDS eluate to 1 ml freshly prepared OPA reagent solution in the cuvette. Close the cuvette using a cap and mix the solutions thoroughly by shaking.

Determine the extinction after 3 min.

Any turbidity in the SDS eluate or a fingerprint on the cap of the cuvette will falsify the result. Plastic materials should be tested to establish that they do not release plasticizers that influence the OPA reaction.

An extinction value of $< 0{,}020$ is indicative of a low level of proteinaceous residual contamination.

Run a positive and negative control for each series of tests carried out.

The residual contamination can be expressed in µmol OPA sensitive amino groups per ml or 5 ml of the 1 % SDS used for sampling. For calculating this value, 6,42 l/mmol/cm may be used as the absorption coefficient, i.e. 0,1 µmol OPA sensitive amino groups give an extinction of 0,642.

In calculating the residual contamination present, the dilution factor should be considered.

C.2.4 Acceptance criteria

When tested in accordance with C.2.3, the extinction value shall be $< 0{,}020$.

C.2.5 Safety aspects

The information provided by the manufacturer of chemicals, for example in the Safety Data Sheet, shall be applied and the appropriate personal protective equipment worn.

C.3 Semi-quantitative protein test method using the biuret method

C.3.1 General

The biuret as bicinchoninic acid (BCA) method is suitable for the determination of proteins containing two or more peptide bonds (CO-NH). In an alkaline solution with specific pH, the nitrogen atoms (N) of the peptide chain complex with the copper ions reducing Cu^{2+} to Cu^{1+}. Cu^{1+} then forms an intense purple colour with BCA. The intensity of the colour depends on the amount of protein present. If no protein is present, the BCA reagent turns from blue to an apple green which is a complex of BCA and Cu^{2+}. For references see [22] and [23].

The biuret method can be used as a semi-quantitative method for the determination of protein residues on medical devices which have been processed in a washer-disinfector.

NOTE Test kits using this biuret/BCA method or the modified reverse reaction which gives equal results are commercially available.

C.3.2 Equipment and materials

The equipment and material shall consist of the following:

— chemicals: bicinchoninic acid, sodium carbonate, sodium tartrate, sodium hydroxide, sodium hydrogen carbonate, copper sulfate pentahydrate, sodium dodecyl sulfate (SDS);

— solution A consisting of an aqueous solution of 1 % BCA-Na_2, 2 % sodium carbonate monohydrate, 0,16 % sodium tartrate, 0,4 % sodium hydroxide and 0,95 % sodium hydrogen carbonate[1)] ;

— solution B consisting of 4 % copper sulfate pentahydrate in deionized water;

— test tubes;

— test tube rack;

— protein-free protective gloves;

— protein-free swabs and/or protein-free plastic bag;

— graduated pipettes of 1 ml and 10 ml;

— protective gloves to avoid contamination from the assistant's hand.

C.3.3 Sampling

C.3.3.1 Sampling using the swab method

C.3.3.1.1 General

The swab method is used to determine the presence of protein on a pre-determined sampling surface area but also on pre-determined small surfaces, such as the joint of an instrument.

C.3.3.1.2 Procedure

Swab a defined surface area of the instrument to be tested. Take care that the swab does not react with any of the reagents, nor inhibit the reaction by using a supposed protein-free swab and a bovine serum albumin contaminated swab for analytical test procedure.

The size of the surface should be about 10 cm^2. If necessary, other suitable sizes can be chosen.

If the surface is dry, moisten the swab with a drop of isopropanol or 1 % SDS solution before use. Then swab the surface twice in both directions, and transfer the swab to a test tube.

C.3.3.2 Sampling using the rinse method

C.3.3.2.1 General

The rinse method is used to determine the presence of protein residues on an entire object, e.g. a surgical instrument. It cannot pin-point the position of possible protein residues but allows better access to the lumens of small instruments and to instrument joints.

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1) Suitable chemicals are available commercially from Merck and Aldrich. This information is given for the convenience of users of this part of ISO 15883 and does not constitute an endorsement by ISO of these product(s). Equivalent products may be used if they can be shown to lead to the same results.

C.3.3.2.2 Procedure

Put the object into a protein-free polyethylene bag containing 5 ml or 10 ml of 1 % SDS solution depending upon the size of the instrument to obtain enough eluate for the test procedure.

Carry out elutriation by tilting the polyethylene bag back and forth for 10 min to 30 min. Then, pipette 1 ml of the solution into a test tube.

C.3.4 Test procedure

Add 1ml alkaline of solution A and 2 drops of solution B to the test tube (see C.3.3.1.2 or C.3.3.2.2). Adjust the pH to 11,25, if deviating, by use of solid sodium hydrogen carbonate. Shake the test tube gently. After incubation for 30 min at 37 °C, note any change in colour at defined intervals.

NOTE 1 Test results are unreliable if readings are not taken at defined intervals.

An intense purple coloration indicates a significant protein residue, an apple green colour indicates a protein-free sample. The colour change from green over grey to purple is in the range of 30 µg to 50 µg equivalent bovine serum albumin per ml 1 % SDS solution.

It is recommended to use appropriate concentrations of bovine serum albumine in 1 % SDS solution or distilled water as colour reference samples. 10 mg bovine albumin (fraction V) are dissolved in 100 ml 1 % SDS to give a concentration of 100 µg/ml and an intense purple colour. Other concentrations may be prepared by dilution.

NOTE 2 Residues containing denatured protein will not necessarily be detected because they might not be dissolved totally by the solution.

NOTE 3 The test cannot be used on a coloured solution, e.g. a solution stained with blood or haemoglobin. But in this case contamination is visible.

NOTE 4 The sensitivity of the biuret/BCA test method is altered by the presence of saccharose contained in mucus.

C.3.5 Acceptance criteria

When tested in accordance with C.3.4, the colour shall remain apple green.

C.3.6 Safety aspects

C.3.6.1 Safe handling of chemicals

The information provided by the manufacturer of chemicals, for example in the Safety Data Sheet, shall be applied and the appropriate personal protective equipment worn.

C.3.6.2 Disposal

All chemicals can be disposed of as non-risk waste.

C.3.6.3 Surroundings

Any spills onto the surroundings, e.g. on the table, can be wiped up with a disposable cloth.

C.3.6.4 Tested instruments or objects

The tested instruments or objects can be processed again in a washer-disinfector.

Larger stationary surfaces can be cleaned and disinfected with a cloth by hand.

Annex D
(normative)

Microbiological recovery medium for estimation of bacterial contamination of water

D.1 Constituents

The microbiological recovery medium for the estimation of bacterial contamination of water (R_2A medium) shall consist of:

- Yeast extract 0,50 g
- Proteose peptone 0,50 g
- Casein hydrolysate 0,50 g
- Glucose 0,50 g
- Starch 0,50 g
- Na-pyruvate 0,30 g
- K_2HPO_4 0,30 g
- $MgSO_4$ 0,024 g
- Agar 15,00 g
- Purified water 1 000,00 ml

D.2 Preparation

Adjust the pH so that after sterilization it is pH 7,2 with crystalline K_2HPO_4 or KH_2PO_4 before adding agar. Add agar, heat medium to boiling to dissolve agar, and autoclave for 15 min at 121 °C.

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