BS EN 285:2015

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Sterilization — Steam sterilizers — Large sterilizers

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National foreword

This British Standard is the UK implementation of EN 285:2015. It supersedes BS EN 285:2006+A2:2009 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/198, Sterilization and Associated Equipment and Processes.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 15 November 2015.

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Contents

Page

European foreword

This document (EN 285:2015) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document supersedes EN 285:2006+A2:2009.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2016, and conflicting national standards shall be withdrawn at the latest by December 2018.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN 285:2006+A2:2009:

— introduction has been implemented;

— scope was modified to differentiate small and large sterilizer by chamber size and to exclude equipment intended to use, contain or be exposed to flammable substances or substances which could cause combustion, and equipment intended to process pathogenic substances or human tissues;

— normative references and bibliography have been updated;

— terms and definitions improved, deleted or new definitions such as, “cycle parameter”, “fault”, “maintenance”, “measuring chain” “operating cycle stage”, “pressure”, “risk assessment”, “risk control”, “services”, “sterilization process”, “software validation” and “verification” added;

— new subclauses 4.3.1.3 *Protection at moving door*, 4.5 *Loading equipment*, 4.6 *Transport* and 7.3 *Software verification and validation* added;

— Clause 6 on measuring system, indicating and recording devices completely redrafted;

— requirements on sound power and vibration completely redrafted;

— requirements on safety, risk control and usability (Clause 11) completely redrafted including normative Annex F and reference to EN ISO 14971;

— requirements on packaging and marking (Clause 12) revised and extended;

— requirements on service and working environment (Clause 13) extended, e.g. 13.4 *Lighting* added, 13.7 *Electromagnetic interference* improved;

— clause on sound power test deleted;

— requirements on test measurement equipment redrafted;

— clauses on documentation and information revised and extended;

— Annex A on environmental aspects redrafted;

— Annex C on recommended material deleted;

— normative Annex F on protective measures added;

— Annex ZA relationship with the essential requirements of the Directive 93/42/ECC on Medical Devices including Tables ZA.1 and ZA.2 completely revised

— editorial revision of whole document.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This European Standard specifies test procedures and acceptance criteria to confirm whether the sterilizer is safe and can deliver an operating cycle for sterilizing the range of medical devices and loading configurations used in healthcare. It can also be used in other manufacturing sectors and industries. In addition, national regulations can necessitate consideration of the impact the sterilizer could have on the environment.

A steam sterilization process uses water in its liquid and vaporous state to penetrate as steam into the load and to condense on the surfaces of a device. The distribution of moisture and temperature throughout the sterilization load and the process of sterilization itself cannot be measured directly for each routine sterilization process. This is done by comparison of measurement results with cycle parameters shown previously by validation to deliver an efficient sterilization process to the exposed medical devices.

An instruction manual supplied with the sterilizer is required to have comprehensive information on the sterilizer, programmed operating cycles and safe operation. Requirements for the validation and routine control of sterilization are not addressed as they are specified EN ISO 17665-1.

Medical devices used in health care can differ in properties such as materials, mass, shape, volume and packaging. Each sterilizer load can comprise a variable number of packages each containing different types of variably distributed medical devices.

The reproducibility of the sterilization process can be affected by this variability and also by other changes which can include:

— deviation of the defined cycle parameters,

— retention of air in the load, air leakage and non-condensable gases in the steam,

— excessive accumulation of non-condensable gases and/or condensate,

— overheating of the steam,

— selection of an inappropriate operating cycle, and

— orientation of the load.

The state “sterile” is specified in EN 556-1. For the steam sterilization in health care national regulations and the European Pharmacopoeia require or recommend combinations of minimum process parameters to produce a substantial overkill. This European Standard identifies combinations of sterilization temperatures and holding times, with tolerances, recommended by the “Working Party on Pressure-steam Sterilisers”[1)]. The use of these values is justified when also considering the variable characteristics of sterilizer loads in healthcare.

Process variables and process parameters as defined in EN ISO 17665-1 characterize the microbicidal effectiveness of the sterilization process. Cycle parameters are associated with the control of the operating cycle and have implications on the attainment of process parameters, the uniformity of steam penetration, the removal of air, drying and deterioration of medical devices and their packaging.

1) Working Party on Pressure-steam Sterilisers (JW Howie, Allison VD, JH Bowie, Darmady EM, Knox R, EJK Penikett, Shone JAV, Sykes G, Weir CD, Wells CA, Wyllie CAP, Kelsey JC): Sterilization by Steam Under Increased Pressure, The Lancet (1959), p. 425-435.

This European Standard specifies test loads and test pieces designed to present a specific challenge to the operating cycle. The results from each test collectively contribute to a presumption that the sterilizer and the operating cycles are suitable for use in health care facilities. A test load does not necessarily mimic a configuration of medical devices. The suitability of an operating cycle for a particular product will require validation (see EN ISO 17665-1). By specifying numeric pass and fail-conditions the tests are used to confirm that the cycle parameters of the operating cycle are attained and maintained.

Limiting values for the properties and the purity of the services are related to the characteristics of the medical devices, therefore this European Standard does not include specific requirements on services. However, it does provide guidance and information on recommended properties, limit values and test methods.

Condensate derived from the sterilizer chamber will include additional impurities from the load and as a consequence is not representative of the quality of the supplied steam. Recommended limits for the purity of feed water and condensate are different from the requirements of the European Pharmacopeia for purified water. This difference is to compensate for increased corrosion to the sterilizer chamber and instruments resulting from a higher condensate temperature. The level of bacterial endotoxins contained in the steam will depend on the quality of feed water and the steam generation equipment[2)].

To minimize human errors during routine use this European Standard specifies automatic control of the operating cycle and a fault detection system designed to automatically detect changes to both services and operating cycle significant to affect sterility assurance. An air detector is an optional provision which when set and tested according to this European Standard will routinely challenge the operating cycle and register a pass/failure. Other methods for routinely assessing specific performance aspects can be used, such as chemical or biological indicators, providing their performance is determined and verified using validated test procedures.

Software can only be used in combination with hardware. The tests described in this standard can be used for the verification and final validation of the repeatability, reliability and performance of the control system. The requirements of this European Standard are intended to prevent products being considered “sterile” whenever a single fault condition occurs in the control and measuring system. In addition, this European standard specifies the provision of an electronic or permanent record of the operating cycle.

This European Standard refers to sections in the all risks safety standard EN 61010-1 and specific safety standard for sterilizers EN 61010-2-040 and offers as alternatives EN ISO 12100 and other harmonized safety standards listed in the Official Journal of the European Union under the Medical Devices Directive or Machinery Directive. Information on the relationship of this European Standard and the Essential Requirements of the Directives on medical devices and machinery is provided in the Tables ZA.1 and ZA.2.

The European Directive on pressure equipment applies to sterilizers and this is addressed by reference to harmonized standards on pressure equipment. Outside the EU other pressure equipment specifications can apply.

This European Standard contains no specific requirements for the sterilization of liquids or test methods to assess the heat transfer into a liquid. The sterilization of a liquid or the sterilization of contained product requires specific means for monitoring the temperature profile in the liquid or by reference to a challenge device.

2) A. Steeves*, R.M. Steeves: Endotoxin and Reprocessing of Medical Devices, ZentrSteril 2006 (5), 364-368 and D. Goullet, V. Flocard & J. Freney: Evaluation of the endotoxin risk posed by use of contaminated water during sterilisation of surgical instruments, WFHSS Conference 2007.

The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

1 Scope

This European Standard specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories contained in one or more sterilization modules. The test loads described in this European Standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizers for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads.

This European Standard applies to steam sterilizers designed to accommodate at least one sterilization module or having a chamber volume of at least 60 l.

Large steam sterilizers can also be used during the commercial production of medical devices.

This European Standard does not specify requirements for large steam sterilizers intended to use, contain or be exposed to flammable substances or substances which could cause combustion. This European Standard does not specify requirements for equipment intended to process biological waste or human tissues.

This European Standard does not describe a quality management system for the control of all stages of the manufacture of the sterilizer.

NOTE 1 Attention is drawn to the standards for quality management systems e.g. EN ISO 13485.

NOTE 2 Environmental aspects are addressed in Annex A.

2 Normative references

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

EN 764-7:2002, *Pressure equipment - Part 7: Safety systems for unfired pressure equipment*

EN 867-5:2001, *Non-biological systems for use in sterilizers - Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

EN 13445-1:2014, *Unfired pressure vessels - Part 1: General*

EN 13445-2:2014, *Unfired pressure vessels - Part 2: Materials*

EN 13445-3:2014[3)], *Unfired pressure vessels - Part 3: Design*

EN 13445-4:2014, *Unfired pressure vessels - Part 4: Fabrication*

EN 13445-5:2014, *Unfired pressure vessels - Part 5: Inspection and testing*

EN 13445-8:2014, *Unfired pressure vessels - Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys*

EN 14222:2003, *Stainless steel shell boilers*

3) This document is impacted by the stand-alone amendment EN 13445-3:2014/A1:2015.

EN 22768-1:1993, *General tolerances - Part 1: Tolerances for linear and angular dimensions without individual tolerance indications (ISO 2768-1:1989)*

EN 60204-1:2006, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements (IEC 60204-1:2005, modified)*

EN 60584-1:2013, *Thermocouples - Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN 60770-1:2011, *Transmitters for use in industrial-process control systems - Part 1: Methods for performance evaluation (IEC 60770-1:2011)*

EN 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)*

EN 61010-2-040:2005, *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005)*

EN 61326-1:2013, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC 61326-1:2012)*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads - Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*

EN ISO 3746:2010, *Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 11140-3:2009, *Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007)*

EN ISO 12100:2010, *Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)*

EN ISO 13408-2:2011, *Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)*

3 Terms and definitions

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

NOTE Other definitions relevant to moist heat sterilization are given in EN ISO 17665-1:2006, Clause 3.

3.1
absolute pressure
pressure for which the zero value is associated with absolute vacuum

[SOURCE: EN 764-1:2004, 3.4]

3.2
access device
means used to permit access to restricted parts of the equipment

Note 1 to entry: This can be by dedicated key, code or tool.

3.3
air removal
removal of air from the sterilizer chamber and sterilizer load to facilitate sterilant penetration

3.4
automatic controller
programmed device that, in response to cycle parameters, operates the sterilizer sequentially through the operating cycle(s)

3.5
chamber
that part of equipment in which a load is processed

3.6
chamber volume
internal volume of a sterilizer chamber, including the volume of nozzles to the first connection or weld and excluding the volume of permanent internal parts

[SOURCE: 2014/68/EU, Art. 2, definition 10, modified: “chamber” added to term; symbol (V) removed from term; “sterilizer” added to definition]

3.7
cycle complete
indication that an operating cycle has been completed

3.8
cycle parameter
physical value used for control, indication and recording of the operating cycle

3.9
double ended
with separate doors for loading and unloading

3.10
equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load

[SOURCE: EN ISO 17665-1:2006, 3.13, modified — replaced “reference measuring point” by “reference measurement point” and left out “sterilization” before load]

3.11
fault
<operating cycle> one of the cycle parameters lying outside of its specified tolerance range

[SOURCE: ISO/TS 11139:2006, 2.19, modified — “<operating cycle>” has been added, “or more” has been deleted, process has been replaced by “cycle” and “its/their specified tolerance(s)” has been replaced by “its specified tolerance range”]

3.12
holding time
period for which the temperatures at the reference measurement point and at all points within the load are continuously within the sterilization temperature band

3.13
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[SOURCE: ISO/TS 11139:2006, 2.22]

3.14
maintenance
combination of all technical and associated administrative actions intended to retain an item at/or restore it to a state in which it can perform its specified function

[SOURCE: EN ISO 17665-1:2006, 3.22, modified — "required" replaced by "specified"]

3.15
measuring chain
series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quality subject to measurement) to the output (the result of the measurement)

[SOURCE: EN ISO 17665-1:2006, 3.24]

3.16
medical device
instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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

[SOURCE: EN ISO 13485:2012, 3.7]

3.17
non-condensable gas
air and/or other gas which will not liquefy under the conditions of saturated steam sterilization processes

[SOURCE: EN ISO 17665-1:2006, 3.27 modified: “sterilization” included]

3.18
operating cycle
specified sequence of operations, designed to accomplish a specified process

3.19
operating cycle stage
part of the operating cycle with a specified function related to the process

EXAMPLE Air removal stage, plateau period, drying stage and final air admission stage.

3.20
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

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

3.21
plateau period
equilibration time plus the holding time

3.22
pressure
pressure relative to atmospheric pressure

Note 1 to entry: I.e. gauge pressure; as a consequence, vacuum is designated by a negative value.

[SOURCE: 2014/68/EU, Art. 2, definition 7, modified: “means” removed and Note 1 to entry included]

3.23
pressure vessel
housing and its direct attachments up to the coupling point connecting it to other equipment, designed and built to contain fluids under pressure

Note 1 to entry: A vessel can be composed of more than one chamber.

[SOURCE: EN 13445-1:2014, 3.2]

3.24
reference measurement point
point where the temperature probe used for the operating cycle control is located

3.25
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, 2.18]

3.26
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19 modified — "protective" has been added.]

3.27
saturated steam
water vapour in a state of equilibrium between its liquid phase and its gas phase

[SOURCE: EN ISO 17665-1:2006, 3.44, modified — "condensation and evaporation" replaced by "its liquid phase and its gas phase"]

3.28
services
supplies from an external source, needed for the function of equipment

EXAMPLE Electricity, steam, water, compressed air, drainage.

[SOURCE: ISO/TS 11139:2006, 2.41]

3.29
sterile
condition of a medical device that is free from viable microorganisms

[SOURCE: EN 556-1:2001, 3.4]

3.30
sterilization
validated process used to render a product free from viable microorganisms

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is described by an exponential function. Therefore the presence of a viable microorganism on any individual item can be expressed in terms of probability. This probability can be reduced to a very low number, it can never be reduced to zero.

Note 2 to entry: For "free from viable microorganisms" see EN 556–1.

[SOURCE: ISO/TS 11139:2006, 2.47 modified: Note 2 to entry has been added]

3.31
sterilization module
rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

3.32
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

Note 1 to entry: This series of actions includes pre-treatment of product (if necessary), exposure to the sterilizing agent under defined conditions and any necessary post treatment. The sterilization process does not include any cleaning, disinfection or packaging operations that precede sterilization.

[SOURCE: ISO/TS 11139:2006, 2.49]

3.33
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

3.34
sterilization temperature band
temperature range the minimum of which is the sterilization temperature

3.35
sterilizer
apparatus designed to deliver an operating cycle for the purpose of sterilization

3.36
sterilizer door
lid or similar device provided as a means of closing and sealing the sterilizer chamber

3.37
type test
series of checks and tests for a particular design of sterilizer

3.38
usable space
space within the sterilizer chamber which is not restricted by fixed parts and which is available to accept the load

3.39
software validation
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: EN ISO 9000:2015, 3.8.13, modified — “software” has been added and without notes to entry]

3.40
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

[SOURCE: EN ISO 9000:2015, 3.8.12; modified — without notes to entry]

3.41
works test
series of tests performed during or after manufacture to demonstrate compliance of each equipment with the requirements of the test specified

4 Mechanical components

4.1 Dimensions

The sterilizer chamber volume shall be at least 60 l or the usable space within the sterilizer chamber shall accommodate one or more sterilization modules.

The usable space shall be defined.

4.2 Materials

Materials in contact with steam shall:

— resist attack from steam and condensate;

— not cause deterioration of the quality of the steam;

— not release any substances known to be toxic in such quantities that could create a health or environmental hazard.

NOTE 1 Guidance on steam contaminants is given in Table 4.

NOTE 2 Because of the different types of sterilizers and the large number of uses, it is not possible to specify detailed requirements for materials for specific applications.

4.3 Pressure vessel

4.3.1 General

4.3.1.1 The pressure vessel shall comply with EN 13445-1:2014, EN 13445-2:2014, EN 13445-3:2014, EN 13445-4:2014, EN 13445-5:2014 and EN 13445-8:2014 or equivalent specifications.

4.3.1.2 The sterilizer door seal shall be a replaceable component.

It shall be possible to inspect and clean the surface of the sterilizer door seal which comes into contact with the sealing faces without the need to dismantle the sterilizer door assembly.

NOTE Personnel protective equipment can be needed if the adjacent surface is hot.

4.3.1.3 Systems shall be provided to permit the removal of persons or objects trapped by the moving sterilizer door before the force and temperature specified in EN 61010-1:2010, 7.3.4 and 10.1 are exceeded.

For the protection against entrapping of a person inside the sterilizer chamber EN 61010-2-040:2005, 7.102 applies.

NOTE This can be achieved, e.g. by reversing the direction of the sterilizer door movement.

4.3.1.4 After closing the sterilizer door, it shall be possible to open it before an operating cycle has been started.

4.3.1.5 It shall not be possible to open a sterilizer door(s) during a cycle.

4.3.2 Double ended sterilizers

4.3.2.1 Except for maintenance purposes it shall not be possible for more than one sterilizer door to be open at the same time.

4.3.2.2 It shall not be possible to open the unloading door in routine use until “cycle complete” is indicated.

4.3.2.3 Except by the use of a key, code or tool it shall not be possible to open the unloading door if a Bowie and Dick cycle or an air leakage test has been carried out (see 7.1.13 and 7.1.14).

4.3.2.4 The control used to start the operating cycle shall be located at the loading side of the sterilizer.

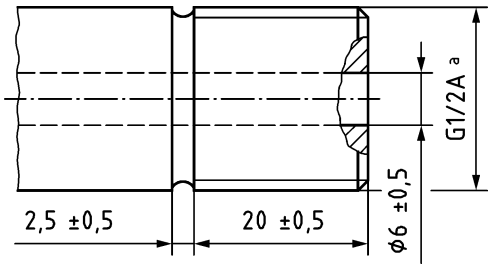
4.3.3 Test connections

4.3.3.1 The connections as required by 4.3.3.2 and 4.3.3.3 shall be provided.

The test connection for pressure test and temperature test as shown in Figure 1 and Figure 2 may be either attached to the sterilizer chamber or as a combined detachable adapter.

4.3.3.2 A test connection in accordance with Figure 1 shall provide direct connection with the sterilizer chamber providing it causes no adverse effect on the measurement of the pressure in the sterilizer chamber. The test connection which is used for the connection of a test instrument shall be provided with a cap, marked PT (pressure test) and sealed with either an O-ring-seal or a flat seal.

Dimensions in millimetres



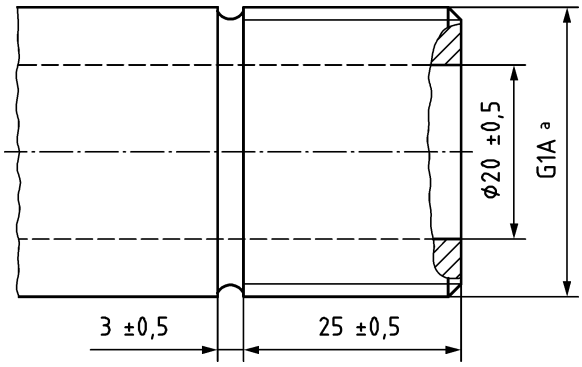
Key

a pipe thread ISO 228-G 1/2 A

Figure 1 — Connection for test

4.3.3.3 A straight connecting sleeve, in accordance with Figure 2, shall be provided in order to pass flexible cords to the temperature probes.

Dimensions in millimetres



Key

a pipe thread ISO 228-G 1 A

Figure 2 — Connection sleeve for thermo elements

The connecting sleeve with its O-ring-seal or flat seal shall be closed with a cap, and a temperature proof and mechanically resistant soft packing. The cap shall be marked with the letters TT (temperature test).

4.3.3.4 Test tee(s) and valve cock(s) with sealing plug(s) shall be fitted to permit connection of reference instruments for the calibration of all pressure instruments connected to the sterilizer chamber and jacket.

4.3.4 Insulation

Except where insulation would interfere with the function and operation of the sterilizer, external surfaces of the pressure vessel shall be insulated [see 11.1 f)].

4.4 Framework and panelling

4.4.1 Where sides of the sterilizer are visible to the person operating equipment for its intended purpose when the sterilizer door(s) is/are closed, they shall be enclosed with panelling.

The panelling shall be corrosion-resistant to recommended cleaning and disinfection agents and specified working environment conditions [see 25.2 t) and 25.3 c)].

Removal or opening of panel used as a physical barrier to provide protection (guard) shall require the use of an access device.

4.4.2 Access for operation, adjustment and maintenance of the sterilizer shall take into account integrity of sterilized product, human body dimensions, position, mass and dimensions of components.

NOTE 1 Guidance is provided in EN ISO 12100:2010, 6.2.2.1 and 6.2.7, EN 547–1, –2, –3 concerning dimensions, EN ISO 14738:2008, Figure B.2 for anthropometric requirements. See also EN 61010–1:2010, Tables 13 and 14.

Parts of the sterilizer accessible with closed panelling and closed door(s) should be free from sharp edges, sharp angles and rough surfaces.

NOTE 2 Information on prevention of sharp edges, sharp angles and rough surfaces is given in EN ISO 12100:2010, 6.2.2.1 and 6.3.3.2.6.

Fixings for these panels shall remain attached to either the panels or to the body of the sterilizer when panels are removed.

If the pressure equipment is housed in a frame, this frame shall not promote corrosion of the equipment.

4.4.3 The sterilizer shall be designed to operate when installed on a surface which is horizontal within the tolerance limits specified in Tables 1 and 2 and which will support the maximum floor loading [see 25.2 a)].

The floor should be impervious to water and collect or drain water spillage from the sterilizer.

4.4.4 Sterilizers sealed into an aperture shall have a continuous joint when the contact surfaces comply with Table 1 and Table 2.

Table 1 —Tolerances for the aperture into which the sterilizer is installed

Aperture dimension m	**Tolerance** mm	
	Horizontal plane	Vertical plane
up to 3	±12	±16
above 3 to 6	±16	±16
above 6 to 15	±24	±20
above 15 to 30	±24	±20
above 30	±30	±30

Table 2 — Deviation from vertical and horizontal flatness and alignment

Distance between any two measuring points m	**Deviation** mm	
	Finished surfaces of walls and ceilings	Finished floor (bearing surface)
0,1	3	2
1	5	4
4	10	10
10	20	12
15	25	15

4.5 Loading equipment

If required for ergonomic reasons, loading equipment shall be available as a separate accessory to the sterilizer.

NOTE Loading equipment is not specified in this standard.

4.6 Transport

Where the weight, size or shape of the sterilizer or its various component parts prevents them from being moved by hand, the sterilizer, or each component part shall either be fitted with attachments for lifting gear, or be designed so that it can be fitted with such attachments, or be shaped in such a way that standard lifting gear can easily be attached see 12.5.

The sterilizer and its components (if applicable) shall be packed for transportation and storage in a way that, when handled or transported, all parts of the sterilizer shall remain in their position and orientation so that the sterilizer remains stable.

5 Piping system and components

5.1 Pipework and fittings

5.1.1 Materials in contact with steam shall comply with 4.2.

5.1.2 Pipe joints and fittings shall be visibly pressure tight and, if applicable, vacuum tight according to 8.2.3.

5.1.3 Except where this will interfere with the function of the sterilizer the pipework for steam or water at a temperature greater than 60 °C shall be thermally insulated to reduce heat transmission to the environment [see also 25.2 g) and h)].

To reduce the formation of condensation cold water pipework should be insulated.

5.1.4 Means shall be provided to prevent the ingress of particulates of a size and quantity which could affect the performance of a sterilizer.

Strainers of a relevant pore size may be used.

5.2 Steam source

5.2.1 Steam supply from a dedicated steam generator

5.2.1.1 Stainless steel shell boilers shall comply with EN 14222:2003 or equivalent specifications.

NOTE 1 Parts of EN 12953 series can apply.

NOTE 2 For contaminants of steam entering the sterilizer chamber see 13.3.4.

5.2.1.2 The feed water inlet shall be designed to prevent backflow into the feed water supply system.

5.2.1.3 The power requirements and the capacity of the steam generator shall be sufficient to ensure that the steam demand specified for the sterilizer can be met.

5.2.2 Steam supply from a central source

The quality and quantity of the steam to be supplied for use with the sterilizer shall be specified [see 25.2 c)].

NOTE For contaminants of steam entering the sterilizer chamber see 13.3.4.

5.3 Air filter

5.3.1 Where the operating cycle requires the admission of air into the sterilizer chamber after the plateau period, the air shall be admitted through a filter.

Air filters should be constructed from material resistant to corrosion and biodegradation. The filter material should be supported in a manner which prevents damage to the filter medium.

5.3.2 The filter shall comply with EN ISO 13408-2:2011, Clause 5 and in addition the nominal penetrating particle size shall be 0,3 µm or smaller.

5.3.3 The filter unit shall be accessible, replaceable and mounted externally to the sterilizer chamber in such a manner that the filter material is kept dry.

5.3.4 Except where the filter is designed to be sterilized in place means shall be provided to prevent the penetration of steam, water and/or condensate from the sterilizer chamber into the filter.

5.4 Vacuum system

A vacuum system shall be a component of the sterilizer and used for air removal and drying.

NOTE The vacuum system can be installed behind the panelling or at an external location.

6 Measuring system, indicating and recording devices for temperature, pressure, time and status indicators

6.1 General

6.1.1 All instruments and indicating devices specified in Clause 6 shall be located in a position where they can be readily viewed by the sterilizer operator under normal operation of the sterilizer and their function shall be identified.

6.1.2 Unless otherwise specified instruments and status indicating devices shall be readable by normal or corrected vision from a distance of (1,00 ± 0,15) m and with a minimum external illumination of (215 ± 15) lx.

6.2 Measuring system

Sterilizers shall be provided at least with the following measuring system for:

a) temperature in the sterilizer chamber for indication;

b) temperature in the sterilizer chamber for control;

c) temperature in the sterilizer chamber for recording;

d) absolute pressure in the sterilizer chamber for indication; for double ended sterilizers this indication shall be provided at each end;

NOTE 1 National regulations can require gauge pressure to be indicated.

e) absolute pressure in the sterilizer chamber for control;

f) absolute pressure in the sterilizer chamber for recording;

g) pressure in the jacket for indication (if the sterilizer is fitted with a jacket intended to be pressurized);

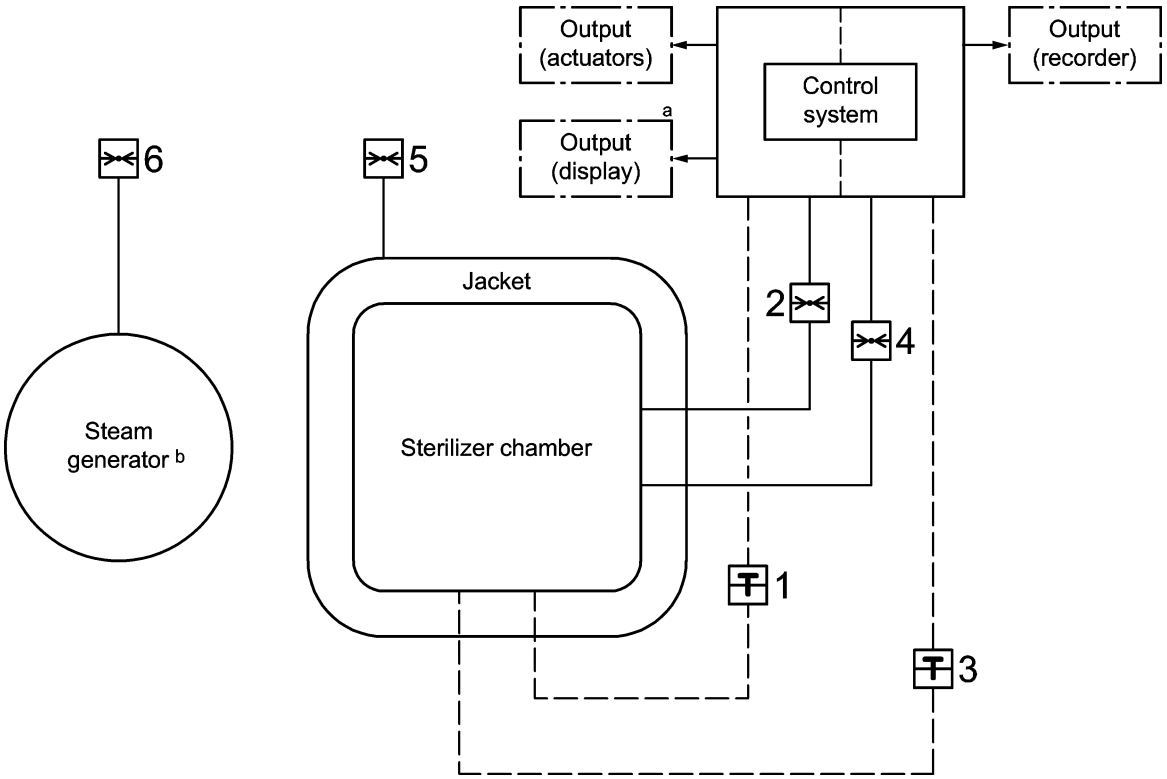
h) steam pressure for indication (if a steam generator is incorporated within the sterilizer panelling).

Measuring systems a) and b) as well as d) and e) may be combined (see Figure 3). These may be combined into a system whereby the display of any measurement may be selected for process analysis.

The indication a), d), g) and h) may be incorporated in a display system.

NOTE 2 Values of c) and f) can be indicated in addition.

For the purpose of g) absolute pressure transducers may be used providing the offset from ambient pressure is considered.



Key

1 Measuring system for temperature of the sterilizer chamber, whereat measuring system for indication and control may be combined [see 6.2 a) and b)]

2 Measuring system for absolute pressure of the sterilizer chamber, whereat measuring system for indication and control may be combined [see 6.2 d) and e)]

3 Measuring system for recording of temperature in the sterilizer chamber [see 6.2 c)]

4 Measuring system for recording of absolute pressure in the sterilizer chamber [see 6.2 f)]

5 Measuring system for relative pressure of the jacket, see 6.2 g)

6 Measuring system for relative pressure of the steam generator (if fitted), see 6.2 h)

[a] Display of chamber temperature, jacket pressure and steam generator pressure may be combined in one display panel, see 6.2

[b] If steam generator is integrated

Figure 3 — Illustration of the measuring systems

6.3 Status indicators

6.3.1 Sterilizers shall be provided with at least the following status indicators:

a) visual display indicating “sterilizer door(s) locked”;

b) visual display indicating “in progress”;

c) visual display indicating “cycle complete”;

d) visual display indicating “fault” (see 7.2);

e) indication of the operating cycle selected;

f) operating cycle counter;

g) operating cycle stage indication.

The operating cycle stage indication may incorporate items a), b) and c).

6.3.2 Double ended sterilizers shall be provided on both ends of the sterilizer with at least:

a) visual display indicating “sterilizer doors locked”;

b) visual display indicating “in progress”;

c) visual display indicating “cycle complete”;

d) visual display indicating “fault” (see 7.2).

6.3.3 The “cycle complete” shall be cancelled when the sterilizer door opening has been initiated.

6.4 Measuring chains and time equipment

6.4.1 Temperature probes

Temperature sensors shall be either platinum resistance types complying with Class A of EN 60751:2008 or thermocouples complying with one of the tables specified in Tolerance Class 1 of EN 60584-1:2013.

NOTE 1 Other sensors of demonstrated equivalence in measurement characteristics can be used.

The temperature probe shall have a response time $\tau_{0,9} \leq 5$ s when tested in running water according to EN 60751:2008, 6.5.2.

NOTE 2 The following method can also be used to establish the response time:

a) Equilibrate probe to (20 ± 5) °C in air;

b) Plunge probe into a stirred water bath at (95 ± 2) °C;

c) Record the temperature rise and calculate the time to reach 90 % of the temperature difference ($\tau_{0,9}$).

The probe used for control of the operating cycle and for the indication of sterilizer chamber temperature and also the independent probe used to record the operating cycle shall be located at the point identified as the reference measurement point.

6.4.2 Temperature measuring chains for control, recording and indication

At least two independent temperature measuring chains shall be provided such that the failure of an element in one chain will not cause error or failure in the second chain.

The temperature measuring chains shall:

a) indicate in degrees Celsius;

b) have a scale which includes the range 50 °C to 150 °C;

c) have a measurement error not exceeding 1 % over the scale range 50 °C to 150 °C;

d) have a resolution not exceeding 0,1 K;

e) ensure a measurement error not exceeding 0,5 K at the used sterilization temperatures;

f) have a temperature error compensation that a measurement error caused by the ambient temperature does not exceed 0,04 K/K.

6.4.3 Pressure transducers

Pressure transducers shall:

a) be absolute pressure transducer;

b) include the range 0 kPa to 400 kPa absolute;

c) have a time constant for rising pressure $\tau_{0,9} \leq 0,2$ s according to EN 60770-1:2011;

d) have a measurement error for the pressure transducer not exceeding 1,6 % over the scale range 0 kPa to 400 kPa.

6.4.4 Pressure measuring chains for control, recording and indication

At least two independent absolute pressure measuring chains shall be provided such that the failure of an element in one chain will not cause error or failure in the second chain.

Pressure measuring chains shall:

a) indicate in kilopascals or bars;

b) include the range 0 kPa to 400 kPa absolute pressure;

c) have a resolution not exceeding 1 kPa (0,01 bar);

d) have a maximum permissible measurement error of the whole measuring chain not exceeding 5 kPa after adjustment under the condition of sterilization temperature(s);

e) be calibrated at following working pressures:

   1) specified lowest pressure transition point (see 6.5.2.2 and 7.1.2);

   2) environmental pressure;

   3) maximum working pressure during plateau period;

f) maximum measurement error at these points shall be smaller than the tolerances established for the operating cycle parameters;

g) have measurement error compensation that a measurement error caused by the ambient temperature does not exceed 0,04 %/K over the scale range 0 kPa to 400 kPa.

6.4.5 Time control and indicating equipment

The time control and indicating equipment shall:

a) be graduated in hours, minutes and seconds as applicable;

b) have a measurement error not exceeding 1 % of each defined time interval of the operating cycle.

6.5 Recording systems

6.5.1 General

6.5.1.1 Equipment and functions as specified in 6.5 shall enable the recording of data for each operating cycle carried out by the sterilizer. Data shall be sufficient to enable the efficiency of the operating cycle to be judged for the release of sterilized product and for further data processing.

The generation of digitized data shall be performed by the sterilizer. The system shall be designed to ensure the integrity of the raw data while stored in the sterilizer.

6.5.1.2 The components for recording of data and/or printing of the records may be either:

a) part of the sterilizer, or

b) a specified interface using specified data format connecting the sterilizer by a data link to an external system.

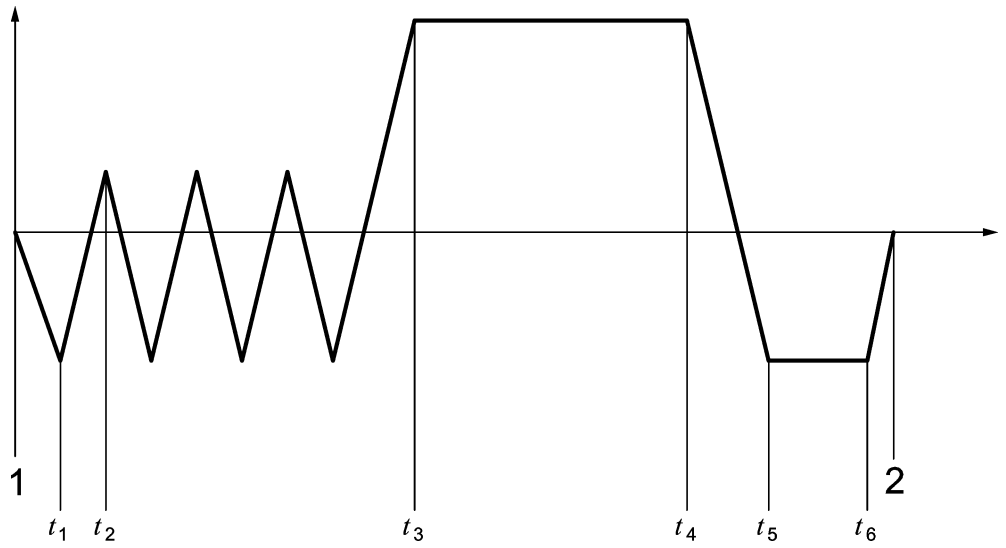
NOTE The external system can be provided by a third party.

6.5.1.3 If used, the submitted data shall allow the external system to generate records, which are compliant to all applicable specifications of 6.5.2.

6.5.2 Records

6.5.2.1 The records shall be either graphically or tabular or both.

6.5.2.2 It shall be possible to confirm by the data that the cycle parameters have been attained and maintained within the permitted tolerances throughout the operating cycle (see also Clause 8). Records shall include the values for the pressure transition points throughout the operating cycle. Examples are illustrated in Figure 4 and Table 3.



Key

1	start of the operating cycle	t_4	time at the end of the plateau period
t_1	time at the start of the first steam injection	t_5	time at the start of the drying period
t_2	time at the start of the second vacuum pulse	t_6	time at the end of the drying period
t_3	time at the start of the plateau period	2	end of the operating cycle

Figure 4 — Diagram of specimen operation cycle given as an example only

Table 3 — Examples of data to be recorded

Programme step	Time	Temperature	Pressure	Sterilization [a]		Date[a] and sterilizer identification
		(measured value)		Cycle identification	Counter No	
START	X			X	X	X
t_1	X		X[b]			
t_2	X		X[b]			
t_3	X	X	X			
t_4	X	X	X			
t_5	X		X			
t_6	X		X			
END	X					

[a] Optional for analogue records

[b] For each change:

t_1 time at the start of the first steam injection;

t_2 time at the start of the second vacuum pulse;

t_3 time at the start of the plateau period;

t_4 time at the end of the plateau period;

t_5 time at the start of the drying period;

t_6 time at the end of the drying period.

START start of the operating cycle

END end of the operating cycle ("cycle complete", see 3.7)

NOTE For example see also Figure 4

6.5.2.3 Printed and stored records shall be retrievable and readable as defined in 6.5.2.4 when stored in specified conditions for a period of not less than 11 years.

NOTE National regulations can apply to the length of time records can be retained.

6.5.2.4 Printed records shall be readable when viewed at a distance of (250 ± 25) mm with normal or corrected vision in an illumination of (215 ± 15) lx.

6.5.3 Data processing

6.5.3.1 General

The generation of measurement data for recording shall be independent from cycle controller functions, except data processing for export of these data at the specified interface.

The data processing for export shall be performed using software modules, segregated from the modules for the cycle control functions.

In addition data from the controller, e.g. cycle identification, fault indications, shall be provided at the data interface.

NOTE For software validation see 7.3.

6.5.3.2 Resolution of graphic records of pressure and temperature

If recording devices producing graphic records of pressure and temperature are used:

a) temperature differences of 1 K shall be readable;

b) pressure differences of 5 kPa shall be readable;

c) the operating cycle shall be plotted completely.

6.5.3.3 Resolution of tabular records of pressure and temperature

Recording devices producing tabular records of pressure and temperature shall:

a) have data defined by alphanumeric characters (data to be recorded see Figure 4 and Table 3);

b) record with increments of ≤ 0,1 K;

c) record with increments of ≤ 1 kPa;

d) record with increments of ≤ 1 s.

7 Control systems

7.1 General

7.1.1 The sterilizer shall be operated by an automatic controller which has one or more pre-set operating cycles.

NOTE 1 An access device for the selection and/or starting of the cycle(s) can be used for production or test.

NOTE 2 Automatic loading and unloading can be carried out before the start and after the end of an operating cycle.

7.1.2 The cycle parameters identified as critical to the operating cycle shall be reproducible within the tolerances that ensure the performance requirements in Clause 8 will be met.

NOTE Examples are given in Figure 4 and Table 3.

7.1.3 The reference measurement point shall be determined in such a way that throughout the plateau period the temperature at this point correlates with the temperature in the usable space, see also 25.3 g).

NOTE A suitable position can be approx. 100 mm into the active chamber discharge.

7.1.4 A device shall be fitted such that if a failure of the automatic controller occurs, the pressure within the sterilizer chamber can be returned to atmospheric pressure to allow the door to be opened through which the load has been put into the sterilizer chamber prior to processing.

7.1.5 Measurement systems for sterilizer chamber temperature and pressure shall be fitted with broken sensor detection system (see 7.2.4) which will cause a fault to be indicated.

7.1.6 The deviation of any controlled time period shall not exceed 1 % of the specified value.

7.1.7 The adjustment of control settings shall only be possible by the use of an access device.

7.1.8 For maintenance, test purposes and in cases of emergency, means shall be provided to permit the sequential manual progression through the operating cycle. The selection of this manual facility shall be by means of an access device different from the one specified above.

The selection of the manual advance system shall be indicated.

7.1.9 The sterilizer shall be protected against effects of short circuit in inputs and outputs that are connected to the automatic controller.

7.1.10 The automatic controller shall have a status indicator for each digital input and output.

NOTE This can be located within the control cabinet.

7.1.11 Means shall be provided to ensure that any fault occurring shall be detected for each operating cycle used for production or test.

7.1.12 If the operating cycle has been completed according to programme and no fault has occurred the "cycle complete" shall be generated.

7.1.13 A separate test cycle shall be provided if the time and temperature specified for the indicator used to determine the efficacy of steam penetration is different to the plateau period used for the operating cycle used for production. This cycle shall have the same air removal stage as the one used for the operating cycle used for production.

NOTE Indicators and indicator systems for steam penetration test are specified in EN ISO 11140-3 and EN ISO 11140-4.

7.1.14 An automatic test cycle shall be provided to carry out the air leakage test (see Clause 18) and display the rate of pressure rise caused by air leakage in kilopascals per minute.

The measurement error for a pressure difference of any 1,5 kPa (15 mbar) shall not exceed 0,1 kPa (1 mbar) over the pressure range that may occur during the test.

7.1.15 Whenever a test cycle is provided the indication at the end of the test cycle shall be different to the indication at the end of an operating cycle used for production.

7.2 Fault indication system

7.2.1 The fault indication system of the control system shall compare the data from the measuring chains for pressure, temperature and time for the recording with the values of the control measuring chains for pressure, temperature and time.

7.2.2 If the cycle parameters (see 7.1.2) are outside the specified limits, or the difference between signals measured according to 7.2.1 are outside the specified limits, or an operating cycle has been interrupted, the automatic controller shall:

a) cause a visual indication that a fault has occurred;

NOTE 1 An audible system, preferably incorporating a mute facility, can be provided additionally.

NOTE 2 After a fault it is assumed that the sterilizer load has not been subjected to the sterilization process.

b) cause a visual indication of the operating cycle stage at which the fault occurred;

NOTE 3 Additional requirements for safety are specified in Clause 11.

c) ensure that "cycle complete" does not occur.

Verification shall be performed by analysis and tests.

7.2.3 If the sterilizer is fitted with a printer, the indication of a fault shall be distinguishable.

7.2.4 After a fault has been indicated a visual display of the fault shall continue at least until the sterilizer door is open (see 4.3.2.2).

NOTE Conditions for the opening of access doors are specified in EN 13445–5:2014.

7.2.5 When a broken sensor occurs the fault detection system shall cause a fault to be indicated (see 7.1.5).

7.2.6 Verification of fault indication shall be performed by analysis and tests.

7.2.7 If an air detection system is the method used to routinely check for the presence of residual air during the plateau period this system shall include facilities for the display of measurements and for the adjustment of settings.

7.3 Software verification and validation

7.3.1 Software for automatic controllers shall be demonstrated to function as intended. The classification of software with respect to safety shall be established as part of the risk assessment.

7.3.2 Software parts related to safety of patients, users or any other persons shall be verified and validated. The methods used in the validation and verification process shall be justified and documented.

NOTE EN 61508 (all parts), EN 62061 and EN 62304 can support activities to be performed according to 7.3.1 and 7.3.2.

8 Performance requirements

8.1 Steam penetration

8.1.1 When tested in accordance with 16.1, the result shall be in accordance with 8.2.1.2.

8.1.2 When tested in accordance with 16.2, the result shall be in accordance with 8.2.1.3.

8.1.3 When tested in accordance with Clause 17, the result shall be in accordance with 8.2.2.

NOTE 1 Each steam sterilization process is a unique event. While a steam penetration test carried out on a periodic basis provides a very useful equipment control function, provision can be made to indicate adequate steam penetration occurs during every cycle.

NOTE 2 In healthcare there has been an increase in the use of instruments with long lumens. For some of these instruments the air removal efficacy identified by the tests based on textile loads can be inadequate. These tests have their origin in the steam penetration test using a textile pack [45]. It was designed to establish that at the commencement of the plateau period, air removal had been sufficient to achieve a vapour temperature throughout a textile load equivalent to the vapour pressure of the steam in the sterilizer chamber. The hollow load test complements these tests and is regarded as an addition to, and not as a replacement to them. A fail result of any steam penetration test can be caused by an inefficient air removal stage, the presence of an air leak into the sterilizer chamber, and/or the presence of non-condensable gases in the steam supply.

NOTE 3 If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, conformity with the performance requirements for the steam penetration test specified in this European Standard indirectly establishes the air dilution generated by the sterilization process. Conformity can be regarded as a pre-requisite for the definition of process parameters as required by EN ISO 17665-1:2006, 8.1 for the range of products (e.g. hollow items and lumen) a sterilizer conforming to this European Standard is intended to process.

8.1.4 When tested in accordance with Clause 15, the result shall be in accordance with 8.2.5.

8.2 Physical parameters

8.2.1 Temperature characteristics

8.2.1.1 Sterilization temperature band

The sterilization temperature band shall have the lower limit defined by the sterilization temperature and an upper limit of + 3 K (see also Figure C.1). This upper limit value should not be exceeded throughout the whole operating cycle.

Compliance shall be tested in accordance with 16.1 and 16.2 respectively.

8.2.1.2 Small load, thermometric

8.2.1.2.1 The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

8.2.1.2.2 During the plateau period the temperature measured above the test pack (see 16.1) shall not exceed the temperature measured at the reference measurement point of the sterilizer chamber by more than 5 K for the first 60 s and 2 K for the remaining period (see also Figure C.1).

8.2.1.2.3 Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the theoretical temperature of the saturated steam determined from the measured sterilizer chamber pressure shall:

a) be within the sterilization temperature band;

b) not differ from another by more than 2 K.

See also Figure C.1.

The correlation between steam pressure and temperature of saturated steam shall be determined.

NOTE 1 Guidance on the calculation is provided in publication [46] or [47] and CEN ISO/TS 17665-2:2009, Annex C. The calculation assumes the presence of saturated steam.

The following Formula (1) can be used:

$$T = A + B \cdot (\ln P + C)^{-1} . \quad (1)$$

where

T is the saturated steam temperature in Kelvin;

P is the measured pressure in megapascals, time averaged to result in a time constant between 1 s and 2,5 s;

A is 42,677 6 K;

B is –3 892,70 K;

C is –9,486 54.

NOTE 2 Further information is provided in CEN ISO/TS 17665-2:2009, Table C.1 and IAPWS Tables.

8.2.1.2.4 The holding time shall be not less than 15 min and 3 min for sterilization temperatures of 121 °C and 134 °C respectively.

NOTE The values assume the presence of saturated steam.

8.2.1.2.5 Compliance with 8.2.1.2.1 to 8.2.1.2.4 shall be tested in accordance with 16.1.

8.2.1.3 Full load, thermometric

8.2.1.3.1 The equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers.

8.2.1.3.2 At the end of the equilibration time, the temperature measured at the reference measurement point of the sterilizer chamber and the temperature measured at the nominal geometric centre and below the top sheet of a standard test pack (see 23.1) located in the test load shall be within the sterilization temperature band.

8.2.1.3.3 Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the theoretical temperature of saturated steam calculated from the measured sterilizer chamber pressure shall:

— be within the sterilization temperature band;

— not differ from one another by more than 2 K.

The theoretical temperature of saturated steam shall be calculated from Formula (1).

8.2.1.3.4 The holding time shall be not less than 15 min and 3 min for sterilization temperatures of 121 °C and 134 °C respectively.

NOTE The values assume the presence of saturated steam.

8.2.1.3.5 Compliance with 8.2.1.3.1 to 8.2.1.3.4 shall be tested in accordance with 16.2.

8.2.2 Bowie and Dick test

When the sterilizer is tested as described in Clause 17 the indicator shall show uniform colour change throughout the indicator in accordance with EN ISO 11140-3:2009 and the instructions for the use of the indicator.

8.2.3 Air leakage

When the sterilizer is tested as described in Clause 18 the rate of pressure rise shall be within the specified limits [see 25.4 c)] and in any case shall be not greater than 0,13 kPa/min (1,3 mbar/min).

8.2.4 Air detector

8.2.4.1 General

If an air detector is fitted the performance requirements in 8.2.4.2 to 8.2.4.4 shall apply.

8.2.4.2 Air detector, small load

When tested as described in 19.2 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the operating cycle causes a difference in temperature of more than 2 K. This difference is evaluated between the lowest measured temperature in a standard test pack (see 23.1) or reduced pack (see 23.2) and the temperature measured at the reference measurement point of the sterilizer chamber at the commencement of the equilibration time.

8.2.4.3 Air detector, full load

When tested as described in 19.3 an air detector shall cause a fault to be indicated if the volume of air or other non-condensable gases retained or introduced into the sterilizer chamber during the air removal and steam admission of the operating cycle causes a difference in temperature of more than 2 K. This difference is evaluated between the lowest measured temperature in a standard test pack (see 23.1) and the temperature measured at the reference measurement point of the sterilizer chamber at the commencement of the equilibration time.

8.2.4.4 Air detector function

When the sterilizer is tested as described in 19.4 the test result shall be regarded as satisfactory if a fault is indicated.

8.2.5 Hollow load test

When the sterilizer is tested in accordance with Clause 15, the indicator system shall have reached its specified pass-condition.

NOTE The performance of the hollow load test as defined in EN 867–5 is under discussion within ISO/TC 198. Test data has been generated and published that shows variability in the performance of the hollow load test associated with variation of the rate of pressure change during the air removal stage of the cycle.

8.3 Load dryness

8.3.1 Load dryness, small load, textiles

When the sterilizer is tested as described in 20.1, the mass of the test pack shall not increase by more than 1 %.

8.3.2 Load dryness, full load, textiles

When the sterilizer is tested as described in 20.2, the mass of the standard test pack shall not increase by more than 1 %.

8.3.3 Load dryness, metal load

When the sterilizer is tested as described in 20.3, the mass of the test pack, metal shall not increase by more than 0,2 %.

9 Sound power and vibration

9.1 Sound power

9.1.1 Noise emission from sterilizers shall be reduced by design and selection of components with low noise emission levels, particularly at source.

NOTE Guidance to reduce noise at source is provided in EN ISO 12100:2010, 6.2.2.2 and 6.3.4.2.

9.1.2 If equipment produces noise (except alarms) at a level which could cause a hazard, A-weighted sound power and emission sound pressure levels shall be determined and specified for each type of sterilizer. For testing and calculation EN ISO 3746:2010 shall apply.

NOTE 1 For limiting values see Directive 2003/10/EC on noise risk.

The noise emission tests shall be performed in normal use condition with empty sterilizer chamber.

If the emission sound pressure level is required it shall apply for the operator's position in front of the sterilizer at a distance of 1 m and a height of 1,6 m. If the A-weighted emission sound pressure level at workstation is 70 dB (A) or less at least this fact shall be indicated in the equipment information.

If not evaluated different from dedicated tests, the standard deviation for the sound power and emission sound pressure levels shall be stated to be +5 dB (see EN ISO 3746:2010, Table D.1).

NOTE 2 For test and calculation other methods of demonstrated equivalence can be used. Guidance is provided in EN ISO 3740.

If changes or modification of tested equipment have previously been identified as not contributing to more than 3 dB (A) to the total sound power level, further testing and change of the specification may be omitted.

9.1.3 The sound power level for any additional devices supplied for use with the sterilizer shall be specified.

9.2 Vibration

Vibrations from sterilizers shall be reduced by design, selection of components and devices limiting vibrations, particularly at source.

NOTE Guidance to reduce vibration at source is provided in EN ISO 12100:2010, 6.2.2.2, 6.2.3; 6.2.6 and 6.3.4.3.

10 Rate of pressure change

The average pressure change for any 3 s interval during the operating cycle shall not exceed 1 000 kPa/min (10 bar/min). Compliance shall be tested as described in Clause 22.

NOTE This level has been chosen to limit the risk for product and packaging integrity.

11 Safety, risk control and usability

11.1 Protective measures

As an alternative to the referenced parts of EN 61010-1:2010 and EN 61010-2-040:2005 specific harmonized standards for machinery may be used to address relevant hazards, including EN 60204-1:2006 for electricity supply and safety of electric circuits of the sterilizer, together with other specific standards to address specific hazards. These alternatives are specified in Annex F.

The following protective systems and measures shall apply:

a) For marking sterilizers shall comply with EN 764-7:2002, Clause 9, EN 13445-5:2014, 12.1, EN 14222:2003, Clauses 7 and 8, EN 61010-1:2010, Clause 5, as modified by EN 61010-2-040:2005, Clause 5.

b) For the protection against electric shock sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 6, Annexes A, B, C, D, F, H, K, as modified by EN 61010-2-040:2005, Clause 6.

c) For the protection against mechanical hazards and hazards related to mechanical functions sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 7, as modified by EN 61010-2-040:2005, Clauses 4 and 7.

d) For the protection against hazards the mechanical resistance to shock and impact of sterilizers shall comply with EN 61010-1:2010, Clauses 4 (except 4.4) and 8.

e) For the protection against the spread of fire sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 9 (except 9.5), as modified by EN 61010-2-040:2005, Clauses 4 and 9.

f) For the protection against hazards in relation to equipment temperature and to heat sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 10, as modified by EN 61010-2-040:2005, Clauses 4 and 10.

g) For the protection against hazards from fluids sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 11, as modified by EN 61010-2-040:2005, Clauses 4 and 11.

h) For the protection against radiation, including laser sources, sterilizers shall comply with EN 61010-1:2010, Clauses 4, 12.1, 12.3 and 12.6.

i) For the protection against liberated gases, substances, explosion and implosion sterilizers shall comply with EN 61010-1:2010, Clause 4 and 13.2.2, as modified by EN 61010-2-040:2005, Clause 4, 13.1.102 and 13.101.6.

j) For the protection against hazards related to components sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 14, as modified by EN 61010-2-040:2005, Clauses 4 and 14.

k) For the protection by interlocks sterilizers shall comply with EN 61010-1:2010, Clauses 4 and 15.

l) For the protection against hazards in relation to safety for pressure equipment and assemblies sterilizers shall comply with EN 764-7:2002, EN 14222:2003, EN 13445-1:2014, EN 13445-2:2014, EN 13445-3:2014, EN 13445-4:2014, EN 13445-5:2014 and EN 13445-8:2014 or equivalent specifications.

NOTE 1 EN 13445 series, EN 14222 and EN 764–7 are deemed to address essential requirements of the Directive 2014/68/EU on pressure equipment [41].

NOTE 2 Additional guidance is given in EN ISO 12100.

11.2 Risk control, usability

11.2.1 Risk assessment and risk control for sterilizer design and software should be performed following the method and requirements given in EN ISO 14971.

11.2.2 Risk analysis should address the specific sterilizer design and features. Measures taken for risk reduction shall consider aspects as user knowledge, experience, training, ergonomics and usability.

NOTE EN ISO 12100 or EN 61508–1 or EN 62366 can provide further helpful information.

12 Packaging and marking

12.1 The sterilizer package shall be designed to protect the sterilizer and preserve its characteristics during intended transport, storage and installation.

NOTE Sterilizer and packaging design are elements that either individually or collectively provide protection against transport challenges.

12.2 Markings for safety on packaging or the sterilizer itself shall comply with 11.1 a).

NOTE For symbols EN ISO 15223-1 can apply.

12.3 Other markings shall include at least:

— name/company and address of the manufacturer; address shall include: street/road, number/house/floor, postal code, city, state/region and country;

— name and address of authorized representative within the European Community in the case where the manufacturer does not have a registered place of business in the community; address shall include: street/road, number/house/floor, postal code city, state/region and country;

— unique identification number;

— model identification;

— year of manufacture (not required if this is included in the identification markings);

— the CE-mark accompanied by the European registration number(s) of the notified body or bodies engaged for medical device and pressure equipment as applicable.

12.4 Each part intended for replacement, used for safety or control, listed as a spare part in accordance with 25.4 a) and also when 25.5 applies, shall have a mark that is traceable to its specification.

NOTE Reference numbers or written descriptions can be used.

12.5 Instructions for handling, unpacking, transport, storage and disposal of the sterilizer wrapping shall be clearly indicated on the outside of the package.

12.6 Marking of sterilizer and components shall be verified by visual inspection and comparison with documentation (see Clause 24), information to be supplied with the sterilizer [see Clause 25 including plans and diagrams in accordance with 25.4 a)].

13 Service and working environment

13.1 General

Sterilizers installed and operated according to information specified in Clause 25 shall meet the requirements of this European Standard when supplied with services meeting the following requirements.

NOTE The performance of a sterilizer is dependent upon its design and construction together with the quality of services provided. When services do not meet the specified requirements the performance of the sterilizer can be affected adversely.

13.2 Electrical supply

The sterilizer shall be designed to operate with an electrical supply in accordance with EN 61010-1:2010, 1.4, 4.3.2.5, 6.10 or EN 60204-1:2006, 4.3, 4.4.3, 4.4.4, 4.4.5 and Clause 5 (see Clause 11).

13.3 Steam supply to the sterilizer chamber

13.3.1 Non-condensable gases

The sterilizer shall be designed to operate with saturated steam containing up to 3,5 ml non-condensable gases collected from 100 ml condensate when tested as described in 21.1.

NOTE This method does not necessarily express the true content of NCG in steam. The limiting value was defined experimentally in the 1960s in relation to the sensitivity of air detectors commonly used in the UK at that time. Repeated measurements give an idea of the true picture of NCGs in the steam supply.

13.3.2 Dryness value

The sterilizer shall be designed to operate with saturated steam with a dryness value not less than 0,95, where the dryness value denotes the mass of the gas fraction in the mass of saturated steam, when tested as described in 21.2.

13.3.3 Superheat

When the supplied steam is expanded to atmospheric pressure the superheat shall not exceed 25 K when tested in accordance with 21.3.

13.3.4 Contaminants

The sterilizer shall be designed to operate with steam that does not contain contaminants in quantities that can impair the sterilization process or harm or contaminate the sterilizer or sterilized load.

NOTE 1 Suggested maximum values of some contaminants are given in Table 4.

NOTE 2 A method for obtaining a condensate sample is given in 21.4.

Table 4 — Suggested maximum values of contaminants in condensate from steam supply to the sterilizer chamber

Determinant	Condensate
Silicate	≤ 0,1 mg/l
Iron	≤ 0,1 mg/l
Cadmium[c]	≤ 0,005 mg/l
Lead[c]	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead[b]	≤ 0,1 mg/l
Chloride	≤ 0,1 mg/l
Phosphate	≤ 0,1 mg/l
Conductivity (at 20 °C)[a]	≤ 4,3 µS/cm
pH (20 °C) value	5 to 7
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l

[a] See European Pharmacopeia.

[b] If the condensate meets the requirements on conductivity, it is not necessary to perform heavy metal tests.

[c] The limiting values meet the requirements for potable water.

13.3.5 Pressure fluctuation

If steam is supplied from an external source, the sterilizer shall be designed to operate with a pressure fluctuation not exceeding ± 10 % of the pressure measured at the inlet to the final pressure reduction valve.

13.3.6 Feed water

If a dedicated steam generator is used (see 5.2.1), the sterilizer shall be designed to operate with steam produced from water free from contaminants in a concentration that can impair the sterilization process or harm or contaminate the sterilizer or sterilized load. If the quality of feed water can affect the quality of steam supplied to the sterilizer chamber (see Annex B) it shall be specified [see 25.2 m)].

NOTE Non-condensable gases dissolved in the feed water can cause an increase in non-condensable gases in the steam, see 13.3.1.

13.4 Lighting

The sterilizer shall be designed to operate with a minimum external illumination of 200 lx.

13.5 Water, except water specified in 13.3.6

The sterilizer shall be designed to operate with water that is of potable quality and supplied at a temperature not exceeding 20 °C and with a hardness value of water (Σ ions of alkaline earth), between 0,7 mmol/l and 2,0 mmol/l.

NOTE 1 Regional variations in water supplies can mean that the hardness values of potable water fall outside the given limits and this can cause scaling and corrosion problems.

NOTE 2 Higher water temperatures can affect the final vacuum level attained and pressure change rates.

NOTE 3 For the protection against pollution of potable water supply installations a system in accordance to EN 1717:2000, 5.7 and 5.8 can be used.

13.6 Compressed air

If supplied form an external source, the sterilizer shall be designed to operate with a compressed air supply at a pressure of 5 bar to 7 bar, free of liquid water, filtered to particle size 25 µm and oil droplets greater than 2 µm [see 25.2 f)].

NOTE Additional information is provided in ISO 8573-1:2010, 6.3.

13.7 Electromagnetic interference

Sterilizers shall comply with EN 61326-1 regarding electromagnetic compatibility (EMC).

Sterilizers operating in areas intended for medical electrical equipment shall be regarded as Class B equipment as specified by EN 61326-1:2013, 7.2.

The immunity performance criteria selected shall ensure that sterilizer performance as specified by 7.1.2 is met when exposed to disturbance phenomena of EN 61326-1:2013, Table 2.

13.8 Drains

The sterilizer shall be designed to operate with a drainage system resistant to water at 100 °C, and be capable of passing the maximum flow rate of water, air and condensed steam.

NOTE National regulations can require the drain be trapped and vented and not connected to other drains, which can cause a back pressure or obstruction to flow. An air break can also be necessary.

13.9 Working Environment

The sterilizer shall be designed to operate in an ambient temperature and humidity as specified in EN 61010-1:2010, 1.4.

NOTE The heat transmitted from the sterilizer and from the sterilized load during unloading can contribute to the heat burden of ambient air [see 25.2 g) and h)].

13.10 Service connections

The sterilizer shall be designed to operate with all service connections for electricity and fluids (e.g. water, steam, compressed air) provided with a disconnecting device in accordance with the installation instruction (see 25.2).

Operation of disconnecting devices and isolating valves should be possible without causing a hazard.

14 Testing

14.1 General

14.1.1 Documentary evidence that the sterilizer complies with the requirements of this European Standard shall be established, maintained and declared (see also Clause 24).

NOTE 1 The tests described in Clauses 15 to 22 are reference tests intended for use in demonstrating conformity with the performance requirements specified in this European Standard. They can be used in type tests, works tests, in validation and requalification, or in periodic and routine tests carried out by the user. Reproducibility can be demonstrated by consecutive triplicate tests (see also Annex D).

NOTE 2 A recommended test programme is identified in Table 5.

NOTE 3 Requirements and guidance on validation and requalification are given in EN ISO 17665-1:2006, Clause 9, 12.4 and CEN ISO/TS 17665-2.

14.1.2 In addition to specific tests or if a specific test procedure is not prescribed, visual inspection and observation of the relevant aspect shall be performed with equipment in and out of operation, accompanied by visual examination of the certificates, records and documents, which are specified in Clauses 24 and 25.

NOTE No requirement is given in this European Standard to deliver the risk assessment documentation or quality management documentation together with the sterilizer.

14.1.3 Assessment of time periods shall be based on comparison of records obtained during tests from sterilizer and test equipment, see Clauses 15 to 20 and 22.

14.1.4 If adjustment is made to the sterilizer during a test sequence such that the cycle parameters of the operating cycle are affected, the sequence of tests shall be repeated.

Table 5 — Recommended test programme

Test	Requirement according to	Test method according to	Type test (see Annex E)	Works test
Thermometric tests				
– Small load	8.2.1.2	16.1	X	
– Full load	8.2.1.3	16.2	X	
Air removal and steam penetration				
– Bowie and Dick test	8.2.2	17	X	X
– Air leakage	8.2.3	18	X	X
– Air detector, small load [a]	8.2.4.2	19.2	X	X
– Air detector, full load [a]	8.2.4.3	19.3	X	
– Air detector function [a]	8.2.4.4	19.4	X	X
– Hollow load test	8.2.5	15	X	
Load dryness tests				
– Small load, textiles	8.3.1	20.1	X	
– Full load, textiles	8.3.2	20.2	X	
– Metal	8.3.3	20.3	X	
Sound power	9.1	9.1	X	
Rate of pressure change	10	22	X	
Steam quality tests				
– Non-condensable gases	13.3.1	21.1	X	
– Dryness value	13.3.2	21.2	X	
– Superheat	13.3.3	21.3	X	
X = denote a recommended test				
[a] If an air detector is fitted (see 8.2.4.1).				

14.2 Calibration

All measuring chains of the sterilizer shall be calibrated [see 24 a)].

Before carrying out any of the tests the calibration status of all test instruments shall be verified.

14.3 Environment

The impact on the environment shall be reduced by planning and carrying out the tests in a sequence which will reduce unnecessary repetition.

NOTE A test sequence can be as follows:

a) safety checks and tests;

b) tests to demonstrate conformity with the specification for each operating cycle;

c) steam quality tests;

d) air leakage test and dynamic pressure test (can be performed simultaneously);

e) thermometric tests, small load;

f) thermometric tests, full load;

g) if more than one operating cycle having the same air removal stage is to be tested, it is preferable to carry out initial thermometric tests for those cycles before continuing;

h) Bowie and Dick tests;

i) air detector tests, small load, full load and function;

j) hollow load test;

k) load dryness tests, full load textiles, small load textiles and metal;

l) sound power test.

15 Hollow load test

15.1 General

The hollow load test is used to demonstrate that at the levels at which the controls are set, air removal from within the test piece is sufficient to permit even steam penetration into it. The test is performed using the hollow device unwrapped.

NOTE The performance of the hollow load test as defined in EN 867-5 is under discussion within ISO/TC 198. Test data has been generated and published that shows variability in the performance of the hollow load test associated with variation of the rate of pressure change during the air removal stage of the cycle.

15.2 Apparatus

15.2.1 One hollow device as described in EN 867-5:2001, 4.5 and 4.6 and preconditioned such that the internal environment within the lumen and capsule are at a temperature of between 20 °C and 30 °C and a relative humidity between 40 % and 60 %.

NOTE Residual moisture from previous use, trapped within the hollow device will have a deleterious effect on the test results.

15.2.2 Indicator in accordance with EN 867-5:2001, 4.5 and 4.6 for the hollow load test.

15.2.3 Connected services complying with Clause 13.

15.3 Procedure

15.3.1 Select the operating cycle to be tested. Ensure the plateau period is within the time and temperature exposure limits specified for the indicator identified in 15.2.2.

15.3.2 Carry out an operating cycle with the sterilizer chamber empty and without any extended drying time.

This cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

15.3.3 Open the capsule of the hollow device and then following the instructions for use of the indicator system, confirm:

a) liquid water is not visually present;

b) the seal and its mating surfaces are satisfactory.

15.3.4 Following the instructions for the use of the indicator system, insert into the capsule an indicator and then close the capsule with the sealing cap.

15.3.5 Place the hollow device above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

15.3.6 Carry out an operating cycle in accordance with the instructions for use (see 7.1.13).

15.3.7 At the end of the test examine the indicator for compliance with the requirements specified in 8.2.5.

For disposal of used indicators attention should be paid to instructions for use of the indicator.

16 Thermometric tests

16.1 Small load, thermometric

16.1.1 General

The small load test, thermometric is used to demonstrate that after the air removal stage of the operating cycle sterilizing conditions are obtained within the sterilizer chamber and standard test pack.

16.1.2 Apparatus

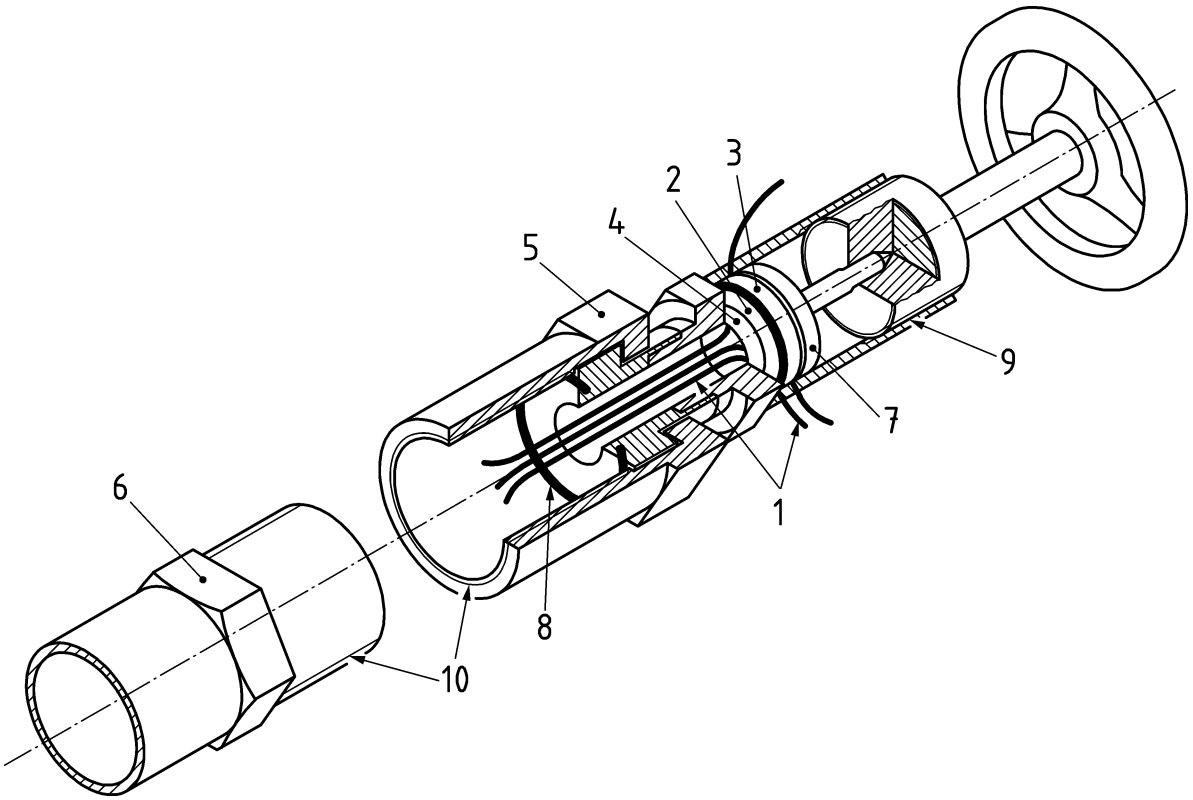
16.1.2.1 Test pack as described in 23.1 for sterilizers exceeding one sterilization module and 23.2 for sterilizers of one sterilization module.

16.1.2.2 Thermometric and pressure recording instrument as described in 23.3.4.1 and 23.3.4.2.

16.1.2.3 Seven temperature probes as described in 23.3.3.1.

16.1.2.4 Connection fitting with a pipe thread ISO 228-G1 A through which the temperature probes can be introduced into the sterilizer chamber (see Figure 5).

16.1.2.5 Connected services complying with Clause 13.



Key

1	temperature probes wire	6	adaptor
2	silicon rubber washer	7	metal thrust spigot
3, 4	metal thrust washer	8	O-ring
5	metal body	9	castellated to permit entry of leads
		10	pipe thread ISO 228-G1 A

Figure 5 — Example of a method used to introduce temperature probes into a sterilizer chamber

16.1.3 Procedure

16.1.3.1 Introduce the temperature probes into the sterilizer chamber through the temperature probes entry connection and fitting.

Figure 5 shows an example of a fitting which can be used to introduce temperature probes into a sterilizer chamber. Other methods that guarantee a gas tight seal are equally acceptable. If a handle is used either the whole device or the handle should be removed after use.

16.1.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

16.1.3.3 Place one of the temperature probes at the reference measurement point.

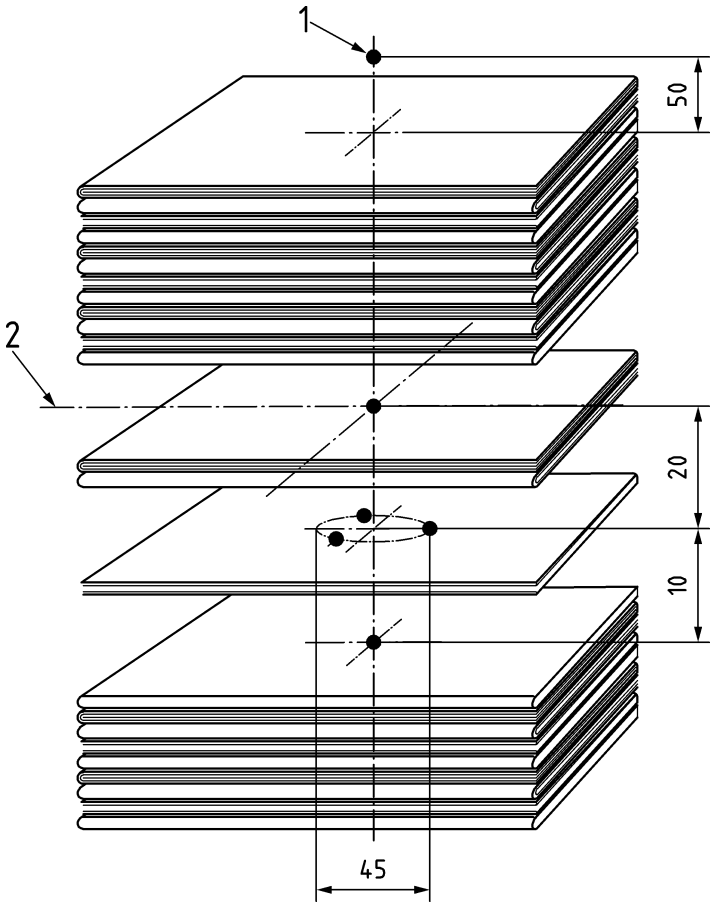
16.1.3.4 Select the operating cycle to be tested.

16.1.3.5 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

16.1.3.6 Remove the wrapping from the test pack and place five temperature probes within the test pack at locations as indicated in Figure 6. Reassemble and secure as described in 23.1 or 23.2 as appropriate.

Dimensions in millimetres



Key

1 position of sensor

2 centre layer

Figure 6 — Location of temperature probes

16.1.3.7 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

16.1.3.8 Secure the 7th temperature probes (50 ± 10) mm above the upper surface of the test pack and on its nominal vertical centre.

16.1.3.9 Carry out an operating cycle and:

— from the independent test records, observe and record the physical conditions that are characterized by duration, number of pulses, temperatures, and pressures at all significant parts of the operating cycle;

— at the beginning, middle and end of the holding time, observe and record the indicated sterilizer chamber temperature and the indicated sterilizer chamber pressure;

— ensure that a recording of the operating cycle is made by the recording system used with the sterilizer (see 6.5).

16.1.3.10 At the completion of the test, proceed as follows:

— check that a visual display of "cycle complete" is obtained;

— examine the records for compliance with the performance requirements specified in 8.2.1.2;

— examine the records specified above for compliance with the operating cycle specification [see 25.3 f)].

16.2 Full load, thermometric

16.2.1 General

The full load test, thermometric is used to demonstrate that at the levels at which the controls are set the required sterilizing conditions will be produced in a test load of specified maximum mass and of sufficient size to fill the usable space.

16.2.2 Apparatus

16.2.2.1 Full load, textiles, as described in 23.4.

16.2.2.2 Thermometric recording and pressure instrument as described in 23.3.4.1 and 23.3.4.2.

16.2.2.3 Seven temperature probes as described in 23.3.3.1.

16.2.2.4 Connection fitting with a pipe thread ISO 228-G1 A through which the temperature probes can be introduced into the sterilizer chamber (see Figure 5).

16.2.2.5 Connected services complying with Clause 13.

16.2.3 Procedure

16.2.3.1 Introduce the temperature probes into the sterilizer chamber through the temperature probes entry connection and fitting.

16.2.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

16.2.3.3 Place one of the temperature probes at the reference measurement point.

16.2.3.4 Select the operating cycle to be tested.

16.2.3.5 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

16.2.3.6 Remove the wrapping from the standard test pack and place five temperature probes within the standard test pack at locations as indicated in Figure 6 and one below the top sheet (16 layers). Reassemble and secure as described in 23.1.

16.2.3.7 Place the standard test pack and stacks of sheets comprising the test sterilizer load into the usable space as described in 23.4.6.

16.2.3.8 Carry out an operating cycle and:

— from the independent test records, observe and record the physical conditions that are characterized by duration, number of pulses, temperatures and pressures at all significant parts of the operating cycle;

— at the beginning, middle and end of the holding time, observe and record the indicated sterilizer chamber temperature and the indicated sterilizer chamber pressure;

— ensure that a recording of the operating cycle is made by the recording systems used with the sterilizer (see 6.5).

16.2.3.9 At the completion of the test, proceed as follows:

— check that a visual display of "cycle complete" is obtained;

— examine the records and sheets comprising the standard test pack for compliance with the performance requirements specified in 8.2.1.3;

— examine the records specified above for compliance with the operating cycle specification [see 25.3 f)].

17 Bowie and Dick test

17.1 General

The Bowie and Dick Test is described as a reference test [45].

The Bowie and Dick test was conceived as a test for successful air removal for vacuum porous load sterilizers. A successful Bowie and Dick test indicates rapid and even penetration of steam into the standard test pack or reduced test pack. Retention of air within the pack due to

— an inefficient air removal stage,

— an ambient or high pressure air leak during the operation cycle,

— the presence of non-condensable gases in the steam supply,

are circumstances which can lead to fail result for the test.

The result of the test can also be affected by other factors which inhibit steam penetration. These factors should be investigated if inefficient air removal, leaks or the presence of non-condensable gases in the steam supply are found not to be the cause of process failure.

The test is designed to complement the small load thermometric test. Both tests should meet their acceptance criteria before acceptable air removal and steam penetration is verified. The chemical indicators used in the test are designed to respond to the presence of air and other non-condensable gases which could be found in the textile pack when inadequate process conditions are present. Thermometric methods can be inappropriate for differentiating between hot air and hot steam. In some processes, particularly those employing relatively slow steam admission pressure rise rates, air remaining within the textile pack can be heated and attain steam temperature. In these circumstances thermometric methods will be insensitive to the presence of air whereas chemical indicators will identify the process failure.

Commercially produced alternatives are available which are commonly used for conducting the daily steam penetration test.

NOTE See EN ISO 17665-1:2006, 12.1.6 and EN ISO 11140-4:2007.

17.2 Apparatus

17.2.1 Test pack as described in 23.1 for sterilizers exceeding one sterilization module and 23.2 for sterilizers of one module.

17.2.2 Indicator in accordance with EN ISO 11140-3:2009.

17.2.3 Connected services complying with Clause 13.

17.3 Procedure

17.3.1 Select the operating cycle to be tested (see 7.1.13).

17.3.2 Carry out an operating cycle with the sterilizer chamber empty and without any extended drying time.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

17.3.3 Remove the wrapping from the test pack and place the indicator in the sheet located in the approximate centre of the test pack. Reassemble and secure as described in 23.1 or 23.2 as appropriate.

17.3.4 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

17.3.5 Carry out an operating cycle in accordance with the instructions for use.

17.3.6 At the end of the test examine the indicator for compliance with the requirement specified in 8.2.2.

For disposal of used indicators attention should be paid to the instructions for use of the indicator.

18 Air leakage test

18.1 General

The air leakage test is used to demonstrate that the quantity of air leakage into the sterilizer chamber during the periods of vacuum does not exceed a level that will inhibit the penetration of steam into the sterilizer load and will not be a potential cause of re-contamination of the sterilizer load during drying.

18.2 Apparatus

18.2.1 Pressure instruments as described in 23.3.2.

If the sterilizer is fitted with an absolute pressure instrument complying with 23.3.2 this additional instrument is not required.

18.2.2 Stopwatch, with a maximum permissible measurement error of not more than ± 0,5 s over a period of 15 min.

18.2.3 Connected services complying with Clause 13.

18.3 Procedure

18.3.1 Connect the pressure instruments to the sterilizer chamber.

18.3.2 Stabilize the temperature of the sterilizer chamber by carrying out one of the following:

— if the pressure vessel incorporates a heated jacket, carry out an operating cycle with the sterilizer chamber empty;

— if the pressure vessel does not incorporate a heated jacket, ensure that the temperature of the sterilizer chamber is not more than 20 K from ambient.

NOTE As an example, in a closed vessel at 4 kPa pressure, the pressure changes by approximately 0,1 kPa for each 10 K change in temperature, over the range 20 °C to 140 °C; at 7 kPa the change is approximately 0,2 kPa. The test can be compromised if the temperature changes by more than 10 K during the period in which the sterilizer chamber pressure is monitored.

18.3.3 With the temperature stabilized and the sterilizer chamber empty except for fixed furniture and necessary sensors, start the test cycle. When the absolute pressure in the sterilizer chamber is 7 kPa or below close all the valves connected to the sterilizer chamber and stop the vacuum pump. Observe and record the time (t_1) and the pressure (p_1). Wait at least 300 s and not more than 600 s to allow evaporation of condensate in the sterilizer chamber and then observe and record the pressure (p_2) in the sterilizer chamber and the time (t_2). After a further (600 ± 10) s, again observe and record the pressure (p_3) and the time (t_3).

NOTE This procedure can be carried out automatically according to 7.1.14.

18.3.4 At the end of the test calculate the rate of pressure rise for the 600 s period and check for compliance with 8.2.3.

NOTE If the value of (p_2 - p_1) is greater than 2 kPa, this can be due to the initial presence of excessive condensate in the sterilizer chamber.

19 Air detector tests

19.1 General

An air detector can be fitted to a sterilizer and used to determine whether the non-condensable gases contained in the steam delivered to the sterilizer and the air remaining after the air removal stage of the operating cycle are sufficient to cause the sterilizing process to be of uncertain efficacy.

19.2 Air detector, small load

19.2.1 Apparatus

19.2.1.1 Test pack as described in 23.1 for sterilizers exceeding one sterilization module and 23.2 for sterilizers of one module.

19.2.1.2 Thermometric recording instrument as described in 23.3.4.1.

19.2.1.3 Six temperature probes as described in 23.3.3.1.

19.2.1.4 Connection fitting with a pipe thread ISO 228-G1 A through which the temperature probes can be introduced into the sterilizer chamber (see Figure 5).

19.2.1.5 Metering device as described in 23.6.

19.2.1.6 Pressure instruments as described in 23.3.2.

If the sterilizer is fitted with an absolute pressure instrument complying with 23.3.2 this additional gauge is not required.

19.2.1.7 Connected services complying with Clause 13.

19.2.2 Procedure

19.2.2.1 Connect the metering device to the sterilizer chamber using the port specified for this purpose.

19.2.2.2 Introduce the temperature probes into the sterilizer chamber through the temperature probes entry connection and fitting.

19.2.2.3 Carry out an air leakage test as described in Clause 18. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

19.2.2.4 Place one of the temperature probes at the reference measurement point.

19.2.2.5 Select the operating cycle to be tested.

19.2.2.6 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

19.2.2.7 Remove the wrapping from the test pack and place the temperature probes within the test pack at locations as indicated in Figure 6. Reassemble and secure as described in 23.1 or 23.2 as appropriate.

19.2.2.8 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

19.2.2.9 Carry out an operating cycle, but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of the air so that, at the start of the plateau period, the lowest temperature measured within the test pack is not more than 2 K lower than the temperature measured at the reference measurement point.

NOTE It can be necessary to conduct a number of tests in order to establish the air leakage required.

When repetitive tests are performed, a conditioned test pack for each individual test shall be used.

19.2.2.10 Carry out a further air leakage test as described in Clause 18 and then calculate the rate of pressure rise caused by air leakage.

19.2.2.11 If the air leakage causes the sterilizer chamber pressure to rise more than 1,1 kPa/min re-adjust the metering device to cause a pressure rise of (1,0 ± 0,1) kPa/min.

19.2.2.12 Carry out an operating cycle and check that a fault is indicated either during or at the end of the operating cycle.

To facilitate subsequent re-testing, it is recommended to record the setting of the metering device at which the air detector causes a fault to be indicated.

19.3 Air detector, full load

19.3.1 Apparatus

19.3.1.1 Full load, textiles as described in 23.4.

19.3.1.2 Thermometric recording instrument as described in 23.3.4.1.

19.3.1.3 Six temperature probes as described in 23.3.3.1.

19.3.1.4 Connection fitting with a pipe thread ISO 228-G1 A through which the temperature probes can be introduced into the sterilizer chamber (see Figure 5).

19.3.1.5 Metering device as described in 23.6.

19.3.1.6 Pressure instruments as described in 23.3.2.

If the sterilizer is fitted with an absolute pressure instrument complying with 23.3.2 this additional gauge is not required.

19.3.1.7 Connected services complying with Clause 13.

19.3.2 Procedure

19.3.2.1 Ensure that the sterilizer complies with the requirements for the air detector test, small load (see 8.2.4.2).

19.3.2.2 Connect the metering device to the sterilizer chamber using the port specified for this purpose.

19.3.2.3 Connect the test instrument to the sterilizer chamber.

19.3.2.4 Introduce the temperature probes into the sterilizer chamber through the temperature probes entry connection and fitting.

19.3.2.5 Carry out an air leakage test as described in Clause 18. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

19.3.2.6 Place one of the temperature probes at the reference measurement point.

19.3.2.7 Select the operating cycle to be tested.

19.3.2.8 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

19.3.2.9 Remove the wrapping from the standard test pack and place the temperature probes within the standard test pack at locations as indicated in Figure 6. Reassemble and secure as described in 23.1.

19.3.2.10 Place the standard test pack as part of the full load in the sterilizer chamber as described in 23.4.

19.3.2.11 Carry out an operating cycle but during the air removal stage admit air to the sterilizer chamber by means of the metering device. Control the rate of entry of air so that, at the start of the plateau period, the temperature measured at the centre of the test pack is not more than 2 K lower than the temperature measured at the reference measurement point.

NOTE It can be necessary to conduct a number of tests in order to establish the air leakage required.

When repetitive tests are performed, a conditioned test pack for each individual test shall be used.

19.3.2.12 Carry out a further air leakage test as described in Clause 18 and then calculate the rate of pressure rise caused by air leakage.

19.3.2.13 If the air leakage causes the sterilizer chamber pressure to rise more than 1,1 kPa/min re-adjust the metering device to cause a pressure rise of (1,0 ± 0,1) kPa/min.

19.3.2.14 Carry out an operating cycle and check that the air detector causes a fault to be indicated either during or at the end of the test cycle.

To facilitate subsequent re-testing it is recommended to record the setting of the metering device at which the air detector causes a fault to be indicated.

19.4 Air detector function

19.4.1 General

The air detector function test is used to provide assurance that the setting of the air detector remains valid.

19.4.2 Apparatus

19.4.2.1 Test pack as described in 23.1 for sterilizers exceeding one sterilization module and 23.2 for sterilizers of one sterilization module.

19.4.2.2 Metering device as described in 23.6.

19.4.2.3 Connected services complying with Clause 13.

19.4.3 Procedure

19.4.3.1 Connect the metering device to the sterilizer chamber using the port specified for this purpose.

19.4.3.2 Carry out an air leakage test as described in Clause 18. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

19.4.3.3 Select the operating cycle to be tested.

19.4.3.4 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

19.4.3.5 Open the valve on the port specified for this purpose.

19.4.3.6 Set the metering device to the setting determined during the air detector test, small load (see 19.2).

19.4.3.7 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

19.4.3.8 Carry out an operating cycle.

19.4.3.9 At the end of the operating cycle check for compliance with the requirement specified in 8.2.4.4.

19.4.3.10 Close the valve on the port specified for this purpose.

20 Load dryness test

20.1 Load dryness, small load, textiles

20.1.1 General

The load dryness test, small load, textiles, is used to demonstrate that the operating cycle will not cause an unacceptable level of moisture to be absorbed by a standard test pack.

20.1.2 Apparatus

20.1.2.1 Test pack as described in 23.1 for sterilizers exceeding one sterilization module and 23.2 for sterilizers of one module.

20.1.2.2 Balance, capable of weighing a load of at least 8 kg and with a maximum permissible measurement error of ± 1 g.

20.1.2.3 Stop watch.

20.1.2.4 Connected services complying with Clause 13.

20.1.3 Procedure

20.1.3.1 Allow the sheets of the test pack to equilibrate as described in 23.1 or 23.2 as appropriate.

20.1.3.2 Weigh the test pack (m_1).

20.1.3.3 Select the operating cycle to be tested.

20.1.3.4 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

20.1.3.5 Place the test pack above the nominal geometric centre of the horizontal plane of the usable space supported between 100 mm and 200 mm above the sterilizer chamber base.

For sterilizers of one sterilization module the method shall be modified such that the test pack is supported above the base of the sterilizer chamber.

20.1.3.6 Carry out an operating cycle. Start the operating cycle within 60 s of placing the test pack in the sterilizer chamber.

20.1.3.7 Within 120 s after completion of the sterilization weigh the test pack (m_2). Record the result.

20.1.3.8 Calculate the change in moisture content (in per cent) of the test pack using the Formula (2):

$$\Delta m = \frac{(m_2 - m_1)}{m_1} \times 100\% \qquad (2)$$

where

Δm is the change in moisture content, in per cent;

m_1 is the mass of the test pack before operation cycle, in grams;

m_2 is the mass of the test pack after operation cycle, in grams.

20.1.3.9 Check that the result complies with 8.3.1.

20.2 Load dryness, full load, textile

20.2.1 General

The load dryness test, full load, textiles, is used to demonstrate that the operating cycle will not cause an unacceptable level of moisture to be absorbed by a standard test pack located in a full load of textiles.

20.2.2 Apparatus

20.2.2.1 Full load, textiles as described in 23.4.

20.2.2.2 Balance, capable of weighing a load of at least 8 kg and with a maximum permissible measurement error of ± 1 g.

20.2.2.3 Stop watch.

20.2.2.4 Connected services complying with Clause 13.

20.2.3 Procedure

20.2.3.1 Allow the sheets of the standard test pack to equilibrate as described in 23.1.

20.2.3.2 Weigh the standard test pack (m_1).

20.2.3.3 Select the operating cycle to be tested.

20.2.3.4 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

20.2.3.5 Place the test load in the sterilizer chamber as described in 23.4.

20.2.3.6 Carry out an operating cycle. Start the operating cycle within 60 s of placing the test pack in the sterilizer chamber.

20.2.3.7 Within 120 s after completion of the operation cycle weigh the standard test pack (m_2). Record the result.

20.2.3.8 Calculate the change in moisture content (in per cent) of the standard test pack using the Formula (2) in 20.1.3.8.

20.2.3.9 Check that the result complies with 8.3.2.

20.3 Load dryness, metal

20.3.1 General

The load dryness test, metal, is performed with a reference sterilizer load and is used to demonstrate that the operating cycle is unlikely to cause moisture problems in routine production loads.

If moisture problems are identified after the test has been successfully completed the cause can be the type of load and its location in the sterilizer chamber.

20.3.2 Apparatus

20.3.2.1 Test pack, metal as described in 23.5.

20.3.2.2 Balance, capable of weighing a load of at least 15 kg and with a maximum permissible measurement error of ± 1 g.

20.3.2.3 Stop watch.

20.3.2.4 Connected services complying with Clause 13.

20.3.3 Procedure

20.3.3.1 All items used to form the test pack, metal, shall be equilibrated in accordance with 23.5.

20.3.3.2 Weigh the test pack, metal, and record its mass (m_1).

20.3.3.3 Select the operating cycle to be tested.

20.3.3.4 Carry out an operating cycle with the sterilizer chamber empty.

The cycle may be omitted if data are available to demonstrate that conditioning by the previous cycle has a similar effect.

20.3.3.5 Place the test pack, metal, in the usable space, on the lower shelf.

20.3.3.6 Fill the remaining usable space with self-draining steel objects to give a total mass of 15 kg in each sterilization module.

These items shall be equilibrated to ambient conditions.

20.3.3.7 Check that the temperature in the test pack is within (25 ± 2) °C and start an operating cycle within 60 s.

20.3.3.8 At the completion of the operating cycle remove the test pack, metal, from the sterilizer chamber and weigh within a total period of 5 min. Record its mass (m_2).

20.3.3.9 Calculate the change in moisture content (in per cent) using the Formula (3):

$$\Delta m = \frac{(m_2 - m_1)}{m_1} \times 100\% \quad (3)$$

where

Δm is the change in moisture content, in per cent;

m_1 is the mass of the test pack metal before operation cycle, in grams;

m_2 is the mass of the test pack metal after operation cycle, in grams.

20.3.3.10 Check that the result complies with 8.3.3.

21 Steam quality test

21.1 Non-condensable gases

21.1.1 General

The steam quality test, non-condensable gases, is used to demonstrate that the level of non-condensable gases contained in the steam will not prevent the attainment of sterilization conditions in any part of the sterilizer load. The test method described should be regarded not as measuring the exact level of non-condensable gases during normal use of the sterilizer but a method to evaluate compliance with the requirement in 13.3.1. The content of non-condensable gases changes considerably. A peak which occurs for a few seconds can be sufficient to cause a fault during sterilization.

An alternative procedure to the one described in 21.1 may be used providing, that it has been shown to give equivalent results to the method specified in this European Standard.

21.1.2 Apparatus

21.1.2.1 Burette, of 50 ml (nominal) capacity having a scale mark not exceeding 1 ml.

21.1.2.2 Funnel, with parallel sides and with a maximum diameter of 50 mm.

21.1.2.3 Container of 2 000 ml (nominal) capacity and with an overflow pipe to limit the contained capacity to approximately 1 500 ml.

21.1.2.4 Sampling pipe, “U” shaped, made from 6 mm (nominal) outside diameter glass tubing and with a 75 mm (nominal) delivery limb.

21.1.2.5 Small needle valve, having a 1 mm (nominal) orifice and with suitable fittings for connection to the steam pipe and rubber sampling tube.

21.1.2.6 Graduated cylinder of 250 ml (nominal) capacity and having minimum scale mark of 10 ml.

21.1.2.7 Burette stand.

21.1.2.8 Rubber tubing (950 ± 50) mm long, self-draining and having a bore suitable for connection to the sampling pipe and needle valve.

Silicone tubing is permeable to air and therefore should not be used.

21.1.2.9 Temperature measurement system with a maximum permissible measurement error of ± 1 K at 80 °C.

21.1.3 Procedure

21.1.3.1 Connect the needle valve to the steam pipe as shown in Figure 7.

21.1.3.2 Assemble the apparatus as shown in Figure 7 and then locate it in a position, which will allow the free drainage of condensate through the rubber tubing.

21.1.3.3 Fill the container with cold de-aerated water, (water which has been boiled for 5 min and then cooled), until it flows through the overflow pipe.

21.1.3.4 Fill the burette with cold de-aerated water, invert it and place it in the container ensuring that no air is introduced into the burette.

21.1.3.5 With the steam sampling pipe out of the container open the needle valve and purge all air from the pipe. Place the sampling pipe in the container and add more cold de-aerated water until it flows through the overflow pipe.

21.1.3.6 Position the graduated cylinder under the container overflow and locate the steam sampling pipe within the funnel. Adjust the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "steam hammer" to be heard. Ensure that the steam entering the funnel is discharged so that the non-condensable gases are collected in the burette.

21.1.3.7 Close the needle valve, after first noting the "open" position.

21.1.3.8 With the sterilizer chamber empty start an operating cycle and ensure that the graduated cylinder is empty and the container is filled with water. When the steam supply to the sterilizer chamber commences, re-open the needle valve to allow a continuous sample of steam into the funnel sufficient to cause a small amount of "steam hammer" to be heard.

21.1.3.9 Allow the steam sample to condense in the funnel and the non-condensable gases to rise to the top of the burette. Collect the overspill formed by the condensate and the water displaced by the gases in the graduated cylinder. Close the needle valve when the temperature of the water in the container is between 70 °C and 75 °C. Record the volume (V_b) of water displaced from the burette and the volume (V_c) of water collected in the graduated cylinder.

A sequence of tests should be undertaken to determine whether the level of non-condensable gases in the steam is variable.

21.1.3.10 Calculate the content of non-condensable gases in ml per 100 ml of collected condensate using the Formula (4):

$$C_{NCG} = \frac{V_G}{V_C - V_G} \times 100 \qquad (4)$$

where

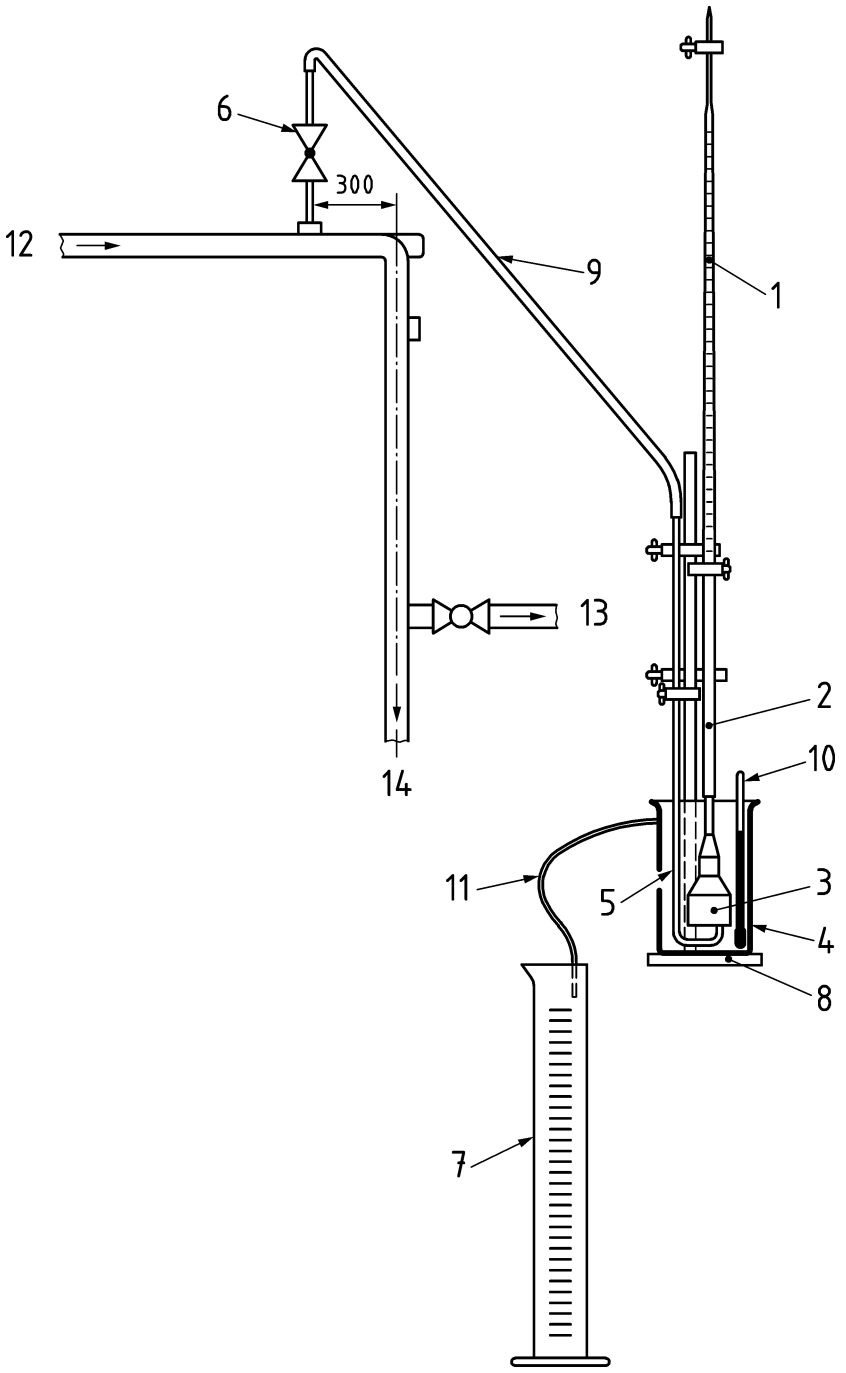
C_{NCG} is the content of non-condensable gases, in ml per 100 ml of condensate from the steam;

V_G is the volume of water displaced from the burette, in ml;

V_C is the volume of water collected in the graduated cylinder, in ml.

21.1.3.11 Carry out at least 3 tests. The maximum result shall comply with the requirements specified in 13.3.1.

Dimensions in millimetres



Key

1	50 ml burette	6	needle valve	12	from steam service
2,9	rubber tubing	7	250 ml measuring cylinder	13	to sterilizer
3	funnel with parallel sides	8	burette stand	14	to trap set
4	2 000 ml container	10	temperature measurement system		
5	steam sampling pipe	11	overflow pipe		

Figure 7 — Diagrammatic representation of the apparatus for the measurement of non-condensable gases

21.2 Dryness

21.2.1 General

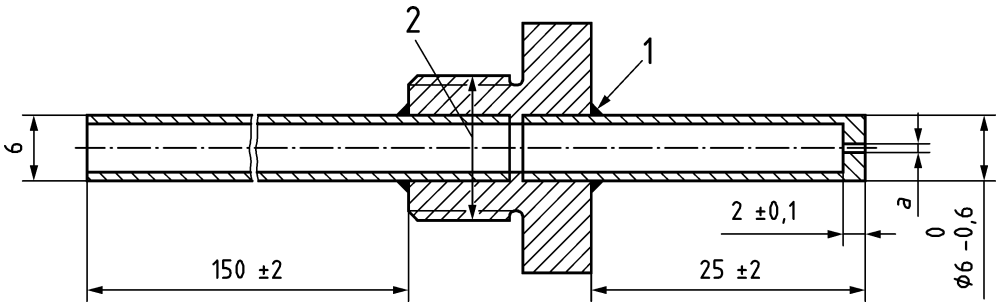
A continuous supply of saturated steam is required for steam sterilization. Excess moisture carried in suspension can cause damp loads, while too little cannot prevent the steam from becoming superheated during expansion into the sterilizer chamber. The accurate measurement of the percentage of moisture content in the steam is difficult and the traditional methods where constant steam flow is required are not suitable for sterilizers. The test method described should be regarded not as measuring the true content of moisture in the steam, but as a method by which the provision of acceptable steam quality can be demonstrated.

An alternative procedure to the one described in 21.2 may be used, providing that it has been shown to give equivalent results to the method specified in this European Standard.

21.2.2 Apparatus

21.2.2.1 Pitot tube constructed as shown in Figure 8 and fitted with a sensing tube having a bore to suit the pressure in the steam pipe from which the sample shall be taken.

Dimensions in millimetres



Steam pressure		Bore a
kPa	bar	mm ± 0,02
up to 300	up to 2	0,8
up to 400	up to 3	0,6
up to 700	up to 6	0,4

Key

1 silver solder

2 pipe thread ISO 228-G 1/4 A

NOTE The values given in the table are for guidance only. When the steam pressure is not within the ranges given, the bore 'a' size can be determined by extrapolation.

Figure 8 — Pitot tube

21.2.2.2 Dewar flask of 1 l nominal capacity.

21.2.2.3 Gland for inserting a temperature probes into the steam pipe.

21.2.2.4 Thermometric recording instrument as described in 23.3.4.1 but having a scale range which includes 0 °C to 200 °C.

21.2.2.5 Two temperature probes as described in 23.3.3.1.

21.2.2.6 Rubber stopper, fitted with two 6 mm (nominal) outside diameter pipes for insertion into the Dewar flask. Nominal lengths of insertion of the pipes 25 mm and 150 mm respectively.

Silicone stopper is permeable to air and therefore should not be used.

21.2.2.7 Rubber tubing, self-draining, having a length of (450 ± 50) mm and a bore suitable for connection to the pitot tube and the longer of the tubes in the rubber stopper.

Silicone tubing is permeable to air and therefore should not be used.

21.2.2.8 Balance, capable of weighing a load of at least 2 kg and with a maximum permissible measurement error of ± 0,1 g.

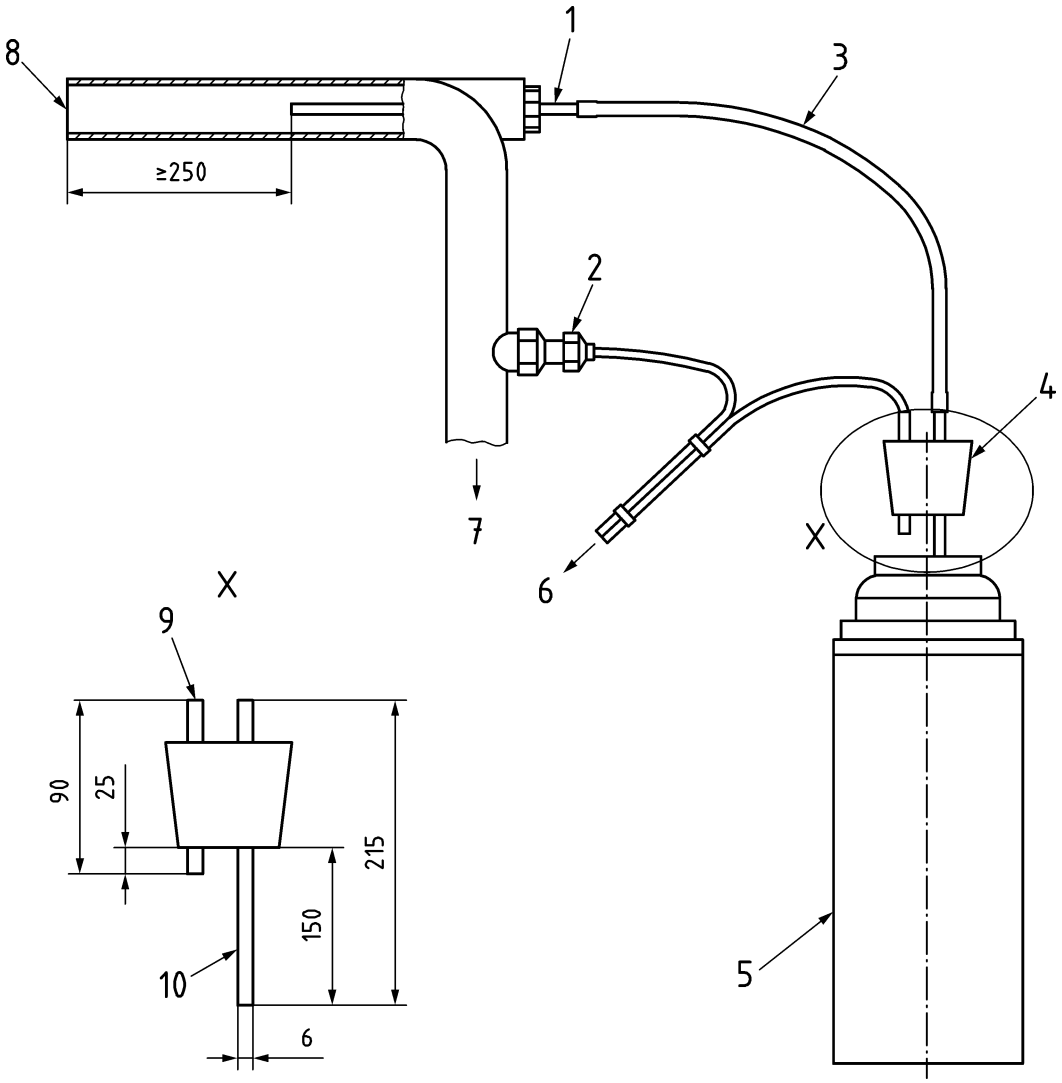
21.2.2.9 Standard test pack as described in 23.1.

21.2.3 Procedure

21.2.3.1 Carry out a steam quality test for non-condensable gases in accordance with 21.1. If the values are not within the limits specified in 13.3.1 the fault shall be corrected before carrying out this test.

21.2.3.2 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 9.

Dimensions in millimetres



Key

1	pitot tube	6	to temperature measuring instrument
2	temperature probes entry gland	7	to sterilizer
3	rubber tube	8	from steam service
4	rubber stopper assembly	9	pipe for temperature probes and vent
5	one-litre Dewar flask	10	sample pipe

Figure 9 — Diagrammatic representation of the apparatus for the measurement of steam dryness value

21.2.3.3 Fit the temperature probes entry gland to the steam service pipe and locate one of the temperature probes at the nominal axial centre of the pipe.

21.2.3.4 Connect the rubber tube to the longer of the pipes in the stopper and then place the stopper in the neck of the Dewar flask, weigh the whole assembly and record the mass (m_e).

21.2.3.5 Where the sterilizer has a number of operating cycles select the textile cycle with a sterilization temperature of 134 °C.

21.2.3.6 Carry out an operating cycle with the sterilizer chamber empty.

21.2.3.7 Remove the stopper and tube assembly and place (650 ± 50) ml of water at a temperature not exceeding 27 °C into the Dewar flask. Replace the stopper and tube assembly, weigh the whole assembly and record the mass (m_s).

21.2.3.8 Support the Dewar flask close to the pitot tube connection point and in a position which is protected from excess heat and draughts.

21.2.3.9 Place the standard test pack as described in 23.1 in the sterilizer chamber.

21.2.3.10 Introduce the second temperature probe through the shorter of the pipes in the stopper and into the Dewar flask.

21.2.3.11 Record the temperature of the water in the Dewar flask (T_1).

21.2.3.12 Carry out an operating cycle. When the steam valve connected to the sterilizer chamber first opens attach the rubber tube to the pitot tube connection point ensuring free drainage of condensate into the Dewar flask.

21.2.3.13 Record the temperature of the steam (T_3).

21.2.3.14 When the temperature of the water in the Dewar flask is approximately 80 °C, disconnect the rubber tube from the pitot tube connection; agitate the flask so that the contents are thoroughly mixed and then record the temperature of the water (T_2).

21.2.3.15 Weigh the Dewar flask complete with water, condensate, stopper and tube (m_f).

21.2.3.16 Calculate the dryness value of the steam from the following Formula (5):

$$D = \frac{(T_2 - T_1)\left[c_{pw}(m_s - m_e) + A\right]}{L(m_f - m_s)} - \frac{(T_3 - T_2)c_{pw}}{L} \quad (5)$$

where

L is the latent heat of saturated steam at temperature T_3, in kilojoules per kilogram;

m_e is the mass of the Dewar flask and rubber stopper assembly, pipes and tube, in kilograms;

m_s is the mass of the Dewar flask, water charge rubber stopper assembly pipes and tube, in kilograms;

m_f is the mass of the flask, water charge, condensate, rubber stopper assembly, pipes and tube, in kilograms;

T_1 is the initial temperature of the water in the Dewar flask, in degrees Celsius;

T_2 is the final temperature of the water, and condensate in the Dewar flask, in degrees Celsius;

T_3 is the temperature of saturated steam delivered to the sterilizer, in degrees Celsius;

c_{pw} is the specific heat capacity of water (4,18 kJ/kg · K);

D is the dryness value of the steam;

A is the effective heat capacity of the apparatus (0,24 kJ/K).

NOTE The effective heat capacity of the Dewar flask is stated. Other assemblies can be used provided the heat capacity [see A in the Formula (5)] can be verified and used in the calculation.

21.2.3.17 Carry out at least 3 tests. The result shall comply with the requirements specified in 13.3.2.

21.3 Superheat

21.3.1 General

The steam quality test, superheat is used to demonstrate that the steam supply system is adequate to prevent the steam from being superheated at the connection point. The test method described in 21.3 uses a low volume sample, continuously taken from the centre of the steam service pipe.

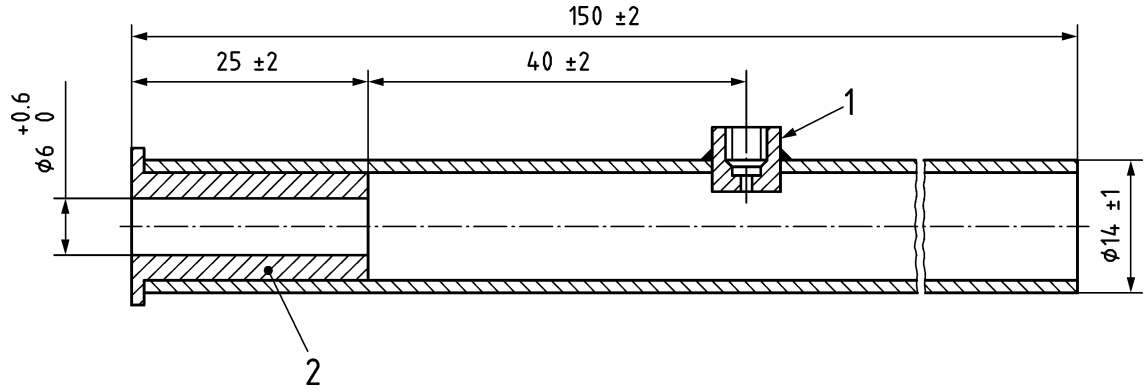
An alternative procedure to the one described in 21.3 may be used providing that it has been shown to give equivalent results to the method specified in this European Standard.

21.3.2 Apparatus

21.3.2.1 Pitot constructed as shown in Figure 8 and having a nominal bore of 1 mm.

21.3.2.2 Expansion tube as shown in Figure 10.

Dimensions in millimetres



Key

1 suitable fitting for locating a temperature probes into the tube

2 polyamide 66 socket, fit into the tube

Figure 10 — Expansion tube

21.3.2.3 150 mm (nominal) length of 15 mm pipe lagging.

21.3.2.4 Thermometric recording instrument as described in 23.3.4.1.

21.3.2.5 Two temperature probes as described in 23.3.3.

21.3.2.6 Gland for inserting a temperature probe into the steam pipe.

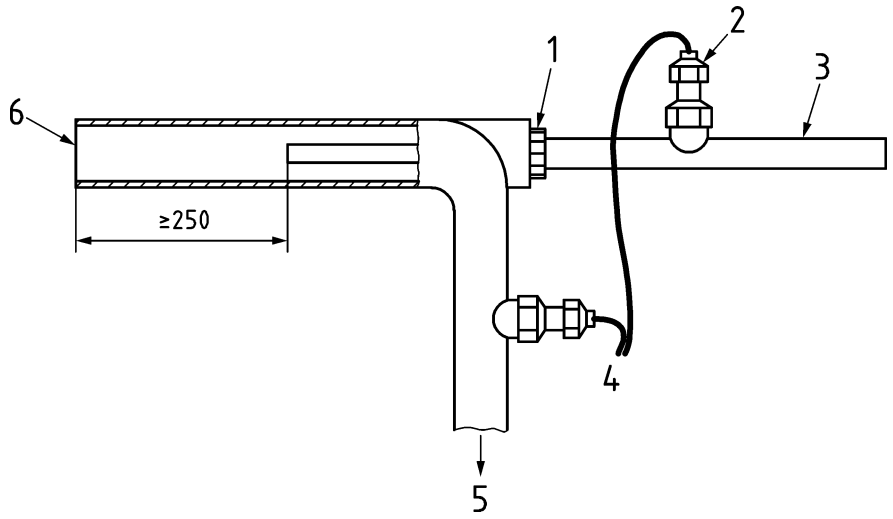
To reduce heat transfer between the fitting and temperature probe, insulation is recommended.

21.3.2.7 Full load, textiles as described in 23.4.

21.3.3 Procedure

21.3.3.1 Fit the pitot tube concentrically within the steam service pipe as shown in Figure 11.

Dimensions in millimetres



Key

1	pitot tube	4	to temperature measuring instrument
2	temperature probes fitting	5	to sterilizer
3	expansion tube	6	from steam service

Figure 11 — Diagrammatic representation of the apparatus for the measurement of superheat

21.3.3.2 Fit the temperature probe entry gland to the steam pipe and locate one of the temperature probes at the nominal axial centre, as shown in Figure 9.

21.3.3.3 Through the gland provided, locate the second temperature probe at the approximate horizontal axis of the expansion tube.

21.3.3.4 Attach the pipe lagging around the expansion tube and push the expansion tube on to the pitot.

21.3.3.5 Connect the temperature probes to the thermometric recording instrument.

21.3.3.6 Carry out an operating cycle with the sterilizer chamber empty.

21.3.3.7 Place the full load, textiles in the usable space as described in 23.4 and within 5 min carry out a further operating cycle.

21.3.3.8 At the end of the operating cycle check the temperature recordings

— for compliance with the requirement specified in 13.3.3,

— to confirm that the temperature measured in the steam pipe did not differ by more than 3 K from that measured in the steam pipe during the steam quality, dryness test.

NOTE This temperature is a parameter from which the variability of the steam pressure between sequential cycles can be assessed. A higher temperature difference can cause operational problems from the moisture content in the steam.

21.4 Sampling of steam condensate

21.4.1 General

An alternative sampling procedure to the one described in 21.4 may be used providing it has been shown not to contaminate the sample.

21.4.2 Apparatus

21.4.2.1 Pitot tube constructed as shown in Figure 8 and fitted with an orifice having a nominal bore to suit the pressure in the steam service pipe from which the sample shall be taken.

21.4.2.2 Polypropylene tube (5 000 ± 50) mm long and having a bore (6 ± 1) mm.

21.4.2.3 Two graduated polypropylene bottles, each having a nominal capacity of 250 ml.

21.4.2.4 Container with a minimum capacity of 8 l.

21.4.2.5 Approximately 1 kg of ice.

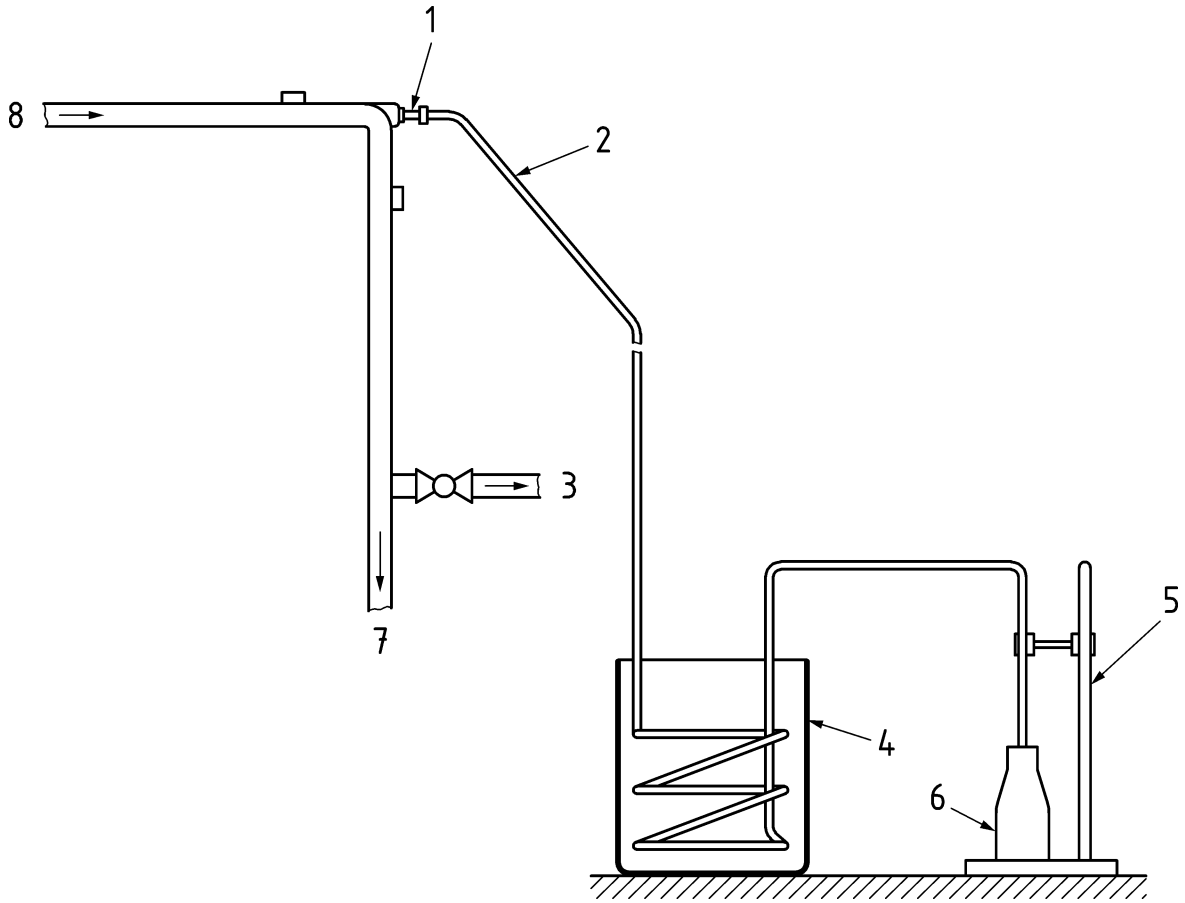
21.4.2.6 A clip or connector which can be used to secure the polypropylene tube to the pitot tube.

21.4.2.7 A piece of metal of a mass and size suitable for retaining a number of coils of the polypropylene tube in the container.

21.4.2.8 Small volume of concentrated hydrochloric acid.

21.4.3 Procedure

21.4.3.1 Fit the pitot tube into the steam service pipe as shown in Figures 9 and 12.



Key

1	pitot tube	5	burette stand
2	polypropylene tube, coiled as shown	6	250 ml polypropylene bottle
3	to sterilizer	7	to trap set
4	8 000 ml container	8	from steam service

Figure 12 — Apparatus for sampling steam condensate

21.4.3.2 Using the clip, secure the polypropylene tube to the pitot tube connection.

21.4.3.3 Open the valve on the steam service pipe and discharge steam condensate through the polypropylene tube for a minimum period of 5 min. Ensure the condensate drains freely.

21.4.3.4 Clean and rinse both the inside of the polypropylene tube and the two bottles with distilled water and then dry them. Close the steam valve.

21.4.3.5 Arrange the burette and one of the bottles as shown in Figure 12.

21.4.3.6 Coil part of the polypropylene tube into sufficient number of coils to ensure condensation of steam. Then place this part of the tube in the container and retain by the piece of metal.

21.4.3.7 Fill the container with the ice and sufficient quantity of cold water to immerse the tubing.

21.4.3.8 Open the steam service valve.

21.4.3.9 Allow at least 50 ml of steam condensate to discharge to waste and then collect 250 ml (nominal) in the first graduated bottle.

21.4.3.10 Seal this polypropylene bottle.

21.4.3.11 Collect 250 ml of condensate and add sufficient concentrated hydrochloric acid to the second polypropylene bottle to give a final concentration of c_{HCl} = 0,1 mol/l and seal the bottle. Mark the bottle "for trace metal analysis".

22 Rate of pressure change

22.1 General

The dynamic sterilizer chamber pressure test is used to demonstrate that the rate of pressure change occurring in the sterilizer chamber during an operating cycle does not exceed a level which can cause damage to the package.

NOTE This level is used as a performance requirement for packaging materials complying with EN ISO 11607-1 and EN 868 series and has been chosen on the basis of a compromise between the need to provide cost effective packaging and short efficacious sterilization processes.

22.2 Apparatus

22.2.1 Pressure recording instrument as described in 23.3.4.2.

22.3 Procedure

22.3.1 Attach the pressure recording instrument to the test connection (see 4.3.3.2).

22.3.2 Carry out a further air leakage test as described in Clause 18 and then calculate the rate of pressure rise caused by air leakage. Do not proceed if the rate of pressure rise caused by air leakage exceeds that specified in 8.2.3.

22.3.3 Select the operating cycle to be tested.

22.3.4 Carry out an operating cycle with the sterilizer chamber empty and observe and record the times, temperatures and pressures at all significant parts of the operating cycle.

22.3.5 At the completion of the test, proceed as follows:

— examine the records specified above for compliance with the cycle specification;

— check that the pressure difference for any interval of 3 s complies with Clause 10.

23 Test apparatus, equipment and material

23.1 Standard test pack

23.1.1 This test pack is used to check that, at the levels at which the cycle parameters are set, rapid and even penetration of steam into the pack is attained.

It is used for the Bowie and Dick test, the small load test, air detector tests, load dryness test, textiles and can be used with other materials to form a full load.

The standard test pack is a reusable item that may be used for testing continuously if the requirements in 23.1.3 and 23.1.4 are met. The environmental aspects regarding cleaning intervals as well as means for cleaning and conditioning should be considered.

23.1.2 The test pack shall be composed of plain cotton sheets, each bleached to a good white and having an approximate size of 900 mm x 1 200 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft (27 ± 5), the weight shall be (185 ± 5) g/m^2. The edges, which are no self-edges shall not be hemmed.

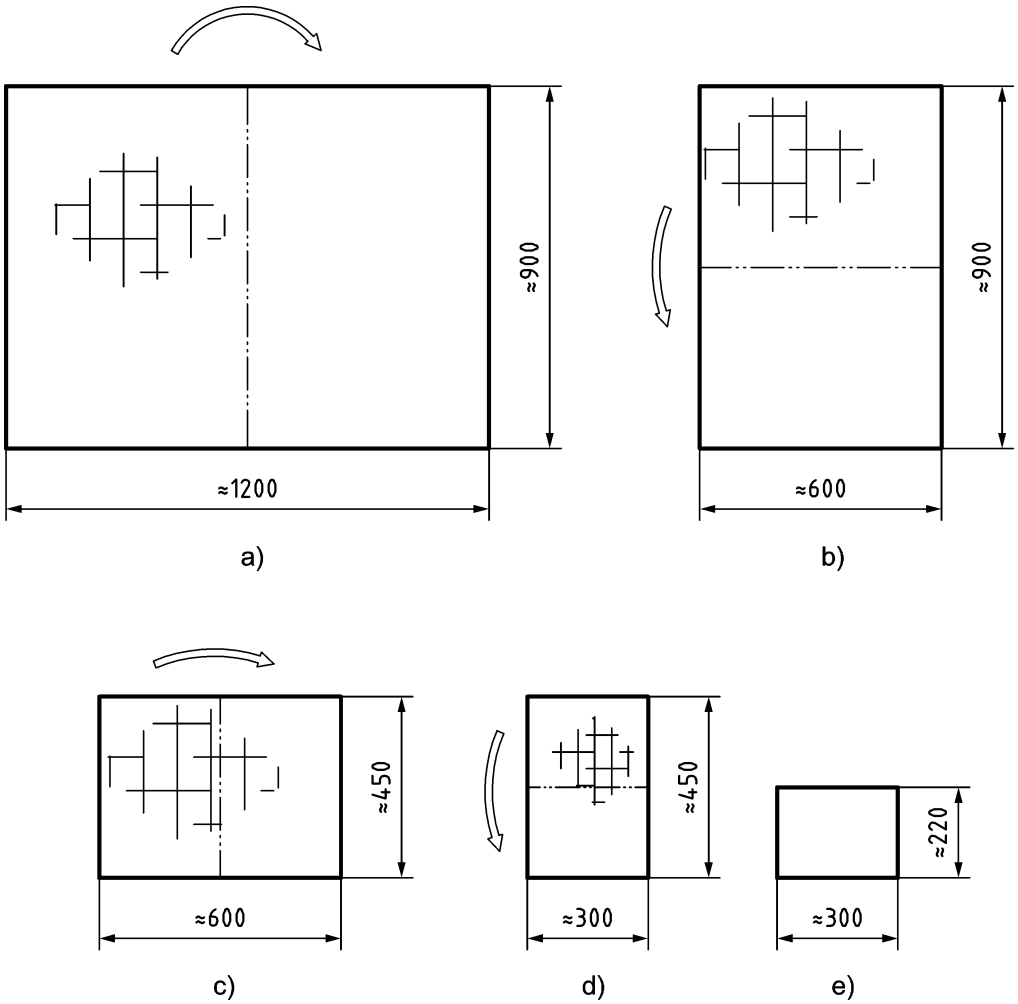
23.1.3 The sheets shall be washed when new or soiled and shall not be subjected to any fabric conditioning agent during laundering.

NOTE Fabric conditioning agents can affect the characteristics of the fabric and can contain volatiles which will contribute to the non-condensable gases in the sterilizer.

23.1.4 The sheets shall be dried and then allowed to equilibrate in a working environment of between 20 °C to 30 °C and a relative humidity of 40 % to 60 %.

23.1.5 The test pack shall be folded and assembled in accordance with Figure 13.

Dimensions in millimetres



Key

a) 1 layer, unfolded

b) 2 layers, 1-times folded

c) 4 layers, 2-times folded

d) 8 layers, 3-times folded

e) 16 layers, 4-times folded

Figure 13 — Folding and assembling the test pack

23.1.6 After equilibration the sheets shall be folded to approximately 220 mm × 300 mm and stacked to a height of approximately 250 mm after compression by hand. The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. The total weight of the pack shall be (7,0 ± 0,14) kg.

NOTE Approximately 30 sheets are required for this.

After processing the pack shall be removed from the sterilizer and aired in a working environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 %. The pack may then be used for testing. The pack shall be equilibrated in a working environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 % between uses.

23.1.7 Prior to use the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C to 30 °C and 40 % to 60 % relative humidity before it is used for test purposes.

NOTE Pack temperature and humidity can be measured using a sword hygrometer.

23.1.8 Test packs comprising different materials and of different sizes and weights may be used provided equivalence with the requirements for the test in which the standard test pack is used is demonstrated.

23.2 Reduced test pack

23.2.1 The reduced test pack is used in a one sterilization module sterilizer to check that, at the levels at which the cycle variables are set, rapid and even penetration of steam into the pack is attained.

It is used for the Bowie and Dick test, the small load tests, air detector tests, load dryness test, textiles and can be used with other materials to form a full load.

The test pack is a reusable item that may be used for testing continuously if the requirements in 23.2.3 and 23.2.4 are met. The environmental aspects regarding cleaning intervals as well as means for cleaning and conditioning should be considered.

23.2.2 The reduced test pack shall be composed of plain cotton sheets, each bleached to a good white and having an approximate size of 900 mm x 1 200 mm. The number of threads per centimetre in the warp shall be (30 ± 6) and the number of threads per centimetre in the weft (27 ± 5), the weight shall be (185 ± 5) g/m^2. The edges, which are no self-edges shall not be hemmed.

23.2.3 The sheets shall be washed when new or soiled and shall not be subjected to any fabric conditioning agent during laundering.

NOTE Fabric conditioning agents can affect the characteristics of the fabric and can contain volatiles which will contribute to the non-condensable gases in the sterilizer.

23.2.4 The sheets shall be dried and then allowed to equilibrate in a working environment of between 20 °C to 30 °C and a relative humidity of 40 % to 60 %.

23.2.5 The reduced test pack shall be folded and assembled in accordance with Figure 13.

23.2.6 After equilibration the sheets shall be folded to approximately 220 mm × 300 mm and stacked to a height of approximately 150 mm after compression by hand. The pack shall be wrapped in a similar fabric and secured with tape not exceeding 25 mm in width. The total weight of the pack shall be (4,0 ± 0,14) kg.

NOTE Approximately 17 sheets are required for this.

After processing the pack shall be removed from the sterilizer and aired in a working environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 %. The pack may then be used for testing. The pack shall be equilibrated in a working environment of between 20 °C to 30 °C and relative humidity of between 40 % to 60 % between uses.

23.2.7 Prior to use the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between 20 °C to 30 °C and 40 % to 60 % relative humidity before it is used for test purposes.

NOTE Pack temperature and humidity can be measured using a sword hygrometer.

23.3 Test instruments

23.3.1 General

Other measuring system may be used as long as they fulfil all the requirements of this standard. When other methods are used the impact of characteristics such as additional mass and heat conductivity shall be considered.

23.3.2 Pressure instruments

23.3.2.1 A test measurement system shall be used to check pressure indicating and recording instruments.

The system may include one or more test gauges or measuring system incorporating transducers.

23.3.2.2 An absolute pressure transducer shall:

a) include the range 0 kPa to 400 kPa;

b) have a time constant for rising pressure $\tau_{0,9} \leq 0{,}12$ s.

NOTE The absolute pressure transducer includes the sensor of pressure, the signal conversion elements and transmitter (if applicable).

23.3.2.3 The pressure measuring chains:

a) shall indicate in kilopascals or bars as absolute pressure;

b) shall include the range 0 kPa to 400 kPa; indication as absolute pressure;

c) resolution shall not exceed 0,1 kPa;

d) maximum permissible measurement error shall not exceed 1 kPa;

e) if used for the air leakage test have a scale range specified for the sterilizer and the measurement error not exceeding 0,1 kPa over any pressure difference of 1,5 kPa during the test.

23.3.2.4 Calibration of each test system shall be carried out using a working or reference standard, which is traceable to the national standard or a primary standard.

23.3.2.5 Each test system shall be calibrated in accordance with the instructions for use of the system.

23.3.3 Temperature instruments

23.3.3.1 Probes for testing

23.3.3.1.1 Temperature probes shall be either platinum resistance thermometer and comply with Class A of EN 60751:2008, Table 3 or thermocouple and comply with one of the tables of Tolerance Class 1 of EN 60584-1:2013, Table 1 and have a response time in water of $\tau_{90} \leq 0,5$ s when tested in running water with > 0,2 m/s according to EN 60751:2008, 6.5.2.

NOTE A possible discrepancy between requirements in 23.3.3.1.1 and 23.3.3.1.2 was noted and is still under discussion.

Other probes for testing of demonstrated equivalence may be used.

23.3.3.1.2 The cross sectional area of any part of the probe for testing and its connecting wires within the usable space shall not exceed 3,1 mm^2.

23.3.3.1.3 The performance characteristic for the temperature probes shall not be affected by the working environment in which it is placed, e.g. pressure, steam, or vacuum.

23.3.3.2 Temperature measuring chains

23.3.3.2.1 The temperature measuring chains, including temperature instruments specified in 23.3.3:

a) shall indicate in degrees Celsius;

b) shall have a scale which includes the range 0 °C to 150 °C;

c) shall have a resolution of 0,1 K or better;

d) shall have a maximum permissible measurement error (without the temperature probes) of ± 0,25 % referring to the scale range 0 °C to 150°C;

e) shall have a maximum permissible measurement error not exceeding 0,5 K at the used temperatures;

f) the test measuring chain shall have a maximum permissible measurement error not exceeding 0,2 K, if the temperature measuring chain is used for calibration or adjustment of measuring chains of the sterilizer, which are used to record and indicate temperature;

g) calibration shall be carried out using a working or reference standard which is traceable to the national standard or a primary standard, at the value(s) used to record the sterilization process and to assess the results of the tests, in which the measuring chain is used;

h) have temperature error compensation such that a measurement error caused by a change in the ambient temperature does not exceed 0,04 K/K.

23.3.3.2.2 When installed in the place of use, the calibration of the temperature measuring chains shall be verified with an independent temperature reference source at a temperature within the sterilization temperature band.

23.3.4 Recording instruments

23.3.4.1 Thermometric recording instrument

23.3.4.1.1 A thermometric recording instrument(s) shall record the temperatures measured in the locations specified in the tests described in this European Standard. It can also be used to check thermometric instruments fitted to the sterilizer.

23.3.4.1.2 The thermometric recording instrument(s) shall:

a) record the temperatures from a minimum of seven temperature measuring chains, each complying with 23.3.3.2;

b) record temperatures in the range and scale specified in 23.3.3.2;

c) the channels can be multiplexed or independent of each other;

d) the sampling rate for each channel shall be 1 s or less.

The temperature measured by all temperature measuring chains shall not differ by more than 0,5 K at the used sterilization temperatures.

The thermometric recording instrument shall produce a record, which shall be retrievable and also in a form, which is readable by other systems, e.g. software systems.

NOTE Access to the record can be protected by key, code or tool.

A thermometric recording instrument producing electronic records shall be designed to ensure the integrity of the records while it exists in the recorder.

Use all data sampled for the interpretation of the results.

23.3.4.2 Pressure recording instrument

23.3.4.2.1 A pressure recording instrument shall be used in conjunction with a pressure sensitive measuring element to record the absolute pressure within the sterilizer chamber during a test operating cycle. It can also be used to check the pressure instrument(s) fitted to the sterilizer.

23.3.4.2.2 The pressure recording instrument may be integrated into the temperature recording instrument as an additional channel calibrated for pressure. All data sampled shall be used for the interpretation of the results.

The recording instrument(s) shall:

a) record the absolute pressure from a pressure measuring chain, complying with 23.3.2.3;

b) record absolute pressures in the range and scale specified in 23.3.2.3;

c) the sampling rate for each channel shall be 1 s or less.

The pressure recording instrument shall produce a record, which shall be retrievable and also in a form, which is readable by other systems, e.g. software systems.

NOTE Access to the record can be protected by key, code or tool.

A pressure recording instrument producing electronic records shall be designed to ensure the integrity of the records while it exists in the recorder.

23.4 Full load, textiles

23.4.1 This test load is designed to represent the maximum mass of textiles which can be processed in the sterilizer and is used to demonstrate that, at the levels at which cycle parameters are set, rapid and even penetration of steam into the centre of a load occurs and the sterilizing condition is achieved.

The full load textiles consist of reusable items that may be used for testing continuously if the requirements in 23.4.3 and 23.4.4 are met. The environmental aspects regarding cleaning intervals as well as means used for cleaning and conditioning should be considered.

23.4.2 The full load shall comprise folded sheets and a standard test pack as described in 23.1.

23.4.3 Each sheet shall contain at least 50 % m/m of cotton fibre and have a mass per unit area of approximately 200 g/m^2. The sheets shall be laundered when new or soiled and not subjected to any fibre conditioning agent (see 23.1).

23.4.4 The sheets shall be dried and then aired for at least 1 h in a working environment between 20 °C and 30 °C and at a relative humidity 40 % to 60 %.

NOTE If the working environment in which the sheets are aired or stored is dryer than stated, exothermic re-hydration of the test pack in the sterilizer can cause wrong results.

23.4.5 After airing, the sheets shall be folded and laid one on top of the other to form a stack with a mass of (7,5 ± 0,6) kg.

23.4.6 The standard test pack shall be located within the sterilizer chamber and in a position previously identified and noted in the instructions for use. In the absence of this information the test pack shall be located within the usable space and where possible approximately 100 mm above the geometric centre of the base of the sterilizer chamber. The remainder of the usable space shall be loaded with stacks of sheets each with the layers of fabric in the baskets dimensionally similar to one sterilization module or they can be loose within the sterilizer chamber.

23.4.7 The mass of fabric in the test load shall be equivalent to (7,5 ± 0,6) kg per sterilization module.

23.5 Test pack, metal

23.5.1 This test pack is used to represent a unit of metal objects, e.g. instruments, which is difficult to dry.

The test pack metal consists of reusable items that may be used for testing continuously.

Tolerances of measures (see Figure 14) shall comply with EN 22768-1:1993.

23.5.2 Sterilizer load shall comprise a test box containing a wire mesh basket and a quantity of metal screws wrapped in textile material.

23.5.3 The test box shall:

— have a sealed lid and comply with the detail given in Figure 14;

— not have additional holes to those shown in Figure 14;

— be constructed from 1 mm (nominal) thick austenitic stainless steel.

NOTE For stainless steel plates see EN 10088–2.

23.5.4 The wire mesh basket shall:

— be constructed from austenitic stainless steel;

NOTE For stainless steel wires see EN 10088–3.

— have a nominal grid size on the base of 5 mm × 5 mm;

— have a nominal grid size on the sides of 5 mm × 5 mm;

— have a load surface separated from the support surface by approximately 6 mm;

— be capable of supporting an evenly distributed load of 10 kg;

— have external dimensions of length (480 ± 5) mm, width (254^{0}_{-4}) mm, and height (50^{+5}_{0}) mm;

— have a mass of (1,3 ± 0,1) kg.

23.5.5 The metal screws used in the test load shall:

— be hexagon head stainless steel screws M12 × 100 fully threaded;

NOTE For hexagon head stainless steel screws see ISO 4017.

— have a total mass of (8,6 ± 0,1) kg;

— be cleaned, degreased and dried.

23.5.6 The textile material used in the test shall:

— be a plain cotton sheet, bleached white and having an approximate size of 900 mm × 1 200 mm;

— have a number of threads per centimetre in the wrap of (30 ± 6) and a number of threads per centimetre in the weft of (27 ± 5);

— be washed when new and when soiled and not subjected to any fabric conditioning agent;

— be dried and aired;

— be stored for at least 1 h in a working environment between 20 °C and 30 °C at a relative humidity between 40 % to 60 %.

NOTE This requirement assumes that before packaging components have been allowed to equilibrate to the working environment.

23.5.7 All metal parts in the test pack shall be equilibrated to a temperature of (23 ± 2) °C.

23.5.8 The test pack shall be assembled as follows:

— place the wire mesh basket onto the sheet;

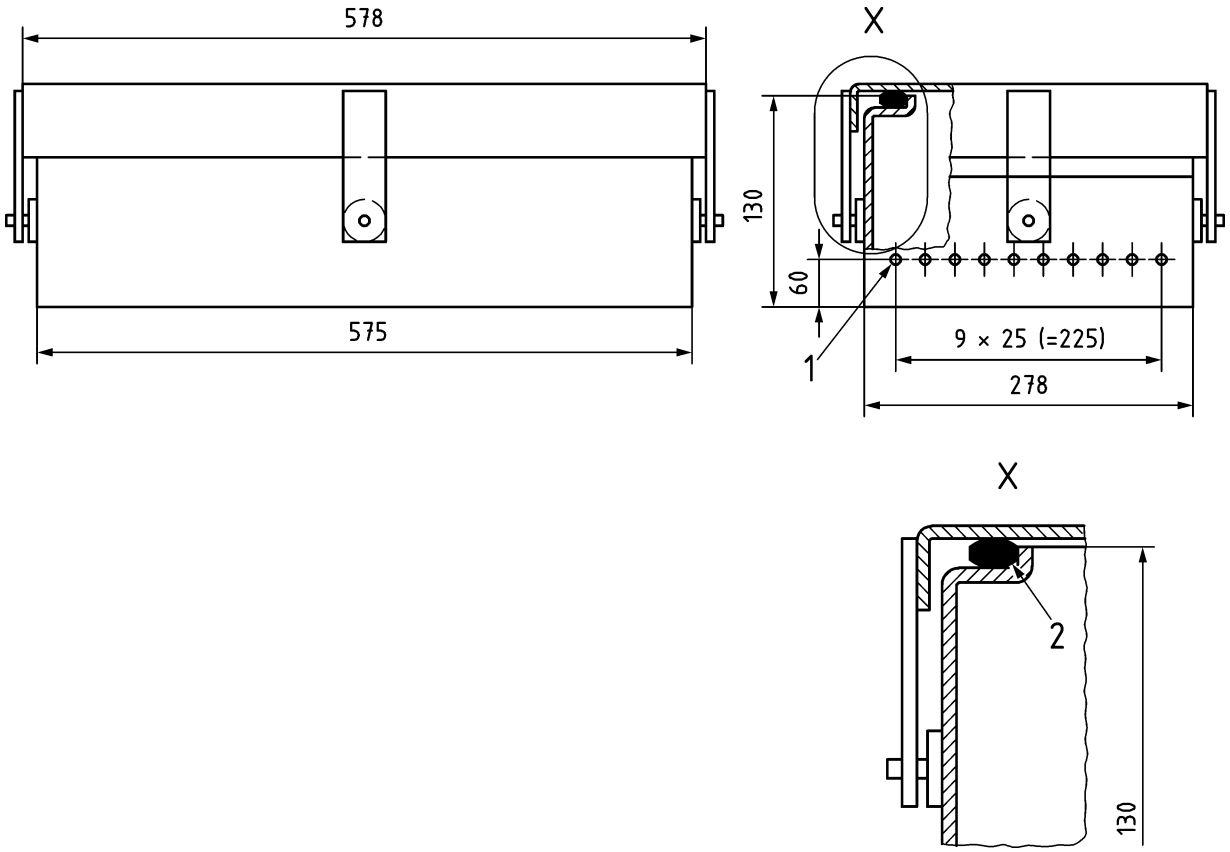
— distribute the screws randomly throughout the wire mesh basket in a manner which allows the free drainage of condensate;

— fold the sheet over the wire mesh basket containing the screws;

— place the wrapped wire mesh basket into the test box.

23.5.9 Store the test pack until required in a working environment maintained within the limits specified for the items used to form the test pack.

Dimensions in millimetres



Key

1 10 drill holes Ø 4 mm on both end walls

2 silicone sealing Ø 6 × 1 550, glued to the lid and compressed to 90 % of its diameter when the lid is closed

Figure 14 — Details of test box for test load dryness, metal

23.6 Metering device

23.6.1 A metering device is used to admit air to the sterilizer chamber to test that a device will cause a failure to be indicated when the mass of air present in the sterilizer chamber is sufficient for the operating cycle to be of uncertain efficacy.

23.6.2 The metering device shall be capable of controlling the flow of air into an evacuated sterilizer chamber.

23.6.3 The metering device shall be adjustable and have a range which includes a flow equivalent to 0 ml/min to 5 ml/min per liter of the sterilizer chamber.

23.6.4 The measurement precision between 10 % and 90 % of the setting range shall not exceed ± 5 %.

24 Documentation to be supplied with the sterilizer

The documentation to be supplied with the sterilizer shall include:

a) evidence of verification of the calibration of all measuring system;

NOTE For measurement traceability and estimation of measurement uncertainty see EN ISO/IEC 17025:2005, 5.4.5, 5.5.4 and 5.6.

b) documents and records to be supplied with the sterilizer as specified in the references given in Clause 11 or Annex F, respectively;

c) evidence of verification of each safety function and that the function of each safety protective device and safety accessory and its setting complies with the specification (see Clause 11);

d) identification of the software release (if applicable);

e) details of the settings of the automatic controller characterized by physical conditions such as pressures, temperatures and times taken for each significant part for each operating cycle;

f) the setting of the air detector if one is fitted;

g) declaration of compliance with the requirements of this European Standard (see Clause 14);

h) declaration of additional cycles and their intended use not covered by this European Standard.

25 Information to be supplied with the sterilizer

25.1 The objective of Clause 25 is to enable the purchaser to prepare for installation, to install and operate the sterilizer and to perform routine maintenance.

Information shall comply with EN 1041:2008+A1:2013 considering the technical knowledge, education and training of different sterilizer operator categories. In addition, the information provided with the sterilizer shall be drafted according to the principles of EN ISO 12100:2010, 6.4 [except 6.4.5.2 b)]. The information shall be in a language which can be easily understood by users, as determined by the user's member state concerned. The information specified in 25.3 shall accompany the sterilizer delivery. The information specified in 25.2, 25.4 and 25.5 shall be provided either in one part prior to sterilizer delivery or in two parts, prior to delivery and before installation qualification.

Consideration should be given to national regulations for installation and operation of the equipment that can apply in the country of use.

25.2 Before delivery of the sterilizer and for installation qualification, the following information shall be provided to the purchaser:

a) installation instructions, including the overall dimensions and overall mass of the sterilizer, the floor loading at each support when the sterilizer pressure vessel is filled with water, the clearance required for access (see 4.4.2) and the masses of the principal heavy components; additional space should be kept for loading and unloading operation;

b) type of electricity supply, e.g. DC or AC, single or three phase, voltage and frequency including minimum and maximum values and maximum continuous power in kilowatts and kilovolt-amperes;

c) the maximum flow and usage rate and the maximum and minimum supply pressure for steam;

d) the quality and quantity of the steam to be supplied for use with the sterilizer, (see Table 4);

e) the minimum and maximum pressure and flow rate at minimum pressure, minimum and maximum temperature, volume used per cycle for water and feed water;

f) the minimum and maximum pressure and flow at minimum pressure for compressed air;

g) the total thermal power in watts transmitted from the sterilizer when it is operated in an ambient temperature of (23 ± 2) °C in still air when the sterilizer door is open and also when the sterilizer door is closed;

   For ergonomic and process performance reasons the user should take into account the heat transmitted by the sterilizer and sterilized load when designing ventilation systems;

h) the thermal power in watts transmitted from the front of the sterilizer when it is operated in an ambient temperature of (23 ± 2) °C in the working area and when the sterilizer door is open and also when it is closed;

i) sound emission levels according to 9.1.2 and 9.1.3, in Decibel (rounded off next integer);

j) the sound power level for any additional devices supplied for use with the sterilizer;

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

   NOTE 1 Additional space can be required for loading and unloading equipment.

l) the maximum flow of water and condensed steam to the drain;

m) the quality including the maximum hardness value, the range of pH and the conductivity of the feed water (see Table B.1);

n) instructions for disposal of the sterilizer wrapping (see 12.5);

o) instructions for handling during transport and storage such as conditions for stability, orientation, temperature, humidity and pressure (see 12.5);

p) any additional device e.g. air compressor which is necessary for the operation of the sterilizer and which is installed separately from it;

q) details of services including disconnection devices required for supply, drainage and ventilation;

r) environmental classification for the sterilizer (see 13.7);

s) ambient lighting and the appropriate lighting for the maintenance area(s) (see 13.4);

   NOTE 2 Guidance for lighting is provided in EN ISO 12100:2010, 6.2.8 and EN 1837.

t) maximum values of ambient temperature and relative humidity in the location where the sterilizer is installed.

25.3 The following information shall be available upon the sterilizer delivery:

NOTE 1 For the possibility of electronic instructions for use of medical devices see: Commission Regulation (EU) Nº 207/2012 of 9 March 2012.

a) instruction for putting into service;

b) instructions for use, short form of manual;

c) instructions for use with at least:

1) identification of sterilizer manufacturer;

2) the CE-mark including, if applicable, the notified body identification number indicating the sterilizer as being a medical device;

3) safety indications and warning advice;

4) intended use;

5) type of load and its packaging;

6) sterilizer chamber volume;

7) sterilizer chamber dimensions;

8) design pressure, allowable working pressure and allowable temperature;

9) description of the available operating cycles;

10) description of controls, indicating and recording devices;

11) description and setting of safety devices;

12) information on residual risk;

13) recommendation(s) for use of personal protective equipment;

14) instructions for malfunctions;

15) characteristics of consumables and accessories dedicated to the sterilizer;

16) instructions for cleaning and cleaning agents to be used;

17) instructions for disinfection and disinfection agents to be used;

NOTE 2 Parts include panelling and accessible internal surfaces of the sterilizer chamber.

18) date of issue or date of latest revision of the instructions for use;

d) dimensions of the usable space of the pressure vessel;

e) loading capacity expressed in sterilization modules in integer numbers;

f) a description of the operating cycle together with:

1) the maximum operating temperature;

2) the maximum pressure change rate as specified in Clause 10;

3) a diagram of the pressure versus time relationship for the operating cycle(s);

4) a temperature versus time record of the operating cycle for each standard test load applicable to the sterilizer supplied;

5) cycle parameters and their tolerances (see 7.1.2);

6) the location of the reference measurement point (see 7.1.3);

g) documentary evidence to show the relationship between the coolest part of the usable space and the reference measurement point shall be provided, if requested.

25.4 Before the installation qualification, the following information shall be provided:

a) maintenance manual including:

1) maintenance and tests and the frequency they should to be carried out;

2) electrical diagrams and circuits;

3) hydraulic plans and circuits;

4) information on safety functions including description and setting of protective devices and safety components (see Clause 11);

5) a complete spare parts list;

6) a list of the tools necessary for maintaining and testing the apparatus (only special tools);

7) list of service stations;

8) guidance on tracing and rectifying causes of malfunction;

9) warnings about handling of possibly hazardous items (e.g. heavy, hot, wet, sharp, with chemical or microbiologic contaminants);

b) instructions for disposal of the sterilizer, the consumables, accessories and packaging;

c) limits from the rate of pressure rise caused by air leakage;

d) information on the tests to be performed during installation qualification and operational qualification (see also Annex D).

25.5 The information required by 25.2, 25.3 and 25.4 shall be provided for any steam generator included within the panelling of the sterilizer, if applicable.

Annex A
(informative)

Environmental aspects

Water according to common sense in both its gaseous and liquid state of aggregation is generally considered not toxic, irritating or allergenic, and has no detrimental impact on the local environment or human beings, except for the risk of burn injuries from accidental human exposure.

The environmental impact generated during testing and normal use by a sterilizer delivering a steam sterilization process is mainly due to:

— the design and selection of materials;

— preproduction activities that use energy and other services;

— the manufacture of the sterilizer including the use of material resources, energy and consumables;

— packaging, transportation and installation;

— maintenance activities including the extent of repair, testing, inspections, cleaning and the use of protecting and cleaning agents;

— the treatment of the feed water and the consumption of energy for generating steam;

— the consumption of electricity, compressed air and water resources for operational and cooling purposes;

NOTE Minimizing their use reduces emissions and-can increase the durability and life of the sterilizer.

— the disposal or recovery of wastewater;

— the release of fluids and substances;

— the generation of noise, vibration and radiation;

— heat emission to the working environment;

— the scrapping of the equipment at the end of its life cycle and the recycling of materials.

To highlight the importance of reducing the environmental burden, this European Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the sterilizer life cycle, see Table A.1.

Table A.1 — Environmental aspects addressing clauses of this European Standard

Environmental aspects (inputs and outputs)		Product life cycle			
		Preproduction, production and installation	**Lifetime, maintenance and testing**	**Use**	**End of life**
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	Clause 4 Clause 5 Clause 6 Clause 7 Clause 9 Clause 10 Clause 11 Clause 12	Clause 4 Clause 5 Clause 6 Clause 7 Clause 8 Clause 9 Clause 11 Clause 12 Clause 13 Clause 14 Clause 15 Clause 16 Clause 17 Clause 18 Clause 19 Clause 20 Clause 21 Clause 22 Clause 23 Clause 24 Clause 25	Clause 11 Clause 13 Clause 25	Clause 25
2	Energy consumption	—	Clause 11 Clause 13 Clause 14 Clause 15 Clause 16 Clause 17 Clause 19 Clause 20 Clause 22	Clause 4 Clause 5 Clause 11 Clause 13 Clause 14 Clause 25	—
3	Emission to air	Clause 11 Clause 13 Clause 25	Clause 11 Clause 14 Clause 25	Clause 25	Clause 11
4	Emission to water	Clause 11 Clause 13 Clause 25	Clause 11 Clause 14 Clause 25	Clause 25	Clause 11
5	Waste	—	Clause 11 Clause 15 Clause 17 Clause 25	Clause 25	Clause 11 Clause 25
6	Noise	Clause 9 Clause 11	Clause 9 Clause 11 Clause 14	Clause 25	—
7	Migration of hazardous	—	—	—	—

Environmental aspects (inputs and outputs)		Product life cycle			
		Preproduction, production and installation	**Lifetime, maintenance and testing**	**Use**	**End of life**
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
	substances				
8	Impacts on soil	—	—	—	Clause 11
9	Risks from accidents or misuse	—	Clause 7 Clause 11	Clause 7 Clause 11 Clause 25	Clause 25

Annex B
(informative)

Suggested maximum values of contaminants in feed water

Table B.1 — Contaminants in feed water supplied to a dedicated steam generator

Determinant	Feed water
Residue on evaporation	≤ 10 mg/l
Silicate	≤ 1 mg/l
Iron	≤ 0,2 mg/l
Cadmium[a]	≤ 0,005 mg/l
Lead[a]	≤ 0,05 mg/l
Rest of heavy metals except iron, cadmium, lead	≤ 0,1 mg/l
Chloride [b]	≤ 0,5 mg/l
Phosphate	≤ 0,5 mg/l
Conductivity (at 20 °C)[c]	≤ 5 µS/cm
pH (20 °C) value	5 to 7,5
Appearance	Colourless clean without sediment
Hardness (Σ Ions of alkaline earth)	≤ 0,02 mmol/l

NOTE Compliance can be tested in accordance with acknowledged analytical methods.

[a] The limiting values meet the requirements for potable water.

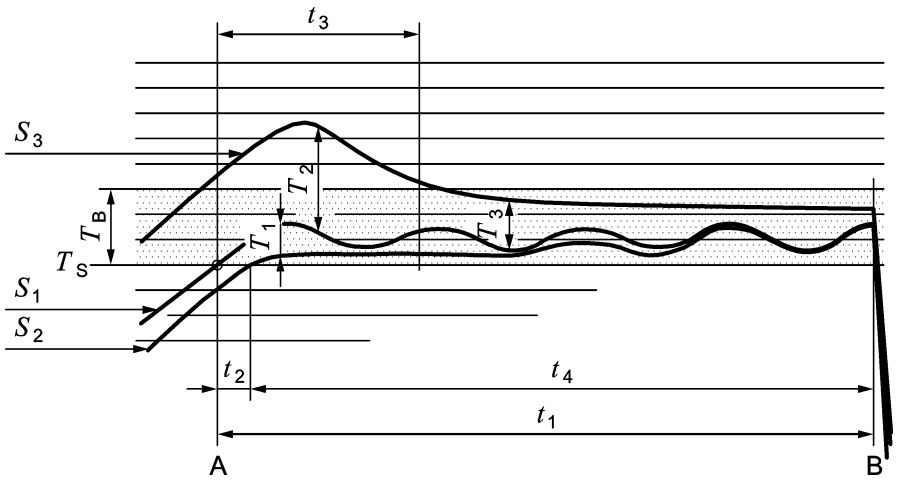
[b] Maximal chloride concentration in feed water influences corrosion in combination with high temperatures.

[c] See European Pharmacopeia.

Annex C
(informative)

Temperature and time tolerances during the small load thermometric test

Temperature and time tolerances during the small load thermometric test are illustrated in Figure C.1.



Key

A	start of plateau period	S_1	trace of sensor at the measurement reference point
B	end of plateau period	S_2	trace of the sensor showing the lowest temperature in the test pack
T_S	sterilization temperature	S_3	trace of sensor 50 mm above the test pack
T_B	sterilization temperature band	T_1	maximum difference between reference temperature and temperature in the test pack during holding time
t_1	plateau period	T_2	maximum difference between reference temperature and temperature above test pack within the first 60 s of plateau period
t_2	equilibration time	T_3	maximum difference between reference temperature and temperature above the test pack during the plateau period after the first 60 s
t_3	60 s		
t_4	holding time		

Figure C.1 — Temperature and time tolerances during the small load thermometric test

Annex D
(informative)

Guidance for installation and operational qualification tests which can be included in the instructions for use supplied with a sterilizer

When installed into its site of operation and connected to the specified services a sterilizer will be subjected to a number of installation qualification (IQ) and operational qualification (OQ) tests see EN ISO 17665-1:2006, 9.2 and 9.3. A suggested list of tests is contained in Table D.1.

The tests listed in Table D.1 can be used as part of the IQ/OQ process. When assessing the suitability of each test due regard should be paid to the intended use of the sterilizer and load items likely to be processed.

Where sterilizers are used for particular loads, specific operation qualification (OQ) /performance qualification (PQ) test will be described for such loads (see EN ISO 17665-1:2006, 6.1.2 e), 9.2 and 9.3). A test listed for OQ in Table D.1 is applicable only when in accordance with the intended use of the sterilizer or its equipment.

Table D.1 — Suggested tests

Test	**Requirements according to clause**	**Test according to clause**	**Installation Qualification**	**Operational Qualification**
Safety Tests and checks	11		XX	—
Steam quality tests				
- Non-condensable gases	13.3.1	21.1	X	X
- Dryness value	13.3.2	21.2	X	X
- Superheat	13.3.3	21.3	X	X
- Contaminants	Table 4	a	X	X
Thermometric tests				
- Small load	8.2.1.2	16.1	—	XX
- Full load	8.2.1.3	16.2	—	XX
Hollow load test [b]	8.2.5	15	—	XX
Bowie and Dick test	8.2.2	17	—	XX
Rate of pressure rise caused by air leakage	8.2.3	18	—	XX
Air detector[c]				
- Small load	8.2.4.2	19.2	—	XX
- Full load	8.2.4.3	19.3	—	XX
- Function	8.2.4.4	19.4	—	XX
Load dryness tests				
- Small load, textiles	8.3.1	20.1	—	X
- Full load, textiles	8.3.2	20.2	—	XX
- Metal	8.3.3	20.3	—	X
Rate of pressure change	10	22	—	X

XX tests which are suggested

X tests which can be considered

— tests which need not be performed during IQ and/or OQ

a Compliance tested in accordance with acknowledged analytical methods.

b This test is not intended to be used as a routine daily test.

c If an air detector is fitted (see 8.2.4.1).

Annex E
(informative)

Criteria for identifying sterilizers as the same type

E.1 Sterilizers classed as the same type should have:

— the same number of sterilizer doors in the same configuration; where it has been demonstrated that for a given size and type of sterilizer door, there is no difference in the influence on the load between a sterilizer door and a back plate, sterilizers with one or two of these sterilizer doors do not constitute different types;

— all service connections into the sterilizer chamber in the same orientation; a mirror image of the original orientation does not constitute a new type;

— the same control system with all sensors located in the same position and orientation; any change in the control system that does not affect the operating cycle and the limiting values;

— the same operating cycle.

Whenever the designed operating characteristics of the air removal stage of the operating cycle are changed delivery of the specified operating cycle within the specified tolerances should be demonstrated. This can be achieved using the small, full, Bowie and Dick and hollow load test(s) specified in Clauses 15 to 17.

E.2 If all other aspects of design remain the same the following variations should not constitute a new type:

— height of sterilizer chamber location above the floor;

— differences in the dimensions of the sterilizer chamber not greater than ± 10 % of the dimensions with congruent sterilizer chamber shapes;

— increasing the time of the plateau period within the operating cycle having the same sterilization temperature and the same air removal stage;

— any change of the design or provenance of equipment providing there is available documented evidence to show there is no adverse effect on the performance of the sterilizer which would affect compliance with this European Standard.

Annex F
(normative)

Protective measures

Annex F is an option to address the protective measures as specified in 11.1.

The following protective systems and measures apply:

a) [Corresponding to 11.1 g), i), l)]

For the protection against hazards related to fluids, liberated gases, substances, explosion and implosion, sterilizers which are or include pressure equipment and assemblies shall comply with EN 764-7:2002, EN 14222:2003, EN 13445-1:2014, EN 13445-2:2014, EN 13445-3:2014, EN 13445-4:2014, EN 13445-5:2014 and EN 13445-8:2014 or equivalent specifications (see Clauses 4 and 5).

NOTE 1 EN 13445 series, EN 14222 and EN 764–7 are deemed to address essential requirements of the Directive 2014/68/EU on pressure equipment [41].

NOTE 2 Additional guidance is given in EN ISO 12100.

NOTE 3 Pipework and services are addressed in Clauses 5, 13, 25 and Annex B.

b) [Corresponding to 11.1 b)]

For the protection against hazards of an electrical nature including electric shock sterilizers shall comply with EN 60204-1:2006, Clauses 4 to 8, 12, 13 and Annex A.

c) [Corresponding to 11.1 c), d) and k)]

For the protection against mechanical hazards related to mechanical functions sterilizers shall comply with EN ISO 12100:2010, 6.2.2.1, 6.2.6, 6.3.3.1, applicable parts of 6.3.3.2 and EN 60204-1:2006, Clauses 9 and 10.

Interlocking guards shall not be used.

NOTE 4 Mechanical hazards are addressed in Clauses 4, 7 and 25.

d) [Corresponding to 11.1 e)]

For the protection against hazards related to the spread of fire and resistance to heat, as far as not addressed in EN 764-7:2002, EN 14222:2003, EN 13445-1:2014, EN 13445-2:2014, EN 13445-3:2014, EN 13445-4:2014, EN 13445-5:2014 and EN 13445-8:2014, sterilizers and their components shall comply with EN 60204-1:2006, 6.3.3, 6.4 and Clause 7.

e) [Corresponding to 11.1 f)]

For the protection against burn and scald hazards sterilizers shall comply with EN 60204-1:2006, 6.3.3, 6.4 and Clause 7.

NOTE 5 Burn hazards are addressed in Clauses 4, 5 and 25. Additional guidance is provided in EN ISO 13732-1.

f) [Corresponding to 11.1 h)]

For the protection against radiation hazards sterilizers shall comply with EN ISO 12100:2010, 6.3.4.5.

NOTE 6 Electromagnetic radiation is addressed in 13.7.

g) [Corresponding to 11.1 j)]

For the protection against hazards related to components and subassemblies sterilizers shall comply with EN 60204-1:2006, Clauses 14 and 15.

NOTE 7 Pressure Equipment is addressed in EN 13445 series and EN 764–7.

NOTE 8 Additional guidance is provided in EN ISO 12100:2010, Clause 6.

h) [Corresponding to 11.2]

For the protection against hazards resulting from application (misuse, ergonomic aspects) sterilizers shall comply with EN ISO 12100:2010, 6.2.8.

i) [Corresponding to 11.1 a)]

For marking sterilizers shall comply with EN 764-7:2002, Clause 9, EN 13445-5:2014, 12.1, EN 14222:2003, Clauses 7 and 8, and EN 60204-1:2006, Clause 16.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN/CENELEC by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EC, as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2; 4.3.1.2; 4.3.1.5; 4.4.1; 5.1.2; 5.1.4; 5.3.1; 5.3.3; 7.1.13; 8.2.3; 8.2.4; 13.1; 13.3; 13.5; 13.6; 13.8; 14.1; 18; 19; 21; 25.3 c); 25.4 c)	7.6	a, d Additional information can be found in 5.3.2.
5.2.1.2; 5.2.2; 5.4; 6.5; 7.1.11; 7.2; 14.1; 25.2; 25.3; 25.5	9.1, 1st sentence	a, d
14.1; 25.2; 25.3; 25.5	9.1, 2nd sentence	a, d
4.3.1.4; 4.3.2; 4.4; 4.6; 7.1.8; 14.1; 25.2; 25.3; 25.4; 25.5	9.2, 1st dash, 1st part	a Additional information can be found in 4.3.1.3.
4.3.1.5; 5.1.2; 14.1	9.2, 1st dash, 2nd part	a
4.3.2; 4.3.4; 4.4; 4.5; 4.6; 5.3.3; 6.1; 6.2; 6.3; 6.5; 7.1.1; 7.1.7; 7.1.8; 14.1; 25.2	9.2, 1st dash, 3rd part	a, b Additional information can be found in 13.9

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.4; 6.4.3; 6.4.4; 13.4; 14.1; 25.2	9.2, 2nd dash	a, b Additional information can be found in 13.7 and 13.9
4.4.1; 14.1	11.1.1	a, b Additional information can be found in 13.7 and 13.9
14.1; 25.2; 25.3	11.4.1	
7.1; 7.2; 7.3; 8; 14, 15; 16; 17; 18; 19; 20; 22	12.1, 1st sentence	a, d
3.11; 6.4.2; 6.4.4; 7.1.2; 7.1.11; 7.2; 14.1	12.1, 2nd sentence	a, d
7.1; 7.2; 7.3; 8; 14, 15; 16; 17; 18; 19; 20; 22	12.1a	
14.1; 25.2 r)	12.5	b Additional information can be found in 13.7
13.10; 14.1; 25.2; 25.4	12.6	a, c Additional information can be found in 13.2
4.3.1.4; 4.3.2; 4.4; 4.6; 7.1.8; 14.1; 25.2; 25.3; 25.4; 25.5	12.7.1	a
9.2; 14.1	12.7.2	
9.1.1; 9.1.3; 14.1; 25.2 i); 25.2 j)	12.7.3	a Additional information can be found in 9.1.2
13.10, 14.1; 25.2	12.7.4	a, c
4.3.1.2; 4.3.3; 4.3.4; 4.4; 5.1.3; 14.1	12.7.5	a
6.1; 6.2; 6.3; 6.5.2; 6.5.3;7.1.8; 7.1.10; 7.1.12; 7.1.15; 7.2; 12; 14.1	12.9, 1st sentence	a
12; 14.1; 24; 25	13.1, 1st and 2nd sentence	a
12; 14.1	13.1, 3rd to 5th sentence	a
12; 14.1	13.2	a
12.2; 12.3; 12.4; 12.5; 12.6; 14.1; 25.3; 25.4	13.3 a), b), d), l), i), j), k)	a, d
12.4, 14.1; 25.4 a); 25.5	13.5	a, d
14.1; 24; 25.3	13.6 a)	a, d
14.1; 24; 25.2 h); 25.3 c); 25.4 d)	13.6 b)	a, d
14.1; 25.2	13.6 c)	a, d
4.4.1; 14.1; 25.3; 25.4; 25.5	13.6 d) and i)	a, d

Clause(s)/subclause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
14.1; 25.3 c)	13.6 q)	

[a] See Directive 2006/42/EC on machinery.

[b] See Directive 2014/30/EU on electromagnetic compatibility.

[c] See Directive 2014/35/EU on electric equipment.

[d] See Directive 2014/68/EU on pressure equipment.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to **Article 3** of amended Directive 93/42/EEC)

Clause(s)/subclause(s) of this EN	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
4.2; 4.3.1.5; 5.2; 6; 7.1; 7.2; 11.1; 13; 14.1; 25.1; 25.2; Annex F	1.1.3	c
13.4; 14.1; 25.1; 25.2 s)	1.1.4	
4.6; 11.1; 14.2; 25.1; 25.2 o); Annex F	1.1.5	c
4.3.4; 4.4.1; 4.4.2; 4.5; 4.6; 5.1.3; 6.1; 6.2; 6.3; 6.5.1; 6.5.2.4; 6.5.3.2; 7.1.1; 7.1.8; 7.1.10; 7.1.11; 7.1.12; 7.1.13; 7.1.14; 7.1.15; 7.2; 9; 11.1; 13.4; 13.9; 14.1; 25.1; 25.2 a), g), h), i), s); Annex F	1.1.6	
7.1; 7.2; 7.3; 11.1; 11.2.2; 13.7; 13.9; 14.1; Annex F	1.2.1, 1st and 2nd paragraph	c
4.3.2; 6.1.1; 7.1.1; 7.1.7; 7.1.8; 7.1.15; 11.1; 14.1; Annex F	1.2.2, 1st to 6th paragraph	c
4.3.2; 6.2; 6.3; 7.1.4; 11.1; 14.1; Annex F	1.2.2, 7th to 9th paragraph	
4.3.1.4; 4.3.1.5; 4.3.2; 7.1.1; 7.1.7; 7.1.8; 11.1; 14.1; Annex F	1.2.3	c
7.1.4; 11.1; 14.1; Annex F	1.2.4.1	c

Clause(s)/subclause(s) of this EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
7.1.11; 7.1.12; 7.2; 14.1; Annex F	1.2.4.2	c
11.1; 14.1; Annex F	1.2.4.3	c
11.1; 14.1; Annex F	1.2.4.4	c
7.1.8, 11.1; 14.1; Annex F	1.2.5	c
7.1.1; 7.1.7; 7.2; 11.1; 14.1; Annex F	1.2.6	c
4.6; 11.1; 14.1; 25.1; 25.2 o); Annex F	1.3.1	c
4.4; 5.1.2; 11.1; 14.1; 25.1; 25.4 a); Annex F	1.3.2	c
11.1; 14.1; Annex F	1.3.3	c
4.4.2;11.1; 14.1; 25.1; 25.4 a); Annex F	1.3.4	
7.1.1; 7.1.7; 7.1.8; 11.1; 14.1; Annex F	1.3.6	c
4.3.1.3; 4.4.1; 4.4.2; 7.1.8; 7.2.1; 11.1; 14.1; 25.1; 25.4 a); Annex F	1.3.7	
4.4.1; 11.1; 14.1; Annex F	1.3.8	
11.1; 14.1; Annex F	1.3.9	
4.4.1; 4.4.2; 11.1; 14.1; 14.2; Annex F	1.4.1	
4.4.1; 4.4.2; 14.1; Annex F	1.4.2.1	
11.1 c); 14.1; Annex F c)	1.4.2.2	
4.3.1; 4.3.2; 11.1; 14.1; Annex F	1.4.3	c
11.1; 14.1; 14.2; Annex F	1.5.1	b
11.1; 13.7; 14.1	1.5.2	
5.1.1; 11.1; 13; 14.1; 25.1; 25.2; Annex F	1.5.3	c
4.3.3; 5.1.2; 11.1; 12.4; 14.1; 25.1; 25.4 a); Annex F	1.5.4	c
4.3.1.3; 4.3.4; 4.4.1; 5.1.3; 11.1; 14.1; 14.2; 25.1; 25.3; 25.4; 25.5; Annex F	1.5.5	
11.1; 14.1; Annex F	1.5.6	
9.1; 14.1; 25.1; 25.2 i); 25.2 j)	1.5.8	
9.2; 14.1; 25.1; 25.2 a)	1.5.9	

Clause(s)/subclause(s) of this EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
4.4.1; 13.7; 11.1; 14.1; 25.2; 25.3; Annex F	1.5.10, 1st paragraph	a
4.4.1; 13.7; 11.1; 14.1; Annex F	1.5.11	a
11.1; 14.1; Annex F	1.5.12	
4.3.1.3; 4.4.1; 11.1; 14.1; 14.2; Annex F	1.5.14	
11.1; 14.1; Annex F	1.5.15	
13.7; 14.1; 25.2 r)	1.5.16	
4.3.3; 4.3.4; 4.4.1; 4.4.2; 5.1.3; 6.1; 6.5.1.1; 7.1.4; 7.1.7; 7.1.8; 11.1; 14.1; 25.3 b); 25.4; Annex F	1.6.1, 1st to 3rd paragraph	
4.3.2.4; 4.4.1; 4.4.2; 11.1; 14.1; 25.1; 25.2 a); Annex F	1.6.2	c
11.1; 13.11; 14.1; 25.2 q); Annex F	1.6.3	c
4.3.1; 4.3.2; 7.1.1; 7.1.7; 7.1.8; 11.1; 14.1; Annex F	1.6.4	c
11; 12; 14.1; 25; Annex F	1.7	c

a See Directive 2014/30/EU on electromagnetic compatibility.

b See Directive 2014/35/EU on electric equipment.

c See Directive 2014/68/EU on pressure equipment.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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[2] EN 547-2:1996+A1:2008, *Safety of machinery - Human body measurements - Part 2: Principles for determining the dimensions required for access openings*

[3] EN 547-3:1996+A1:2008, *Safety of machinery - Human body measurements - Part 3: Anthropometric data*

[4] EN 556-1:2001, *Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

[5] EN 764-1:2004, *Pressure equipment — Terminology — Part 1: Pressure, temperature, volume, nominal size*

[6] EN 868 (all parts), *Packaging for terminally sterilized medical devices*

[7] EN 1717:2000, *Protection against pollution of potable water in water installations and general requirements of devices to prevent pollution by backflow*

[8] EN 1837, *Safety of machinery — Integral lighting of machines*

[9] EN 10088-2, *Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip of corrosion resisting steels for general purposes*

[10] EN 10088-3, *Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes*

[11] EN 12953 (all parts), *Shell boilers*

[12] EN 13060, *Small steam sterilizers*

[13] EN 13445 series, *Unfired pressure vessels*

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[15] EN 61140, *Protection against electric shock - Common aspects for installation and equipment (IEC 61140)*

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[29] EN ISO 14050:2010, *Environmental management - Vocabulary (ISO 14050:2009)*

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