



BSI Standards Publication

Sterilization - Steam sterilizers - Large sterilizers

National foreword

This British Standard is the UK implementation of EN 285:2015+A1:2021. It supersedes BS EN 285:2006+A2:2009 which is withdrawn.

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English Version

Sterilization - Steam sterilizers - Large sterilizers

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

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

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European foreword

This document (EN 285:2015+A1:2021) 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 285:2015 .

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of an identical text or by endorsement, at the latest by December 2021, and conflicting national standards shall be withdrawn at the latest by June 2022.

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

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

This document includes Amendment 1 approved by CEN on 23 May 2021.

The start and finish of text introduced or altered by amendment is indicated in the text by tags  .

The following amendments have been made in comparison EN 285:2015:

- normative references have been updated and corrected in the normative text;
- note to entry was added to 3.17 and 3.27;
- 6.2 was adopted;
- subclause 6.4.4.2 was added;
- note was added to 8.1.3 and 15.1;
- Annex ZA relationship with the General Safety and Performance Requirements of Regulation (EU) 2017/745 including Tables ZA.1, ZA.2 and ZA.3 was added.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This document 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 equipment²⁾.

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 document 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 document 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 document 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 document 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 document does not specify requirements for equipment intended to process biological waste or human tissues.

This document 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 764-7:2002,³ *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 13445-1:2014,⁴ *Unfired pressure vessels - Part 1: General* 

EN 13445-2:2014,⁴ *Unfired pressure vessels - Part 2: Materials* 

EN 13445-3:2014,⁴ *Unfired pressure vessels - Part 3: Design* 

EN 13445-4:2014⁴, *Unfired pressure vessels - Part 4: Fabrication* 

EN 13445-5:2014,⁴ *Unfired pressure vessels - Part 5: Inspection and testing* 

EN 13445-8:2014,⁴ *Unfired pressure vessels - Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys* 

EN 14222:2003, *Stainless steel shell boilers*

³) As impacted by corrigendum EN 764-7:2002/AC:2006.

⁴) Including all amendments and impacted by Issue 5.

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

 EN 60204-1:2018, *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 61010-1:2010,⁵ *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements (IEC 61010-1:2010)* 

 EN 61010-2-040:2015, *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 61010-2-040:2015)* 

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 13408-2:2018, *Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2018)* 

⁵ This document is impacted by the amendment EN 61010-1:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019-04.

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 (quantity 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

[A1] Note 1 to entry: The requirements for steam penetration and the definition of “saturated steam” are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series. **[A1]**

[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, ^{A1} 3.14 ^{A1}]

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

^{A1} Note 1 to entry: The requirements for steam penetration and the definition of “saturated steam” are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series. ^{A1}

[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 61010-2-040:2015 , 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.

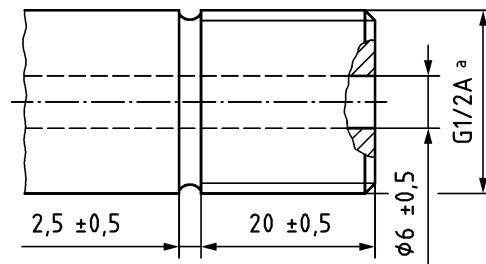
4.3.3 Test connections

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.

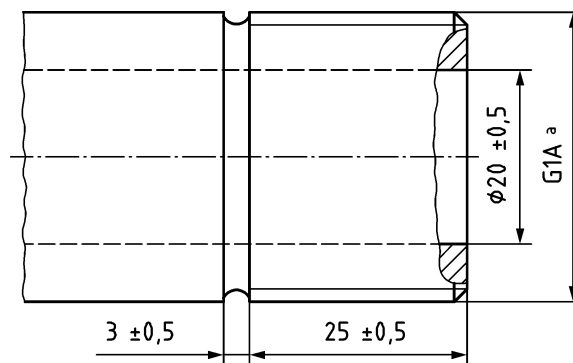
4.3.3.2 A test connection in accordance with Figure 1 shall provide direct connection with the sterilizer chamber providing it causes no adverse effect on the measurement of the pressure in the sterilizer chamber. The test connection which is used for the connection of a test instrument shall be provided 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 13408-2:2018 , 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 $(1,00 \pm 0,15)$ 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.

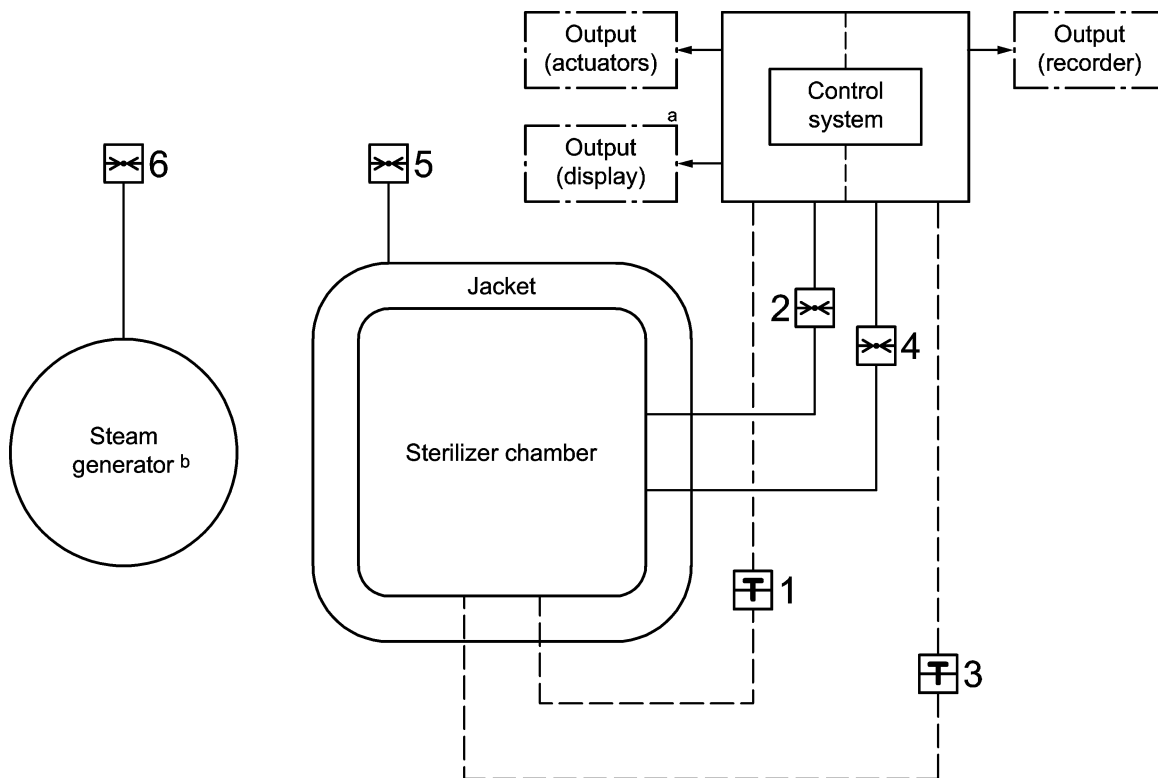
- e) absolute pressure in the sterilizer chamber for control;
- f) absolute pressure in the sterilizer chamber for recording;
- g) pressure in the jacket for indication (if the sterilizer is fitted with a jacket intended to be pressurized);
- h) steam pressure for indication (if a steam generator is 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) $\langle A_1 \rangle$ and h) $\langle A_1 \rangle$ 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

6.4.4.1 Chamber pressure measuring chains

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.

6.4.4.2 Jacket and steam supply measuring chains

Pressure measuring chains shall:

- a) indicate in kilopascals or bars;
- b) have an accuracy of $\pm 1,6$ % or better over the scale range 0 kPa to 400 kPa;
- c) be graduated in divisions not greater than 20 kPa;
- d) have means to adjust *in situ* without dismantling the instrument. 

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.

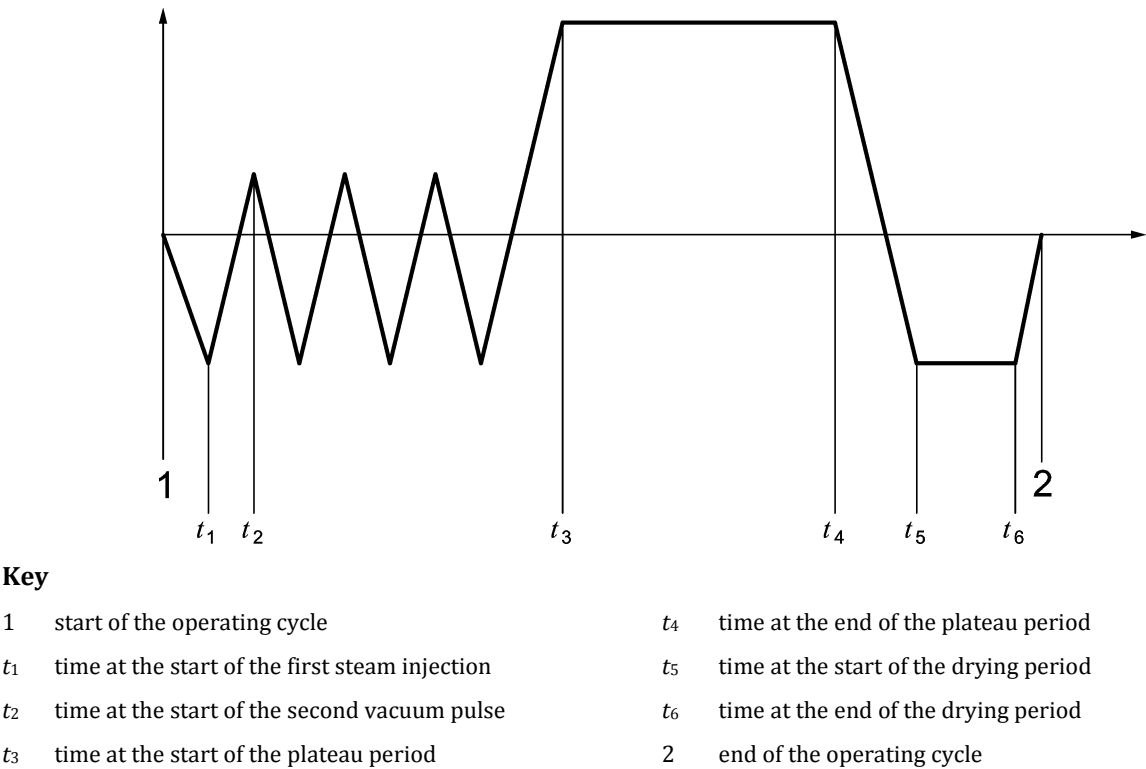


Figure 4 — Diagram of specimen operation cycle given as an example only

Table 3 — Examples of data to be recorded

Programme step	Time	Temperature (measured value)	Pressure	Sterilization ^a		Date ^a and sterilizer identification
				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 $\leq 0,1$ 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.

A1 NOTE 4 The requirements for steam penetration and the definition of “saturated steam” are currently points for discussion in both CEN/TC 102/WG 5 and in ISO/TC 198/WG 3, which is the international working group that deals with the closely related EN ISO 17665-series. **A1**

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 ^{A1} EN 61010-2-040:2015 ^{A1} specific harmonized standards for machinery may be used to address relevant hazards, including ^{A1} EN 60204-1:2018 ^{A1} 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, ^{A1} Clause 11 ^{A1}, EN 14222:2003, Clauses 7 and 8, EN 61010-1:2010, Clause 5, as modified by ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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 ^{A1} EN 61010-2-040:2015 ^{A1}, 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)].