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Interested committees:

Title: BS EN 17180 Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing

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- iii) requires additional national guidance or information

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

English Version

Sterilizers for medical purposes - Low temperature
vapourized hydrogen peroxide sterilizers - Requirements
and testing

Stérilisateurs à usage médical ; Stérilisateurs à la
vapeur de peroxyde d'hydrogène à basse température
; Exigences et essais

Sterilisatoren für medizinische Zwecke -
Niedertemperatur-Sterilisatoren mit verdampftem
Wasserstoffperoxid - Anforderungen und
Prüfverfahren; Deutsche und Englische Fassung PWI
EN 17180:2019

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 17180:2023) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

A first draft (prEN 17180:2017) was published in 2017, but the status of the project was set back to a preliminary work item. The following changes were made to the first draft:

- the structure of the main text has been widely adapted to the structure of ISO/TS 22421:2021 and harmonized with the current revisions of EN 14180 and EN 1422 in 2022;
- most definitions have been adapted with reference to EN ISO 11139:2018;
- a separate clause ‘Protective measures’ has been implemented for referencing to individual clauses of EN IEC 61010-2-040 and an Annex G ‘protective measures’ has been created;
- requirements on the control and monitoring system have been merged into a clause and informative illustrations have been provided in an Annex I;
- an Annex J ‘Technical information and documentation’ has been added to consider Annex II of the European Medical Device Regulation (MDR).

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 Regulation(s), see informative Annex ZA, which is an integral part of this document.

Introduction

This document specifies minimum requirements and test methods for sterilizers performing a low temperature sterilization process using a composition of water and hydrogen peroxide (H₂O₂), vaporized, and injected into the sterilizer chamber as sterilizing agent. Vaporized hydrogen peroxide (H₂O₂) sterilizers process typically below 60°C and are primarily used for the sterilization of thermolabile or moisture-sensitive medical devices in health care facilities but can also be used for sterilization of other reusable medical devices that have been established to be compatible with VH2O2 processes. The sterilizers operate automatically using pre-set cycles. VH2O2 sterilizers can also be used by medical device manufacturers during commercial production.

Like the other standardized low temperature sterilization processes using ethylene oxide (EN 1422 and EN ISO 11135) or low temperature steam and formaldehyde (EN 14180 and EN ISO 25424), the VH2O2 sterilization processes are specified by physical and chemical parameters and verified using physical, chemical, and microbiological means. The sterilizers operate automatically using pre-set cycles.

The tests described in this document are reference tests intended to demonstrate conformity with the performance requirements specified in this document. They may be used in type tests, works tests, in validation and re-qualification, or in periodic and routine tests carried out by the user. Validation and routine control of sterilization processes are essential to ensure their efficacy. This document does not cover validation and routine control of a VH2O2 sterilization process. EN ISO 14937 provides general requirements and guidance on validation and routine control of such processes. ISO 22441 provides specific requirements for validation and routine control of VH2O2 sterilization.

Some VH2O2 sterilizers have processes that demonstrate some level of inactivation of the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy, and Creutzfeldt-Jakob Disease. However, this inactivation is process, cycle, and test protocol specific, and not equipment specific, therefore this inactivation is not addressed in this document, and no specific test methods are provided.

Planning and design of products applying to this document should consider not only technical aspects but also the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex H of this document.

NOTE Specifications on general equipment safety are addressed in EN 61010-1, EN IEC 61010-2-040, and are not repeated in this document. EN 60204-1 can also apply (see Annex G). Requirements on occupational safety and health are not specified in this document. National regulations can exist.

1 Scope

This document specifies requirements and tests for low temperature hydrogen peroxide sterilizers, using vaporized aqueous solution of hydrogen peroxide as the sterilizing agent.

These sterilizers are used for the sterilization of medical devices, particularly thermolabile medical devices.

This document specifies minimum requirements:

- for the performance and design of sterilizers intended to deliver a process capable of sterilizing medical devices;
- for the equipment and controls of these sterilizers needed for operation, control, and monitoring, and which can be used for validation of the sterilization processes;
- for the test equipment and test procedures used to verify the sterilizer performance specified by this document.

This document does not specify requirements for equipment intended to process liquids, biological waste, or human tissues unless part of a medical device.

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

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

This document does not specify requirements and tests for decontamination systems for use in rooms, enclosures, or environmental spaces.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 868-5:2018, *Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods*

EN 868-9:2018, *Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods*

EN 60204-1:2018, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

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

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

EN IEC 61326-1:2021, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements*

EN 62366-1:2015/A1:2020, *Medical devices - Part 1: Application of usability engineering to medical devices*

EN IEC 60751:2022, *Industrial platinum resistance thermometers and platinum temperature sensors*

EN IEC 61010-2-040:2021, *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*

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 11138-1:2017, *Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)*

EN ISO 11607-1:2020, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)*

EN ISO 11607-2:2020, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)*

EN ISO 14971:2019, *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 15223-1:2021, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*

EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

ISO 2861:2020, *Vacuum technology — Dimensions of clamped-type quick-release couplings*

ISO 22441:2022, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

3 Terms and definitions

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

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

- IEC Electropedia: available at <https://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1

access device

means by which entry to restricted parts of equipment is achieved

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

[SOURCE: EN ISO 11139:2018, 3.4]

3.2

accompanying information

information accompanying or marked on a sterilizer and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the sterilizer, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the sterilizer.

Note 2 to entry: The accompanying information can consist of the *label* (see 3.29), marking, instructions for use, technical description, installation manual, quick reference guide, etc.

Note 3 to entry: Accompanying information is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: EN ISO 20417:2021, 3.2, modified — “Medical device or accessory” has been changed to “sterilizer”, the term “processing” has been removed, Note 1 to entry has been modified to exclude a requirement and Note 4 to entry has been deleted.]

3.3

automatic controller

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

[SOURCE: EN ISO 11139:2018, 3.18]

3.4

biological indicator BI

test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: EN ISO 11139:2018, 3.29]

3.5

calibration

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

[SOURCE: EN ISO 11139:2018, 3.31]

3.6

chamber pre-heating

process that raises the temperature of internal chamber surfaces prior to the commencement of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.37]

3.7

chemical indicator

chemical indicator test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

[SOURCE: EN ISO 11139:2018, 3.43]

3.8

conditioning

treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

Note 1 to entry: In this document conditioning is used as conditioning stage

[SOURCE: EN ISO 11139:2018, 3.58]

3.9

control

regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018, 3.63]

3.10

cycle complete

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

[SOURCE: EN ISO 11139:2018, 3.71]

3.11

cycle parameter

value of a cycle variable including its tolerances used for control, monitoring, indication and recording of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.72]

3.12

cycle variable

property used to control, monitor, indicate, or record an operating cycle

[SOURCE: EN ISO 11139:2018, 3.74]

3.13

desorption

removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

[SOURCE: EN ISO 11139:2018, 3.78]

3.14

double-ended

double-ended having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018, 3.92]

3.15**equipment maintenance**

combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: EN ISO 11139:2018, 3.106]

3.16**exposure phase**

cycle stage between the introduction of the sterilizing or disinfecting agent into the chamber and when the agent is removed

[SOURCE: EN ISO 11139:2018, 3.111]

3.17**establish**

determine by theoretical evaluation and confirm by experimentation

[SOURCE: EN ISO 11139:2018, 3.107]

3.18**fault**

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

[SOURCE: EN ISO 11139:2018, 3.116]

3.19**filter**

construct of porous material through which a *fluid* (3.20) is passed to remove viable and/or non-viable particles

[SOURCE: EN ISO 11139:2018, 3.117]

3.20**fluid**

substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma

[SOURCE: EN ISO 11139:2018, 3.120]

3.21**hazard**

potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.22**hazardous situation**

circumstance in which people, property, or the environment is/are exposed to one or more *hazards* (3.21)

[SOURCE: EN ISO 11139:2018, 3.131]

3.23

holding time

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

[SOURCE: EN ISO 11139:2018, 3.133]

3.24

indicate

display a value, condition, or stage of process

[SOURCE: EN ISO 11139:2018, 3.139]

3.25

information supplied by the manufacturer

information related to the identification and use of a sterilizer, in whatever form provided, intended to ensure the safe and effective use of the *sterilizer* (3.63)

Note 1 to entry: For the purposes of this document, shipping documents and promotional material are excluded from information supplied by the manufacturer. However, some authorities having jurisdiction can consider such supplemental information as information supplied by the manufacturer.

[SOURCE: EN ISO 20417:2021, 3.10, modified — “Medical device or accessory” has been changed to “sterilizer” and Notes 1, 3 and 4 to entry have been deleted.]

3.26

inspection

determination of conformity to specified requirements

Note 1 to entry: If the result of an inspection shows conformity, it can be used for purposes of verification.

Note 2 to entry: The result of an inspection can show conformity or nonconformity (3.6.9) or a degree of conformity.

Note 3 to entry: Inspection can be understood as visual inspection and/or application testing.

Note 4 to entry: References to definitions of determination, conformity and specified requirements are removed.

[SOURCE: EN ISO 9000:2015, 3.11.7]

3.27

installation qualification

IQ

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

[SOURCE: EN ISO 11139:2018, 3.220.2]

3.28**instructions for use****IFU**

portion of the *accompanying information* (3.2) that is essential for the safe and effective intended use of a *sterilizer* (3.63) directed to the user of the sterilizer

Note 1 to entry: The instructions for use, or portions thereof, can be located on the display of a sterilizer.

[SOURCE: EN ISO 20417:2021, 3.11, modified — “Medical device or accessory” has been changed to “sterilizer”, “package insert” has been removed, “use” has been changed to “intended use”, Notes 1, 2, 4 and 5 to entry have been deleted and Note 3 to entry has been modified.]

3.29**label**

written, printed, or graphic information appearing on the *sterilizer* (3.63) itself

Note 1 to entry: Label includes the marking on the sterilizer.

[SOURCE: EN ISO 20417:2021, 3.12, modified — The term “item” has been replaced with “sterilizer”, reference to packaging and provision of multiple items has been deleted, Notes 1 and 3 to entry have been deleted, and Note 2 to entry has been designated as Note 1.]

3.30**labelling**

label, instructions for use and any other information that is related to identification, technical description, intended purpose, and proper use of the medical device, but excluding shipping documents

[SOURCE: EN ISO 13485:2016, 3.8]

3.31**load**

product, equipment, or materials to be processed together within an operating cycle

[SOURCE: EN ISO 11139:2018, 3.155]

3.32**load configuration**

distribution and orientation of a *load* (3.31)

[SOURCE: EN ISO 11139:2018, 3.156]

3.33**loading door**

means of access through which a *load* (3.31) is passed into the chamber before processing

[SOURCE: EN ISO 11139:2018, 3.157]

3.34 marking

information, in text or graphical format, durably affixed, printed, etched (or equivalent) to a *sterilizer* (3.63)

Note 1 to entry: For the purposes of this document, the term marked is used to designate the corresponding act.

Note 2 to entry: For the purposes of this document, marking is different from “direct marking” as described in systems for unique device identification (UDI) of medical devices.

[SOURCE: ISO 20417:2021, 3.16, modified — “Medical device or accessory” has been changed to “sterilizer”. Note 2 to entry has been modified. Note 3 to entry has been deleted.]

3.35 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 11139:2018, 3.165]

3.36 measurement uncertainty

non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: EN ISO 11139:2018, 3.164]

3.37 medical device

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

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of *in vitro* examination of specimens derived from the human body;

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

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

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

[SOURCE: EN ISO 11139:2018, 3.166]

3.38

monitoring

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

[SOURCE: EN ISO 11139:2018, 3.180]

3.39

normal operation

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

[SOURCE: EN ISO 11139:2018, 3.185]

3.40

operating cycle

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

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

[SOURCE: EN ISO 11139:2018, 3.188]

3.41

operating pressure

fluid (3.20) pressure occurring during an *operating cycle* (3.40)

[SOURCE: EN ISO 11139:2018, 3.189]

3.42

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: EN ISO 11139:2018, 3.220.3]

3.43

override

system by which an operating cycle can be interrupted or modified as necessary

[SOURCE: EN ISO 11139:2018, 3.191]

3.44

process challenge device

PCD

item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

[SOURCE: EN ISO 11139:2018, 3.205]

3.45

process parameter

specified value for a process variable

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: EN ISO 11139:2018, 3.211]

3.46

process variable

chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

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

[SOURCE: EN ISO 11139:2018, 3.213]

3.47

penetration type test device

PTTD

specified device for use in type tests to ascertain a minimum sterilizing agent penetration performance of a defined sterilization cycle

3.48

recorder

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

3.49

reference measurement point

location of the sensor controlling the operating cycle

[SOURCE: EN ISO 11139:2018, 3.227]

3.50

safety data sheet

SDS

document specifying the properties of a substance, its potential hazardous effects for humans and the environment, and the precautions necessary to handle and dispose of the substance safely

[SOURCE: EN ISO 11139:2018, 3.239]

3.51

serial number

production control containing a combination of letters or numbers, selected by the manufacturer, intended for quality control and identification purposes to uniquely distinguish an individual sterilizer from other sterilizers with the same catalogue number or model number

[SOURCE: EN ISO 20417:2021, 3.22, modified — “Medical device” has been changed to “sterilizer”.]

3.52

services

supplies from an external source needed for the function of equipment

EXAMPLE Electricity, sterilant, compressed air, drainage.

[SOURCE: EN ISO 11139:2018, 3.252]

3.53

stage

<operating cycle> part of an operating cycle with a specified function

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

[SOURCE: EN ISO 11139:2018, 3.262]

3.54

sterilant

chemical or combination of chemicals used to generate a sterilizing agent

[SOURCE: EN ISO 11139:2018, 3.272]

3.55

sterilant/ sterilizing agent injection

introduction of sterilant/sterilizing agent into the evacuated chamber until the set operating pressure has been attained or the specified quantity of sterilant/sterilizing agent has been delivered

[SOURCE: EN ISO 11139:2018, 3.269]

3.56

sterile

free from viable microorganisms

Note 1 to entry: For “free from viable microorganisms” see EN 556-1.

[SOURCE: EN ISO 11139:2018, 3.271]

3.57

sterile barrier system

SBS

minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile product at the point of use

[SOURCE: EN ISO 11139:2018, 3.272]

3.58

sterilization

process used to render product free from viable microorganisms

Note 1 to entry: In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: EN ISO 11139:2018, 3.277]

3.59

sterilization cycle

predetermined sequence of stages performed in a sterilizer to achieve product free of viable microorganisms

[SOURCE: EN ISO 11139:2018, 3.279]

3.60

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 under defined conditions to the sterilizing agent and any necessary post treatment. The sterilization process does not include any cleaning, disinfection or packaging operations that precede sterilization

[SOURCE: EN ISO 11139:2018, 3.284]

3.61

sterilizer chamber

part of equipment in which a load is processed

Note 1 to entry In this document the chamber is the “sterilizer chamber”

[SOURCE: EN ISO 11139:2018, 3.36]

3.62

sterilizing agent

physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under defined conditions

[SOURCE: EN ISO 11139:2018, 3.288]

3.63

sterilizer

equipment designed to achieve sterilization

[SOURCE: EN ISO 11139:2018, 3.297]

3.64

operating temperature band

range of temperatures expressed as the minimum and maximum temperatures in the usable chamber space during a holding time

[SOURCE EN ISO 11139:2018, 3.293, modified]

3.65**type test**

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

[SOURCE: EN ISO 11139:2018, 3.306]

3.66**VH202 temperature band**

operating temperature band (3.64) of each holding time during a VH202-sterilization cycle

3.67**unloading door**

means through which a load is removed from the chamber after processing

[SOURCE: EN ISO 11139:2018, 3.310]

3.68**usable chamber space**

defined space within the chamber that is available to accept the load

[SOURCE: EN ISO 11139:2018, 3.311]

3.69**validation**

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

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

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

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

[SOURCE: EN ISO 11139:2018, 3.313]

3.70**verification**

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

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

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

[SOURCE: EN ISO 11139:2018, 3.314]

3.71**works test**

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

[SOURCE: EN ISO 11139:2018, 3.325]

4 General

4.1 Sterilizer type definition

4.1.1 The “type of sterilizer” concept does establish when design alterations are of a character that requires tests to be repeated.

If kept within the same sterilizer type, design variations in an individual sterilizer are not considered to influence the performance and can therefore be exempted from repeated testing. However, in any case a risk evaluation shall be performed for verification.

4.1.2 When demonstrating that a type of a VH2O2 sterilizer conforms with this document, sterilizers classified as the same type shall have the same intended use with the same sterilizing agent.

NOTE 1 A mirror image of the original orientation can be considered not to constitute a new type.

In addition, unless it has been demonstrated that there is no decrease in the performance of an operating cycle, a sterilizer type shall have:

- a) the same number of doors in the same configuration;
- b) all service connections into the chamber in the same orientation;
- c) the same control system with all sensors located in the same position and orientation;
- d) the same sterilization cycle including the same cycle parameters.

NOTE 2 Where a change within the control system does not affect the sequence of stages of the sterilization cycle, and nor the cycle parameters impairing the cycle performance, or the safety attributes, such a change does not constitute a new type.

Conformance is demonstrated by inspection of the technical documentation.

4.1.3 If all other design aspects remain the same, the following variations shall not constitute a new type:

- a) height of the sterilizer chamber above the floor;
- b) differences in the dimensions of the sterilizer chamber and chamber volume not greater than $\pm 10\%$;
- c) prolonging the duration of the exposure stage of an operating cycle;

NOTE 1 Additional regulatory requirements can apply to prolonging the exposure phase. While not a new sterilizer type, this is a new sterilization cycle (see ISO 22441).

- d) prolonging the desorption, cooling or drying stages after the exposure phase.

NOTE 2 Additional regulatory requirements can apply to prolonging the post-exposure phase. While not a new sterilizer type, this is a new sterilization cycle (see ISO 22441).

Conformance is demonstrated by inspection of the technical documentation.

4.2 Equipment development

4.2.1 The design and development process is a critical element in product realization of a sterilizer. To ensure the consistent implementation of the requirements specified in this document, the necessary development processes shall be established, implemented, and maintained. Processes of particular importance in relation to the design and development of a sterilizer include but are not limited to:

- risk management;
- control of documentation, including records;
- assignment of responsibility;
- provision of adequate resources, including competent human resources and infrastructure;
- control of product, including services, provided by external parties;
- calibration of instrumentation.

NOTE 1 EN ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

NOTE 2 EN ISO 14971 provides requirements for a risk management system for medical devices.

NOTE 3 EN ISO 12100 provides requirements for risk management of machinery.

4.2.2 Where a new type of sterilization process is being developed for implementation into a sterilizer (thus becoming a new type, see 4.1.2 d)), an update of the risk analysis shall be performed to ensure that any additional potential risk is considered for the design.

4.3 Calibration

4.3.1 Instrumentation on the sterilizer and instruments used for test purposes shall be calibrated. The system(s) for calibration of instrumentation shall provide metrological traceability to a primary standard or national standard with a known level of measurement uncertainty.

NOTE National calibration standards are often mutually recognized and traceable to international standards with recognized fixed points.

Conformance is demonstrated by inspection of the technical documentation.

4.3.2 Means shall be provided to permit connection of reference instruments for the calibration of instrumentation.

Conformance is demonstrated by inspection.

5 Equipment design and Construction

5.1 Safety and security

5.1.1 General

5.1.1.1 Safety of the design shall be based on risk assessment. Technical solutions shall consider applicable standards.

NOTE 1 For general design related to safety, see EN 61010-1 and EN IEC 61010-2-040.

NOTE 2 Additional guidance is given in EN ISO 12100.

Conformance is demonstrated by inspection of the technical documentation.

5.1.1.2 Sterilizers shall incorporate means of protection from unauthorized access that could interfere with its performance or create a hazardous situation. If the sterilizer provides a connection to an IT environment or network, means shall be provided to prevent access or interaction:

- a) between that environment or network and the sterilizer that interferes with the sterilizer performance or creates a hazardous situation;
- b) between the sterilizer and that environment or network protocol(s) that interferes with the specified performance of the environment or network.

NOTE See EN IEC 80001-1, EN ISO/IEC 27001, EN ISO/IEC 27002, UL 2900-1 and ISO/IEC 21823-1. EN IEC 80001-1 defines the roles, responsibilities and activities that are necessary for risk management of IT-networks incorporating medical devices to address safety, effectiveness and data and system security. EN ISO/IEC 27001 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system and EN ISO/IEC 27002 gives guidelines for organizational information security standards and information security management practices. UL 2900-1 applies to network-connectable products that need to be evaluated and tested for vulnerabilities, software weaknesses and malware. ISO/IEC 21823-1 provides an overview of interoperability as it applies to Internet of Things systems and a framework for interoperability for such systems.

Conformance is demonstrated by inspection of the technical documentation.

5.1.2 Protective measures

5.1.2.1 As an alternative to the referenced parts of EN 61010-1:2010 and EN IEC 61010-2-040:2021 specific harmonized standards for machinery can be used to address relevant hazards, including EN 60204-1:2018 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 G.

NOTE Regarding specific design aspects, application of EN 60204-1:2018 can reduce testing.

5.1.2.2 The following protective systems and measures apply:

- a) For marking and documentation, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 5.
- b) For the protection against electric shock, sterilizers shall comply with EN IEC 61010-2-040:2021, Clause 6.
- c) For the protection against mechanical hazards and hazards related to mechanical functions, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 7.

- d) For the protection against hazards due to mechanical resistance to shock and impact, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 (except 4.4) and 8.
- e) For the protection against the spread of fire, sterilizers shall comply with, EN IEC 61010-2-040:2021, Clauses 4 and 9 (except 9.5).
- f) For the protection against hazards in relation to equipment temperature and to heat, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 10.
- g) For the protection against hazards from fluids, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 11.
- h) For the protection against radiation, including laser sources, sterilizers shall comply with EN IEC 61010-2-040:2021, 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 61010-2-040:2021, Clauses 4 and 13.
- j) For the protection against hazards related to components, sterilizers shall comply with EN 61010-2-040:2021, Clauses 4 and 14.
- k) For the protection by interlocks, sterilizers shall comply with EN IEC 61010-2-040:2021, Clauses 4 and 15.

NOTE Additional guidance is given in EN ISO 12100.

5.1.2.3 If a powered chamber door is fitted, systems shall be provided to permit the removal of persons or objects entrapped by the moving door before the pressure, force and temperature specified in EN 61010-1:2010, 7.3.4, and 10.1 are exceeded.

NOTE Reversing the direction of the door movement is a way to achieve this.

5.1.2.4 Sterilizers shall conform with EN IEC 61326-1:2021 regarding immunity to electromagnetic interference.

The immunity performance criteria selected shall ensure that sterilizer performance is met when exposed to the applicable disturbance phenomena of EN IEC 61326-1:2021.

Conformance is demonstrated in accordance with EN IEC 61326-1:2021.

NOTE Requirements regarding electromagnetic emissions are provided in 8.1 of this document.

5.1.3 Risk control and usability

5.1.3.1 Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971:2019, Clauses 5, 6 and 7. Specific requirements and results shall be established and documented.

Conformance is demonstrated by inspection of the technical documentation as required by EN ISO 14971.

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

Conformance is demonstrated by inspection of the technical documentation, see also 11.2 and 11.3.

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

5.1.3.3 Usability engineering in accordance with EN 62366-1:2015+A1:2020 provides valuable procedures and information to identify known or foreseeable hazards and hazardous situations. The procedures of EN 62366-1 shall be applied to improve the usability of the equipment and to identify related risks.

Conformance is demonstrated by inspection of the documentation of the usability file.

5.2 Sterilizer chamber

5.2.1 Materials

5.2.1.1 The surfaces of the sterilizer components that can come into contact with process chemicals (including, for example, sterilizer chamber, connected piping, welds) shall be of materials which, under the designed operating conditions:

- a) are not impaired by these chemicals;
- b) do not react with these chemicals, thereby creating a hazard;
- c) do not release any substances known to be toxic in such quantities that can create a health or environmental hazard.

NOTE When dissimilar metals are used in contact, this can cause contact corrosion and defects arising from differential expansion.

Conformance is demonstrated by inspection of the technical documentation as required by EN ISO 14971.

5.2.1.2 Materials for sterilizer furniture including load supporting systems shall be selected to avoid corrosion including galvanic effects.

Conformance is demonstrated by visual inspection and inspection of the technical documentation.

5.2.2 Chamber dimensions

5.2.2.1 Chamber

For the internal dimensions of the chamber the following dimensions shall be specified in millimetres, as applicable:

- a) for cylindrical horizontal or cylindrical vertical internal chamber spaces: 000 × 000 in which:
 - 1. the first three digits give the diameter of the internal chamber space; and
 - 2. the last three digits give the depth of the internal chamber space;
- b) for rectangular parallelepiped internal chamber spaces: 000 × 000 × 000 in which:
 - 1. the first three digits give the width of the internal chamber space;
 - 2. the next three digits give the height of the internal chamber space; and
 - 3. the final three digits give the depth of the internal chamber space;
- c) for other configurations the internal chamber space shall be specified in analogy to a) or b);
- d) if any dimension exceeds 999 mm, then four digits shall be used, without a decimal point.

Conformance is demonstrated by inspection.

5.2.2.2 Usable Chamber space

For the usable chamber space, the following dimensions shall be specified in millimetres, as applicable:

- a) for cylindrical horizontal or cylindrical vertical usable chamber spaces: 000 × 000 in which:
 - 1. the first three digits give the diameter of the usable chamber space; and
 - 2. the last three digits give the depth of the usable chamber space;
- b) for rectangular parallelepiped usable chamber spaces: 000 × 000 × 000 in which:
 - 1. the first three digits give the width of the usable chamber space;
 - 2. the next three digits give the height of the usable chamber space; and
 - 3. the final three digits give the depth of the usable chamber space;
- c) for other configurations the usable space shall be specified in analogy to a) or b);
- d) if any dimension exceeds 999 mm, then four digits shall be used, without a decimal point.

Conformance is demonstrated by inspection.

5.2.3 Doors and interlocks of the sterilizer chamber

5.2.3.1 Sterilizer chambers shall be provided with one or two doors.

Conformance is demonstrated by inspection.

5.2.3.2 After closing the sterilizer door, it shall be possible to open it before a cycle has been started.

Conformance is demonstrated by inspection.

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

Conformance is demonstrated by inspection.

5.2.3.4 In case of an interrupted cycle (e.g. due to a fault), opening of the sterilizer door shall require the use of an access device and conditions that will not create a hazard (e.g. residue of sterilizing agent).

Conformance is demonstrated by inspection of instructions for use.

5.2.3.5 The design shall allow maintenance of the door seal(s) in accordance with the user instructions.

Conformance is demonstrated by inspection.

5.2.3.6 For standard operation with double-ended sterilizers it shall not be possible to open the unloading door until a cycle complete indication is obtained.

Conformance is demonstrated by inspection.

5.2.3.7 For operating cycles dedicated for test or user maintenance purposes only, the cycle complete indication shall be different from that of a normal sterilization cycle. For double-ended sterilizers such “cycle complete” indications shall not permit the unloading door to be opened.

Conformance is demonstrated by inspection.

5.2.3.8 If a fault is indicated, or on completion of an operating cycle for test or equipment maintenance purposes, it shall not be possible to open a door until appropriate action is taken.

Conformance is demonstrated by application testing.

5.2.3.9 The controls used to start the automatic operating cycle shall be located at the loading side of the sterilizer. To cover specific applications, remote start of the cycle may be possible, if supported by a risk analysis.

Conformance is demonstrated by inspection.

5.2.3.10 Except for maintenance purposes, it shall not be possible on double-ended sterilizers to open both sterilizer doors at the same time.

Conformance is demonstrated by inspection.

5.2.3.11 For double-ended sterilizers, both ends of the sterilizer shall be fitted with a device to indicate whether the door at that end can be opened.

Conformance is demonstrated by inspection.

5.2.3.12 Cycle complete shall be cancelled when a door is opened. For double-ended sterilizers the loading door shall remain locked until the unloading door has been opened, closed, and locked again.

Conformance is demonstrated by inspection.

5.2.4 Temperature control and insulation of the sterilizer chamber

5.2.4.1 Sterilizer chamber inner surfaces shall be controlled to achieve pre-set temperatures prior to cycle commencement.

NOTE The chamber doors are part of the chamber.

Conformance is demonstrated by application testing.

5.2.4.2 All measured sterilizer chamber surface temperatures shall be within a specified value range during defined cycle stages, when tested as described in D.2.

Initiation of the sterilization cycle shall not be possible until these conditions have been fulfilled.

Conformance is demonstrated by testing as described in D.2.

5.2.4.3 Where hot outer surfaces of the sterilizer chamber can cause a burn hazard and to reduce heat transmission to the environment, these surfaces shall be insulated, except where this will interfere with the intended function of the sterilizer. This applies as well to the vaporization system.

Conformance is demonstrated by inspection.

5.2.5 Test connections

5.2.5.1 The sterilizer chamber shall be provided with at least one test connection, which is used for the connection of test measuring instruments. This connection shall be at a point of easy access, but not in a pipe for fluid transport, and shall terminate in a flange connection in accordance with ISO 2861:2020. The test connection(s) shall be connected to the chamber with a size of DN16 KF or larger.

5.2.5.2 The test connection shall be sealed with a sterilant proof and mechanically resistant O-ring seal.

Conformance is demonstrated by inspection

5.3 Further functional components

5.3.1 Pipework and fittings

5.3.1.1 Regarding materials for pipework and fittings 5.2.1.1 applies.

5.3.1.2 In pipework used for supplies, means shall be provided to prevent the ingress of contaminants from external sources that could affect the performance of the sterilizer.

NOTE For connections to a potable water supply and to drainage, national or local regulations could apply.

Conformance is demonstrated by inspection.

5.3.1.3 Pipework shall be designed to prevent unintended accumulation of condensate.

NOTE 1 Accumulation of H_2O_2 can create a hazard.

NOTE 2 Insulation can be applied to reduce the formation of condensate. Insulation cannot be applied when it interferes with the function of the sterilizer.

Conformance is demonstrated by inspection.

5.3.1.4 All control valves in the pipework and test connections shall be marked with permanent identification.

Conformance is demonstrated by inspection.

5.3.2 H_2O_2 vaporizer

5.3.2.1 If a vaporizer, which may be part of the chamber, can be disconnected from the feed to the chamber, means shall be provided to give protection from accidental hazardous effluent of fluids to the environment.

Conformance is demonstrated by inspection of the technical documentation.

5.3.2.2 Means shall be provided to prevent any excessive temperature which can create hazards, e.g. explosion.

Conformance is demonstrated by inspection of the technical documentation.

5.3.3 Evacuation system

5.3.3.1 Sterilizers shall be provided with a vacuum system to remove air, humidity, and H_2O_2 to the lowest absolute pressure needed for fulfilling the requirements of Clause 10.2.5.

Conformance is demonstrated by inspection of the technical documentation.

5.3.3.2 The vacuum system shall reduce the H_2O_2 concentration and its possible reaction products to concentrations below that considered harmless to the operator and the environment (see 8.3.2).

5.3.3.3 The sterilizer shall be provided with means for leak testing which shall include the sterilizer chamber and all relevant connected pipework and fittings. During leak testing, the chamber and relevant pipework shall be subjected to a vacuum at or below the lowest set-point applied during the cycle(s) available to the operator, see 6.8.3 If a leakage from the vaporizer can cause a hazard, the vaporizer shall be included in the leak testing or a separate test procedure (which can differ from 6.8.1) for leak testing shall be provided.

Conformance is demonstrated by inspection of the technical documentation and application testing in accordance with D.2.8.

5.4 Framework and panelling

5.4.1 If the sides of the sterilizer do not need to be accessible for normal operation, they shall be enclosed with panelling.

NOTE 1 Side panelling is not required for sterilizers designed to be recessed into existing walls providing continuous joints with the sterilizer front panelling.

NOTE 2 Ventilation openings can be provided in the panelling.

Conformance is demonstrated by inspection.

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

Conformance is demonstrated by inspection.

5.4.3 The panelling shall be corrosion-resistant to recommended cleaning and disinfection agents and specified working environment conditions (11.5.1 j), and 11.4).

Conformance is demonstrated by inspection of the user instructions and the technical documentation.

5.4.4 The panelling of the sterilizer shall allow access for maintenance work. Such panelling shall be demountable, and shall be dimensioned to allow safe personnel access shall not be obstructed.

Conformance is demonstrated by inspection.

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

Conformance is demonstrated by inspection.

5.4.6 The access for maintenance shall be positioned so that it will not compromise the safety of either the product or persons.

NOTE Requirements for access are also specified in EN 61010-1:2010, 7.3.2 and 7.3.5.

Conformance is demonstrated by inspection.

5.5 Vibration

Vibrations from sterilizers shall be reduced by design, selection of components and devices limiting vibrations, particularly at source. If vibrations can cause a loss of stability of the sterilizer, means shall be provided for suitable fixation.

NOTE 1 Vibration from other sources applicable to the intended use of the sterilizer can also be considered.

NOTE 2 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.

Conformance is demonstrated by inspection of the technical documentation

5.6 Ancillary equipment and components

5.6.1 Loading equipment, if required in accordance with usability assessment, shall be available.

Conformance is demonstrated by inspection of the technical documentation.

5.6.2 Specified dedicated accessories intended to be used with or connected to the sterilizer shall not cause any hazard or detrimental effect to the performance of the sterilizer. The mutual compatibility of both systems shall be verified.

Conformance is demonstrated by inspection of the technical documentation.

5.7 Transport

5.7.1 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.

NOTE EN IEC 61010-2-040:2021, 7.5 provides requirements for lifting and carrying the equipment.

Conformance is demonstrated by inspection of the technical documentation.

5.7.2 The sterilizer, its components and dedicated consumables (if applicable) shall be packed for transportation and storage in a way that their performance characteristics are maintained and no moving part can cause a hazard.

Conformance is demonstrated by inspection of the technical documentation.

5.8 User interfaces

5.8.1 The control used to start the automatic operating cycle shall be located at the loading side of the sterilizer or in a remote operating facility.

If used, a remote operating facility shall perform a risk analysis to ensure safe operation and service of the sterilizer and the safety of the installation area.

Conformance is demonstrated by inspection of the technical documentation.

5.8.2 Double-ended sterilizers shall be provided with the indicating devices specified in 6.6.2 at both ends of the sterilizer.

Conformance is demonstrated by inspection.

5.8.3 Means shall be provided for the user to terminate the sterilization cycle without causing a hazardous situation. If a fault results in aborting or terminating a sterilization cycle in progress, the visual indication of the fault shall continue until the user completes a specified action to clear the indication of the fault. If a sterilization cycle is interrupted, opening of the sterilizer door shall require the use of an access device.

Conformance is demonstrated by inspection of the technical documentation.

5.8.4 Means shall be provided to permit operation of the sterilizer for equipment maintenance, test purposes and in cases of emergency, without causing a hazardous situation. The activation of any service mode shall be clearly indicated in order to avoid safety features being inactivated during normal operations.

Conformance is demonstrated by inspection of the technical documentation.

5.8.5 Indicating, measuring, and recording instruments shall be identified as to their function. Instruments and indicating devices shall be located where they can be viewed readily by the user under standard operation of the sterilizer. Instruments and gauges shall be readable by normal or corrected vision from a distance of 1 m and with a minimum illumination of (215 ± 15) lx.

Conformance is demonstrated by inspection.

5.8.6 If an instrument on the sterilizer is adjustable, the adjustment shall require the use of an access device.

Conformance is demonstrated by inspection.

5.8.7 When fitted, acoustic signals not associated with a hazardous situation shall be time-limited to 30 s or it shall be possible to interrupt them.

Conformance is demonstrated by inspection.

6 Indicating, monitoring, controlling, and recording devices

6.1 General

6.1.1 Pre-set Programme

The cycle parameters for controlling, monitoring, recording, and indicating the operating cycle(s) shall be established and incorporated into pre-set programme(s) of the sterilizer.

NOTE 1 They are intended to ensure that all chemical/physical conditions necessary for the efficacy of the operating cycles can be achieved throughout the specific cycle stages.

NOTE 2 A pre-set programme can have a range of cycle parameters selectable by the end user.

Conformance is demonstrated by inspection of the technical documentation and by successful type tests according to Annex A.

6.1.2 Automatic controller

6.1.2.1 The sterilizer shall be operated by an automatic controller which is part of a system comprising in addition different subunits, e.g. measuring chains, instrumentation, timers and interfaces (see illustrations in Annex I).

Conformance is demonstrated by inspection of the technical documentation.

6.1.2.2 The automatic controller shall be protected against short circuit in components or equipment, which are directly or indirectly connected to the controller.

NOTE See EN 60204-1 or EN 60335-1. Verification can be achieved by assessing conformance with EN 60204-1 or EN 60335-1. EN 60204-1 applies to non-portable electrical, electronic, and programmable electronic equipment and systems to machines. EN 60335-1 deals with the safety of electrical appliances for household and similar purposes including appliances not intended for normal household use but which nevertheless may be a source of danger to the public, such as appliances intended to be used by laymen in shops.

Conformance is demonstrated by inspection of the technical documentation.

6.2 Automatic control

6.2.1 The sterilizer shall operate with pre-set programmes permanently stored in the automatic controller. These shall include one or more pre-set sterilization cycles.

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

Conformance is demonstrated by inspection of the technical documentation.

6.2.2 Means shall be provided to ensure that a failure in a control function does not lead to a failure in recording of process parameters such that an ineffective process appears effective. This may be achieved

either by the use of independent systems for control and recording, or by a cross-check between control and recording that identifies any discrepancies and indicates a fault.

NOTE Examples of concepts for control and monitoring systems and the interrelationship between control and recording are discussed and illustrated in Annex I.

Conformance is demonstrated by inspection of the technical documentation.

6.2.3 The automatic controller shall not cause a hazardous situation, if:

- a) the values of cycle parameters are outside the specified limits;
- b) a power failure occurs;
- c) a failure of another utility occurs;

Conformance is demonstrated by inspection of the technical documentation.

6.2.4 The pre-set programmes of the automatic controller shall allow control, indication monitoring and recording of the sterilizer operation to ensure that the pre-set programmes and its parameters perform safely and reproducibly as intended and can be verified.

Conformance is demonstrated by inspection of the technical documentation and the results of type testing.

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

6.2.6 Safety related software including software for monitoring, control, and recorders shall be verified and validated according to its classification (see e.g. EN 62304). The methods used in the verification processes shall be selected based on the intended purpose of the software. The methods shall be justified and specified.

NOTE Regarding software requirements see, for example, EN 61508 series, EN 62304 and EN 62061. The EN 61508 series applies to safety related systems when one or more of such systems incorporate electrical or electronic or programmable electronic devices. EN 62304 defines the life cycle requirements for medical device software. EN 62061 specifies and makes recommendations for the design, integration and validation of safety-related electrical, electronic and programmable electronic control systems for machines.

Conformance is demonstrated by inspection of the technical documentation.

6.2.7 The automatic controller shall have status indicators for each digital input and output.

NOTE This can be located within the control cabinet.

Conformance is demonstrated by visual inspection.

6.2.8 When a sensor is used for a control function, it shall have broken sensor indication that causes the system to fail safe.

NOTE The fail to safe system can be electronic or mechanical.

Conformance is demonstrated by inspection of the technical documentation.

6.2.9 For sensors for indicating or recording purposes, means shall be provided to indicate a sensor failure.

Conformance is demonstrated by inspection of the technical documentation.

6.2.10 The automatic controller shall be located such that the maximum and minimum values of temperature, humidity and pressure specified for the automatic controller are not exceeded.

NOTE Widely used maximum values for the temperature and humidity at the location of the automatic controller are 50 °C and 85 % relative humidity, respectively.

Conformance is demonstrated by inspection of the technical documentation.

6.2.11 Means shall be provided so that if a failure of the automatic controller occurs, the sterilizer shall be brought to a condition that presents no hazard to the operator, any ancillary equipment, or the operating environment. Opening of the chamber door(s) shall not cause a hazardous situation and shall require the use of an access device (see also 5.2.3.4).

Conformance is demonstrated by inspection of the technical documentation.

6.2.12 Means shall be provided so that if a failure of the automatic controller occurs, the door can be opened without causing a hazardous situation.

Conformance is demonstrated by inspection of the technical documentation.

6.2.13 Programming the automatic controller and any change of the pre-set programme or its parameters shall require the use of an access device and shall be documented.

Conformance is demonstrated by inspection of the technical documentation.

6.2.14 It shall not be possible to adjust any process or cycle parameter during the progress of a sterilization cycle.

Conformance is demonstrated by inspection of the technical documentation.

6.2.15 Access to any automatic controller function shall only be possible by use of an access device.

Conformance is demonstrated by inspection of the technical documentation.

6.2.16 For maintenance, test purposes, failure analysis and in cases of emergency, means shall be provided to permit manually controlled progression of the automatic controller using an access device.

NOTE Additional requirements regarding intervention safety and environmental aspects are specified in EN IEC 61010-2-040:2021 (see e.g. 13.1.101, 13.1.102, 13.101, 14.103 and 14.104).

Conformance is demonstrated by inspection of the technical documentation.

6.2.17 The automatic controller shall provide reproducible operating cycles within specified tolerances.

Conformance is demonstrated by inspection of the technical documentation.

6.3 Control and monitoring system

6.3.1 The control and monitoring system shall comprise different subunits (for computing, measuring chains, instrumentation) and directs operation of the sterilizer using software modules for data collection and processing, cycle control, cycle parameter and status indications, operating controls, independent recording and data storage, process evaluation, and fault indication. See also Annex I.

6.3.2 The control and monitoring system shall have separate measuring chains for the measurement of control data and independent data for the monitoring system (see also 6.5 and 6.7). Independent measurement systems with separate measurement chains for controlling and recording shall be applied to defined cycle variables and process variables. Separate analogue to digital converters shall be used for the control data and independent data.

NOTE 1 Examples of concepts for control and monitoring systems and the interrelationship between control and recording are discussed and illustrated in Annex I.

NOTE 2 Measurement systems providing a higher level of redundancy can be used.

NOTE 3 Risk analysis identifies which cycle variables or process variables require redundant supervision.

Conformance is demonstrated by inspection of the technical documentation considering the principles of the concepts described in Annex I.

6.3.3 In order to achieve reproducible sterilization cycles, in VH202 the following cycle variables and process variables shall be considered for control, monitoring, indication and recording, but are not limited to:

- a) temperature (see 6.5.2, 6.6.2.1);
- b) pressure (see 6.5.3, 6.6.2.2);
- c) time (see 6.5.4, 6.6.2.3);
- d) sterilant composition and amount supplied to the process in order to control the sterilizing agent (see 6.5.5, 6.6.2.4).

NOTE 1 E.g. volume, dose, mass flow, concentration, partial pressures can be used as appropriate.

NOTE 2 Residual moisture on product surfaces (e.g. due to deficient drying after washing) can affect the process efficacy [72].

Conformance is demonstrated by inspection of the technical documentation.

6.3.4 The control and monitoring system shall have segregated software modules that process the control data and the independent data independently of each other.

Conformance is demonstrated by inspection of the technical documentation.

6.3.5 The control data shall be provided to the control function from the data processing system and the control measurement chain.

Conformance is demonstrated by inspection of the technical documentation.

6.3.6 The independent data shall be provided as a one-way flow to data retention.

NOTE This does not exclude the transfer of informative data between the control function and failure detection, and data retention, via a combined system for data transfer.

Conformance is demonstrated by inspection of the technical documentation.

6.3.7 The control and monitoring system shall include means for failure detection. This shall receive both processed control data and independent data and shall indicate a failure if the control data and independent data differ from specified conditions.

Conformance is demonstrated by inspection of the technical documentation.

6.3.8 The independent data and the control data shall be stored in a data retention module, along with notification of failures. These data shall be transferred to a recorder, that may be integrated into the control and monitoring system, built into the sterilizer, or as an external device(s).

NOTE The external device can be a specific local device, or a remote data storage device.

Conformance is demonstrated by inspection of the technical documentation.

6.3.9 A printer may be provided as an option.

NOTE If the optional printer is provided it can be either built in or be connected as an external device.

Conformance is demonstrated by inspection:-

6.4 Failure

6.4.1 General

6.4.1.1 Failure of items and parameters identified by risk analysis to be critical to process or safety, including the operating equipment and services, shall be detected by the monitoring system of the equipment.

NOTE 1 A failure can require different types of indications depending upon its potential effects and urgency, for example, audible/visual alarms, warnings, error indications, messages, displays, as well as subsequent automated responses of equipment or correction by the operator.

NOTE 2 The consequences of a failure can depend on the current operation mode of the equipment. Different levels for alarms and indications depending on the related criticality could be provided.

EXAMPLE A failure of the sterilant supply during the conditioning stage of an operating cycle results in an alarm and an abort of the operating cycle. On the other hand, the same failure during the desorption / drying stage does not necessarily affect the successful completion of the operating cycle, but only causes a warning message and prevents the start of a next operating cycle.

Conformance is demonstrated by inspection of the technical documentation.

6.4.1.2 Such failure of items and parameters critical to process or safety detected by the monitoring system of the equipment shall be indicated and explained in the instructions for use regarding the activation conditions, the intended or potential consequences and the required correction.

Conformance is demonstrated by inspection of the technical documentation and the instructions for use.

6.4.2 Fault

6.4.2.1 If a failure addressed by 6.4.1.1 causes one or more of the process or cycle parameters to be outside its/their specified tolerances during an operating cycle, or if an operating cycle is interrupted by the operator, a fault shall be indicated and shall cause an audible or visual alarm.

NOTE Not every failure will result in a fault (see 3.18).

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.2 If the operating cycle has been completed in accordance with the programme and no fault has occurred, cycle complete shall be generated.

After a fault cycle complete shall not be generated.

Conformance is demonstrated by inspection.

6.4.2.3 If a fault occurs prior to or during the sterilization phase, the load is considered non-sterile and the control shall ensure that for single door sterilizers the door, or for double ended sterilizers, the unloading door, cannot be opened (see 6.4.2.6).

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.4 If a fault is indicated, the automatic controller shall:

- a) prevent continuation of the normal sequence of process stages;
- b) indicate the fault and the operating cycle stage at which the fault occurred;

- c) record the fault message and the operating cycle stage at which the fault occurred.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.5 The visual display indicating that a fault has occurred shall continue at least until the release of the loading door locking mechanism (see 6.4.2.3). Any fault indication shall be distinguishable from the indication of a satisfactory sterilization cycle.

Conformance is demonstrated by inspection.

6.4.2.6 After a fault has been indicated, the automatic controller shall either:

- a) initiate automatic progress to a desorption stage (see 8.3) if hydrogen peroxide has already been admitted to the chamber, followed by stages for recovery of the system which, when completed, allows the loading door to be opened without creating a hazardous situation, with no indication of cycle complete, or
- b) initiate automatic progression of stages of the operating cycle to a safe condition, at which there shall be no indication of cycle complete, or
- c) by use of an access device, allow manual progression through the cycle to a safe condition with no indication of cycle complete.

NOTE different faults can require different actions to return to a safe condition.

Conformance is demonstrated by inspection of the technical documentation.

6.4.2.7 After completion of the recovery stages “cycle complete” shall not be indicated, access to the sterilizer load shall require the use of a key, code or tool, and the load shall be considered nonsterile (see also 5.7.4).

NOTE Additional guidance regarding faults and safety can be found in EN IEC 61010-2-040.

Conformance is demonstrated by inspection.

6.4.3 Power failure

In the event of a power failure which causes a fault, 6.4.2 shall apply after restoration of the power.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4 Other failures

6.4.4.1 If a failure of the operating equipment, the current operating cycle, or any service does not create a fault, its indication shall be distinguishable from a fault indication.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4.2 If a failure can create a fault at a later stage of an operating cycle, or after initiation of another operating cycle, a respective warning shall be displayed.

Conformance is demonstrated by inspection of the technical documentation.

6.4.4.3 If a failure can create a hazardous situation, the controller, in combination with other safety systems, shall automatically initiate action to prevent a hazardous situation. The failure shall be indicated by an audible and visible alarm. The alarm indication shall allow the operator to identify the failure and shall provide a directive by text or by reference to an instruction manual for correction. The failure indication shall be recorded in order to allow retrospective identification and analysis.