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Sterilization of health care products — Chemical indicators —

Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 6: Indicateurs de type 2 et dispositifs d'épreuve de procédé destinés à être utilisés pour les essais de performances relatifs aux petits stérilisateurs à la vapeur d'eau

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers and associated equipment for processing of medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 11140 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document includes a description of both hollow and porous process challenge devices (PCDs) and their performance requirements, along with methods by which an alternative PCD can be shown to have equivalent performance to that of the reference PCD. Small sterilizers unable to accommodate a sterilization module [rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)] cannot be tested using the tests described in EN 285 for large sterilizers for wrapped goods and porous loads because

— the chamber size of a small steam sterilizer according to EN 13060 is unable to accommodate the standard test pack from EN 285, and

— the efficacy of the tests is impaired when the test pack occupies a large proportion of the chamber volume (>20 % chamber volume).

Indicators described in this document are intended to be used in conjunction with appropriate PCDs to show penetration of steam into the PCD. The reference indicator systems and alternative indicator systems pose specified challenges to air removal and steam penetration.

The devices described in this document are intended for use only in small steam sterilizers conforming to EN 13060 to monitor steam penetration in type B cycles and some type S cycles.

NOTE Even though the hollow load was originally designed as a type test in EN 867-5 (withdrawn standard replaced by this document) to test the performance of small steam sterilizers conforming with EN 13060, the same test is also used in other standards, for example, EN 285.

Sterilization of health care products — Chemical indicators —

Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers

WARNING — The use of this document can involve hazardous materials, operations and equipment. It is the responsibility of the user of this document to establish appropriate safety and health practices and determine the applicability of any other restrictions prior to use.

1 Scope

This document specifies the performance requirements and test methods for hollow devices and porous devices as well as the chemical indicators and biological indicators that are utilized within these devices for testing a specific steam penetration performance of type B cycles and some type S cycles of small steam sterilizers according to EN 13060.

NOTE The hollow and porous devices described in this document are not intended for use as surrogate devices for hollow and porous medical devices used in health care facilities.

a) Chemical indicators used with a porous device specified in this document are designed to demonstrate the adequacy of steam penetration into a porous device in small steam sterilizers (see EN 13060).

This document specifies the requirements for:

— a reference porous device (RPD) as a reference device by which alternative porous indicator systems (APISs) can be shown to be equivalent in performance according to this document, i.e. a textile test pack in which steam penetration is judged by thermometric means;

— an alternative porous chemical indicator system equivalent in performance to the RPD, i.e. an APIS, usually commercially manufactured, of any design.

b) Chemical indicators used with a hollow load device specified in this document are designed to demonstrate the adequacy of steam penetration into a narrow lumen (previously known as hollow load A) in small steam sterilizers (see EN 13060).

This document specifies the requirements for:

— a reference hollow device (RHD) used as a reference device in this document, i.e. a lumened device with attached capsule in which steam penetration is judged by inactivation or survival of a specified biological indicator;

— an alternative hollow device:

— employing the same specific test load as defined for the RHD and a chemical indicator designed specifically for use in the reference hollow test load, i.e. a lumened device with an attached capsule in which steam penetration is judged by visual examination of a chemical indicator;

— equivalent in performance to the RHD, i.e. an alternative hollow device, usually commercially manufactured, of any design.

2 Normative references

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

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

ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO 11140-4:2007, *Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

EN 285:2015 +A1:2021, *Sterilization — Steam sterilizers — Large sterilizers*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11140-1 and the following apply.

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

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: ISO 11139:2018, 3.29]

3.2
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

Note 1 to entry: See Annex D.

[SOURCE: ISO 11139:2018, 3.43, modified — Note 1 to entry has been added.]

3.3
chemical indicator endpoint
completion of a specified change after a *chemical indicator* (3.2) has been exposed to specified conditions

[SOURCE: ISO 11139:2018, 3.44]

3.4
chemical indicator system
combination of a *chemical indicator* (3.2) and a specific test load

Note 1 to entry: See Annex D.

[SOURCE: ISO 11139:2018, 3.43.1, modified — Note 1 to entry has been added.]

3.5
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: ISO 11139:2018, 3.205]

4 Requirements

4.1 General

4.1.1 Unless specified otherwise in this document, the requirements of ISO 11140-1 shall apply.

4.1.2 The chemical indicator, the biological indicator, the hollow device and porous device shall be conditioned in an environment of (50 ± 10) % relative humidity (RH) and (25 ± 5) °C. Means shall be used to ensure the internal volume of the hollow device is conditioned similarly.

4.1.3 Chemical indicators intended for use with reusable, user-assembled hollow devices shall not transfer indicator reagent to the material of the hollow device during processing. Preassembled hollow devices and porous devices, and indicators for single-use or user-assembled devices shall not transfer indicator reagent to the material of the device during processing to an extent which impairs the utility of the device.

4.1.4 A process challenge device (PCD) intended to be reused shall, when used in accordance with the provided instructions for use, meet the relevant requirements of this document, during its specified shelf life.

NOTE 1 Instruction can include restriction on the number of reuses, as well as important information on service, cleaning procedures, the manner of inspection and criteria, maintenance and replacement of components.

To establish conformity to the performance requirements of this document over the shelf life of the PCD, a study shall be conducted by way of a protocol developed before study commencement. This may be either a real-time study, or be accelerated. An example of an accelerated study is given in Annex F.

NOTE 2 Some regulatory authorities will only accept data from real-time studies.

4.1.5 For chemical indicator systems with reusable user-assembled hollow devices, conformance to this document shall be demonstrated for the whole of the usable life of the chemical indicator system as specified by the manufacturer.

4.1.6 Conformance of steam penetration shall be demonstrated by visual examination of the chemical indicator system before and after testing in accordance with the requirements of 4.2.3, 4.4 and 4.5, as appropriate.

4.1.7 The designs of alternative hollow and porous devices are not restricted provided they meet the requirements of 4.2.3, 4.4 and 4.5.

4.2 Porous devices

4.2.1 Reference porous device (RPD)

4.2.1.1 The reference porous device (RPD) shall be a standardised test pack that is used to assess the steam penetration performance of small steam sterilizers.

4.2.1.2 The pack shall be constructed from plain non-coloured cotton sheets, each having an approximate size of 450 mm × 300 mm. Edges other than selvedge shall be oversewn, not hemmed.

4.2.1.3 The number of threads per 10 mm in the warp shall be (30 ± 6) and the number of threads per 10 mm in the weft shall be (27 ± 5).

4.2.1.4 The mass per unit area shall be (185 ± 5) $g \cdot m^{-2}$.

4.2.1.5 The sheets shall be washed when new and when soiled. During the washing process the sheets shall not be subjected to any fabric conditioning agent.

NOTE Washing includes adequate rinsing to remove bleach and detergent residues.

4.2.1.6 After washing, the sheets shall be dried and aired, but not ironed or calendered.

4.2.1.7 Before use, the sheets shall be equilibrated in an environment at a temperature of (25 ± 5) °C and (50 ± 10) % RH.

4.2.1.8 After equilibration, the folded sheets shall be approximately 110 mm × 150 mm and stacked to a height of approximately 120 mm after compressing by hand. The pack shall be wrapped in a single sheet of the same fabric and secured with tape not exceeding 19 mm in width. The total mass of the pack shall be (900 ± 30) g.

When forming the pack, consecutive sheets should be stacked with the folded side alternating to ensure an even stack.

When the mass of sheets used to form a stack approximately 120 mm high exceeds 930 g, the sheets shall be discarded.

4.2.1.9 Prior to use, the temperature and humidity of the pack shall be measured using a suitable calibrated temperature and humidity probe. The conditions within the pack shall be between (50 ± 10) % RH and (25 ± 5) °C before it is used for test purposes.

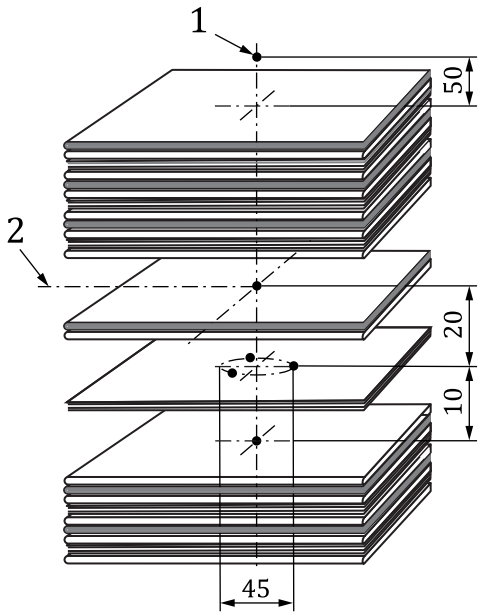
NOTE Pack temperature and humidity can be measured using a sword hygrometer.

4.2.2 Detector for reference porous device (RPD)

4.2.2.1 The detector for the reference porous device (RPD) shall be a thermometric recording instrument and temperature sensors as specified in ISO 11140-4:2007, 4.6.

4.2.2.2 Remove the wrapping from the standard test pack and place five temperature sensors within the test pack at locations as indicated in Figure 1, of which one shall be placed at the geometric centre of the test pack. The others shall be arranged in a pattern around the geometric centre of the test pack to detect a temperature depression occurring within a radius of 30 mm of the geometric centre.

Dimensions in millimetres



Key

1 position of sensors

2 centre layer

Based on EN 285:2015 + A1:2021, Figure 6.

Figure 1 — Location of temperature sensors

4.2.2.3 Place one temperature sensor at the defined reference point within the chamber to measure the chamber reference temperature and one temperature sensor above the test pack at a height of 50 mm. Reassemble the test pack as described in 4.2.1.

4.2.2.4 As the coolest location within the standard test pack will not be predictably at the exact geometric centre, the additional temperature sensors in the standard test pack are used to improve the reproducibility of the test results.

4.2.2.5 The reference temperatures and holding times shall include either 134 °C for 3,5 min or 121 °C for 15 min, or both. The manufacturer of the chemical indicator may specify other time/temperature combinations. All temperature sensors within the test pack shall register a minimum of either 134 °C for 3,5 min or 121 °C for 15 min, or both, during the holding time with a pass cycle when using the reference temperatures and holding times.

NOTE For set up of the standard test pack, the use of a chemical indicator test sheet conforming with ISO 11140-3, cut to the size of the horizontal dimensions of the standard test pack and placed within the pack, can be helpful in visualizing the position of the air pocket and determining the optimum position for the temperature sensors.

4.2.3 Alternative porous indicator system (APIS)

4.2.3.1 The alternative porous indicator system (APIS) shall conform with the requirements of ISO 11140-4 except for the purpose of demonstration of equivalent performance. The performance shall be compared with thermometric monitoring (see 4.2.2) of the RPD given in 4.2.1 and using the steam exposure apparatus defined in Annex A.

4.2.3.2 Carry out the test on three samples for each of three production batches using operating cycles with a sub-atmospheric air removal stage, and on further sets of samples with operating cycles employing a super-atmospheric air removal stage defined in Annex B.

4.2.3.3 Before and after each series of three tests, run an operating cycle containing an RPD monitored with temperature sensors, to verify the operating cycle is performing within the required limits as shown in 4.2.4.

4.2.3.4 The APIS shall show a uniform colour change after exposure to saturated steam at 134 °C for 3,5 min, or at 121 °C for 15 min or at any other time/temperature combination specified by the manufacturer, where the temperature tolerance shall be 0/+1,5 K and the time tolerance shall be ± 5 s, indicating satisfactory air removal and steam penetration.

4.2.3.5 The APIS shall show a fail as specified by the manufacturer indicating unsatisfactory air removal and steam penetration when exposed to a test cycle, previously demonstrated to produce an RPD fault response.

Exposure to a reference fault condition shall produce a fault response regardless of the means of creating the reference fault condition, i.e. the system used to produce the fault may use air retention or air injection. The test cycles used to generate the reference fault conditions shall be as shown in B.4, B.5 and B.6.

The chamber reference temperatures and holding times shall include 134 °C for 3,5 min, or 121 °C for 15 min or another time/temperature combination specified by the manufacturer where the temperature tolerance shall be 0/+1,5 K and the time tolerance shall be ±5 s.

4.2.4 Reference porous device (RPD) response

4.2.4.1 Reference porous device (RPD) pass response

During reference pass conditions there shall be no detectable temperature difference between the centre of the RPD and the chamber reference temperature (within the limits of the accuracy of the measuring equipment) during the exposure time at the sterilization temperature.

4.2.4.2 Reference porous device (RPD) fail response

During reference fault conditions, the centre of the RPD shall show a temperature 2 °C + 1/-0 °C lower than the chamber reference temperature (within the limits of the accuracy of the measuring equipment) during the first 10 % of the exposure time for the sterilization temperature (e.g. for sterilization at 134 °C for 3,5 min a temperature of 132 °C to 131 °C in the centre of the RPD for the first 21 s of the plateau period).

4.3 Hollow devices

4.3.1 Reference hollow device (RHD)

4.3.1.1 This subclause describes the requirements for an RHD, including the physical specifications and an engineering drawing (see Annex E). The manufacturer shall ensure that the internal dimensions, the free capsule volume, the capsule mass and weight distribution around the device are all as specified.

4.3.1.2 The RHD shall consist of a single-ended capsule to contain a biological indicator, connected to a lumen and of uniform internal dimensions throughout its length (see Annex E). The capsule shall be of uniform cross-section over its length of the inserted indicator. Maximal angular deviations of 1° are accepted. The RHD shall have the following specification:

a) tube wall thickness: (0,5 ± 0,05) mm;

b) tube internal diameter: (2,0 ± 0,1) mm;

c) tube length: (1 500 ± 5) mm;

d) free capsule volume (280 ± 50) µl;

e) cap and receptacle material of construction: polytetrafluoroethylene (PTFE);

f) capsule mass: (14,0 ± 1,0) g;

g) lumen material of construction: fluorinated ethylene propylene (PTFE or FEP);

h) seal material of construction: heat- and steam-resistant elastomer.

NOTE The inner and outer dimension of the capsule, and the ratio of the volume of the RHD's tube to the free capsule volume, has an influence on the penetration and air removal characteristics. Physical properties such as mass, heat capacity and heat transfer can also influence the test result.

4.3.1.3 The capsule shall be terminal and of uniform dimensions (cross-sections).

4.3.1.4 There shall be no bubbles visible escaping from the device, when tested according to the method given in 4.5.2.

4.3.1.5 The following items shall be carried out to reduce the number of unnecessary variables under test:

a) the dimension as defined in 4.3.1.2 shall be specified, measured and documented;

b) Place the hollow device on a fine mesh basket; position the terminal orifice of the hollow device at geometric centre of test vessel; position the capsule so that it is higher than terminal orifice;

c) the RHD shall be conditioned by one of the following methods:

1) having ambient air at (50 ± 10) % RH and (25 ± 5) °C drawn through it for not less than 15 min; or

2) drawing a vacuum (<5 kPa) for not less than 15 min at 25 ± 5 °C (e.g. in a desiccator), followed by admission of ambient air at (50 ± 10) % RH and (25 ± 5) °C.

4.3.2 Detector for reference hollow device (RHD)

4.3.2.1 The detector to be used in the RHD shall be a carrier inoculated with *Geobacillus stearothermophilus* and conforming with ISO 11138-3, modified according to Table 1.

Table 1 — Biological indicator specification

	Minimum value	Maximum value
D_{121}value	1,8 min	2,3 min
Population	$1,0 \times 10^6$	$9,9 \times 10^6$
z-value	6 °C	14 °C

NOTE Due to inherent variability in the manufacture of biological indicators, the same lot of biological indicators can help to reduce variability in a given test series.

4.3.2.2 The carrier dimensions shall be: (38,0 + 2/-0) mm × (6,0 ± 1) mm × (0,5 ± 0,05) mm (L × W × H). A different height may be used providing the resulting free capsule volume is maintained as specified by 4.3.1.2 when tested according to 4.5.3.