
**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 stérilisateur à la vapeur d'eau*



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Published in Switzerland

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Foreword

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

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.

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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

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 $(185 \pm 5) \text{ g} \cdot \text{m}^{-2}$.

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 $(25 \pm 5) ^\circ\text{C}$ and $(50 \pm 10) \% \text{ RH}$.

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 $(900 \pm 30) \text{ g}$.

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 $(50 \pm 10) \% \text{ RH}$ and $(25 \pm 5) ^\circ\text{C}$ before it is used for test purposes.

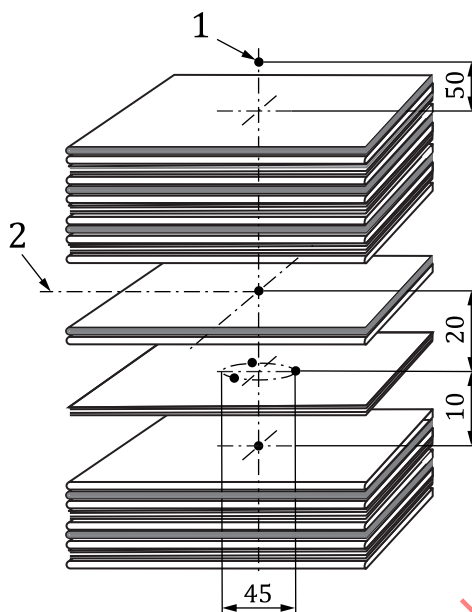
NOTE Pack temperature and humidity can be measured using a sword hygrometer.

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: $(2,0 \pm 0,1)$ mm;
- c) tube length: $(1\,500 \pm 5)$ mm;
- d) free capsule volume (280 ± 50) μl ;
- e) cap and receptacle material of construction: polytetrafluoroethylene (PTFE);
- f) capsule mass: $(14,0 \pm 1,0)$ 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 $\times$ $(6,0 \pm 1)$ mm $\times$ $(0,5 \pm 0,05)$ mm (L $\times$ W $\times$ 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](#).

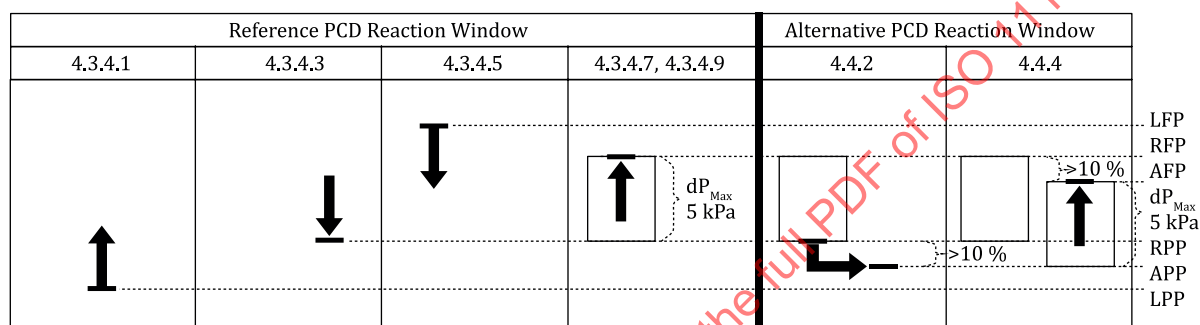
NOTE The porosity of the carrier is an important factor because the porosity volume will increase the free capsule volume.

4.3.3 Reference hollow indicator system (RHIS)

The combination of RHD and detector for RHD shall be used as the RHIS.

4.3.4 Reference hollow indicator system (RHIS) performance determination

Three test cycles (see A.2) are defined for testing of modified air removal. These test cycles represent test cycles adapted from ISO 11140-4. The test cycles are differentiated through particular pre-exposure phases in which the upper pressure change points (endpoint of steam admission process step) and the pressure change rates (during both vacuum and steam admission steps) are defined. Using the test methods described in A.3.2 and A.3.3, characteristic vacuum pressure change points for each test cycle shall be determined by the experimenter using the RHIS in 4.3.3. These characteristic vacuum pressure change points are determined as shown in Figure 2 and described in the corresponding subclauses.



NOTE Numbers and frames give reference to corresponding requirements. Bars and dotted lines show established limits for the limiting pass process (LPP), the reference pass process (RPP), the alternative pass process (APP), the limiting fail process (LFP), the reference fail process (RFP) and the alternative fail process (AFP). Arrows show evaluation of vacuum pressure change points. Boxes show established reaction windows. Sizes of the reaction windows are 5 kPa or smaller.

Figure 2 — Determination of characteristic vacuum pressure change points during testing of modified air removal

4.3.4.1 At the given vacuum set points, three RHIS tested at a time using the test cycles of A.2 shall show no growth in three identical consecutive runs:

- Cycle 1: 17 kPa,
- Cycle 2: 23 kPa,
- Cycle 3: 21 kPa.

For each cycle the given hard limit shall correspond to the limiting pass process (LPP, see Figure 2).

4.3.4.2 Conformance shall be tested in accordance with A.3.2.

4.3.4.3 The highest pressure (vacuum) change point where the reference indicator system always shows no growth in three identical consecutive runs shall be deemed the reference pass process (RPP, see Figure 2). The RPP shall be used as reference for alternative hollow PCD testing (see 4.4.2).

4.3.4.4 Conformance to the RPP shall be tested in accordance with A.3.2.

4.3.4.5 At the given vacuum set points, three reference indicator systems tested at a time at the test cycles of [A.2](#) shall always show growth in three identical consecutive runs:

- Cycle 1: 29 kPa,
- Cycle 2: 42 kPa,
- Cycle 3: 35 kPa.

For each cycle the given hard limit shall correspond to the limiting fail process (LFP), see [Figure 2](#).

4.3.4.6 Conformance shall be tested in accordance with [A.3.3](#).

4.3.4.7 The lowest pressure (vacuum) change point at which the RHIS always shows growth in three identical consecutive runs shall be deemed the reference fail process (RFP) for modified air removal. The RFP (see [Figure 2](#)) shall be used as a reference for alternative hollow PCD testing (see [4.4.4](#)).

4.3.4.8 Conformance shall be tested in accordance with [A.3.3.1](#).

4.3.4.9 The inner reaction window, between the highest pressure change point according to [4.3.4.3](#) and the lowest pressure change point according to [4.3.4.7](#), shall be 5 kPa or smaller.

4.3.5 Leakage test

The leakage test for cycle 1 (see [Table 2](#) and [A.2](#)) of the RHD shall be performed in accordance with [A.3.3](#).

4.4 Alternative hollow indicator system (AHIS)

4.4.1 General

Alternative hollow devices may be manufactured of any alternative design but shall conform with the requirements given in [Annex C](#).

4.4.1.1 The chemical indicator within the alternative hollow device shall reach its chemical indicator endpoint. This indicates satisfactory air removal and steam penetration. This shall be demonstrated in cycles (see [Table 2](#)) previously demonstrated as capable of inactivating a population of *Geobacillus stearothermophilus* spores in the RHD containing the above-specified biological indicator (see [4.3.2.1](#)).

NOTE The chemical indicator endpoint is specified by the chemical indicator manufacturer.

4.4.1.2 Conformance shall be tested in accordance with [Annex A](#) using steam exposure apparatus defined in [A.1](#) and the ability to alter the rate of change of evacuation and steam admission during the air removal stage in accordance with the standard test cycles defined in [A.2](#).

4.4.2 The AHIS shall reach its chemical indicator endpoint at a pressure change point 10 % below the highest pressure set point of the RPP at the test cycles in [A.2](#) in three identical consecutive runs. This process shall be deemed the alternative pass process (APP, see [Figure 2](#)).

4.4.3 Conformance to the APP shall be tested in accordance with [C.2](#).

4.4.4 The lowest pressure (vacuum) change point at which the AHIS does not reach its chemical indicator endpoint in three identical consecutive runs shall be at least 10 % below the RFP. It shall be deemed the alternative fail process (AFP) for modified air removal (see [Figure 2](#)).

4.4.5 Conformance shall be tested in accordance with [C.3](#).

4.4.6 The inner reaction window between the highest pressure change point according to 4.4.2 and the lowest pressure change point according to 4.4.4 shall be 5 kPa or smaller.

4.4.7 The indicator within the alternative hollow device shall show a fail result (has not reached its chemical indicator endpoint) specified by the manufacturer indicating unsatisfactory air removal and steam penetration when exposed to test cycles (see Table 2) previously demonstrated to produce a fail cycle, in accordance with 4.4.4 and A.3. The chamber reference temperatures and holding times shall include 134 °C for 3,5 min and/or 121 °C for 15 min, and/or 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.

4.4.8 Conformance shall be tested using modified test cycles described in A.2 according to the schedule of tests shown in Table 2. The chamber reference temperatures and holding times shall include 134 °C for 3,5 min and/or 121 °C for 15 min and/or other time/temperature combination specified by the indicator manufacturer where the temperature tolerance shall be 0/+1,5 K and the time tolerance shall be ± 5 s.

4.4.9 Where the alternative hollow device incorporates a demountable cap, no bubbles shall be visible escaping from the device, when tested according to the method given in 4.6.

4.5 Alternative hollow devices intended for multiple use

4.5.1 For alternative hollow devices intended for multiple use, conformance to this document shall be demonstrated for the service life of the hollow reference device including indicator as specified by the manufacturer.

Table 2 — Schedule of test cycles for alternative hollow indicator system (AHIS)

Test condition	Cycle 1 ^a	Cycle 2 ^a	Cycle 3 ^a
Pass cycle ^b	Test required	Test required	Test required
Fail – modified air removal stage ^b	Test required	Test not required	Test not required
Fail cycle – induced air leak	Test not required	Test not required	Test not required
^a Test cycles as specified in A.2.			
^b With the vacuum set point determined using the RHD with the detector for the RHIS.			

Failure mode testing shall be conducted for the reference or alternative hollow device for the modified air removal stage; air leak testing is not required for this type of device.

NOTE The RHIS does not detect air leaks in super-atmospheric or trans-atmospheric steam cycles.

4.5.2 Hollow device seal test method

4.5.2.1 Seal the hollow device according to the manufacturer's instructions. Connect the open end of the hollow device to a compressed air supply at 20 kPa $\pm$ 2 kPa above ambient pressure. A suitable adaptor shall be made to give a gas tight fit.

4.5.2.2 Immerse the sealed capsule in a suitable container filled with water until it is just below the water level. Observe the seal. No bubbles shall be visible. Any bubbles of air escaping from the seal, or any other part of the hollow device, indicate that the hollow device is unsuitable. The same test shall be carried out in a suitable container filled with oil at 140 °C. The oil shall be stable and non-fuming at 140 °C.

4.5.3 Reference hollow device (RHD) capsule volume test method (free capsule volume determination)

4.5.3.1 The free capsule volume, consisting of the internal volume of the part of the hollow load PCD which is intended to accommodate the indicator, less the indicator volume, shall be determined by subtraction of the inoculated carrier displacement volume (4.5.3.2) from the empty capsule volume (4.5.3.3).

4.5.3.2 The displacement volume of the detector shall be determined using a pycnometer of about 5 ml or 10 ml volume and a balance of accuracy of at least 1 mg using the following procedure:

- Weigh the dry pycnometer. Repeat three times and average to give m_1 .
- Fill the pycnometer to the target volume with purified water and weigh. Repeat three times and average to give m_2 .
- Empty the pycnometer and dry using isopropanol. Verify that its weight matches m_1 [see a)].
- Calculate the density $\rho(\text{H}_2\text{O})$ of water using [Formula \(1\)](#)

$$\rho(\text{H}_2\text{O}) = \frac{m_2 - m_1}{V_{\text{py}}} \quad (1)$$

where

m_1 is the weight of the empty, dry pycnometer in grams;

m_2 is the weight of the pycnometer filled with purified water in grams;

V_{py} is the defined volume of the pycnometer in mL;

$\rho(\text{H}_2\text{O})$ is the density of purified water used in this procedure in g/mL.

- Place 10 (ten) inoculated carriers in the pycnometer and weigh. Repeat three times and average to give m_3 .
- Fill the pycnometer with purified water, with the carriers inside, to the target volume. Use an ultrasonic bath to degas the water. The pycnometer shall be dry outside when weighed. Repeat three times and average to give m_4 .
- Calculate the inoculated carrier displacement volume V_{cdv} for a single carrier using [Formula \(2\)](#)

$$V_{\text{cdv}} = \frac{m_2 + m_3 - m_1 - m_4}{\rho(\text{H}_2\text{O})} \cdot \frac{1000}{10} \quad (2)$$

where

m_3 is the weight of the dry pycnometer with 10 inoculated carriers, in grams;

m_4 is the weight of the pycnometer filled with 10 carriers and purified water, in grams;

V_{cdv} is the carrier displacement volume of a single carrier, in μL .

4.5.3.3 Determine the empty capsule volume V_{empty} as follows:

- remove the PTFE tubing and any connector from the capsule;
- close the capsule with the cap;
- insert a cylindrical rod of 3 mm diameter and approximately 30 mm long in place of the tube;

NOTE Verification of the exact positioning of the rod during the whole measuring procedure can be done using an external marking.

- d) determine the mass of c) and adjust the tare (unladen mass) to zero;
- e) condition c) and a syringe filled with purified water with a small amount of detergent to a temperature of $20\text{ °C} \pm 1\text{ K}$;

NOTE The detergent reduces the surface tension of the water and aids wetting of the inner surfaces

- f) remove the receptacle and the rod from the capsule;
- g) fill the cap with water from the syringe;
- h) slowly insert the receptacle into the cap so that the capsule is closed, allowing displacement of air bubbles from the capsule;
- i) hold the capsule vertically with the open end upward and insert the rod into the hole of the tubing allowing displacement of the water;
- j) use the tare of the balance [(see d)] and determine the mass difference;

NOTE The mass difference in mg is equivalent to the empty capsule volume V_{empty} in μL .

- k) record the results and dry the capsule.

4.5.3.4 The free capsule volume shall be calculated using [Formula \(3\)](#):

$$V_{\text{free_capsule_volume}} = V_{\text{empty}} - V_{\text{cdv}} \quad (3)$$

where

$V_{\text{free_capsule_volume}}$ is the volume that is not filled by the carrier, in μL ;

V_{empty} is the internal volume of the capsule with receptacle and without carrier, in μL ;

V_{cdv} is the carrier displacement volume of a single carrier in μL [from [Formula \(2\)](#)].

4.6 Test procedure for validation of conformance of the alternative hollow device to the reference hollow device (RHD)

4.6.1 Establish RPP, RFP, APP and AFP with RHIS and AHIS according to [4.3.4.3](#) to [4.4.5](#). The indicator system shall have reached its chemical indicator endpoint for tests of [4.3.4](#) and [4.4](#), indicating a pass process. The indicator system should not have reached its chemical indicator endpoint for tests of [4.3.4](#) and [4.4](#), indicating a fail process.

4.6.2 For each of the cycles 1 to 3, validate the RPP cycle as follows:

- a) set process parameters for RPP;
- b) in each of three consecutive runs, test three RHIS in parallel.

4.6.2.1 At the end of each cycle all RHIS shall show no growth.

4.6.2.2 See [A.2.1](#) to [A.2.3](#) for testing of [4.6.2](#).

NOTE For the RPP cycle, the AHIS is in its reaction window and can show fail and pass results.

4.6.3 For cycle 1, validate the RFP cycle as follows:

- a) set process parameters for RFP;
- b) test three RHIS in parallel. At the end of the cycle, all RHIS shall show growth;
- c) test one AHIS in three consecutive runs. At the end of each cycle, the AHIS shall have not reached its chemical indicator endpoint;
- d) repeat the sequence of b) and c) two times in consecutive runs.

4.6.3.1 Testing of [4.6.3](#) a) to d) shall be carried out in consecutive order.

4.6.3.2 See [A.2.1](#) to [A.2.3](#) for testing of [4.6.3](#).

4.6.4 For each of the Cycles 1 to 3, validate the APP cycle as follows:

- a) set process parameters for APP;
- b) test three RHIS in parallel. At the end of the cycle, all RHIS shall show no growth;
- c) test one AHIS in three consecutive runs. At the end of each cycle, the AHIS shall have reached its chemical indicator endpoint;
- d) repeat the sequence of b) and c) two times in consecutive runs;
- e) repeat b).

4.6.4.1 Testing of [4.6.4](#) a) to e) shall be carried out in consecutive order.

4.6.4.2 See [A.2.1](#) to [A.2.3](#) for testing of [4.6.4](#).

4.6.5 For Cycle 1, validate the AFP cycle as follows:

- a) set process parameters for AFP;
- b) test one AHIS in three consecutive runs.

4.6.5.1 At the end of each cycle, the AHIS shall not have reached its chemical indicator endpoint.

4.6.5.2 See [A.2.1](#) for testing of [4.6.5](#).

NOTE For the AFP cycle, the RHIS is in its reaction window and can show fail and pass results.

5 Chemical indicator dry heat performance

5.1 General

After exposure to the conditions given in [5.2](#) and [5.3](#), each chemical indicator that is available for either alternative hollow or porous devices shall not reach their chemical indicator endpoint after this test according to instructions provided by the chemical indicator manufacturer.

5.2 Test 1

Perform the chemical indicator dry heat test according to ISO 11140-1:2014, 6.1.4, in a dry heat resistometer according to ISO 18472. The test shall be performed at $(140 \pm 2) ^\circ\text{C}$, for a minimum time of 30 min, in triplicate. The indicator shall not reach the chemical indicator endpoint. If testing is greater

than 30 min and all chemical indicators do not show the chemical indicator endpoint, the test shall be interpreted as an acceptable result.

5.3 Test 2

5.3.1 Fit the indicator in combination with its specified test load (the hollow device) with a temperature sensor to monitor the temperature of the indicator and subject it to dry heat at $(140 \pm 2) ^\circ\text{C}$ to determine the time required for the indicator to reach $134 ^\circ\text{C}$. This time is the heat-up time.

NOTE Indicator systems intended for use only at a sterilization temperature of $121 ^\circ\text{C}$ can be subjected to $(130 \pm 2 ^\circ\text{C})$ and the time required to attain $121 ^\circ\text{C}$ is determined.

5.3.2 Transfer the indicator systems to the oven and subject them to dry heat at $(140 \pm 2) ^\circ\text{C}$ for [(heat-up time) + 30 min]. Indicator systems intended for use only at a sterilization temperature of $121 ^\circ\text{C}$ may be subjected to dry heat at $(130 \pm 2) ^\circ\text{C}$.

NOTE Several test samples can be exposed simultaneously.

5.3.3 The test shall be performed in triplicate.

6 Marking and labelling

NOTE See ISO 11140-1 for additional labelling requirements.

6.1 Device labelling

6.1.1 The APIS shall be clearly marked with the following symbol:

ISO 11140-6 POROUS

The symbol shall not be translated.

6.1.2 The RHD shall be clearly marked with the following symbol if it is made commercially available:

ISO 11140-6 REFERENCE HOLLOW

The symbol shall not be translated.

6.1.3 The alternative hollow device shall be clearly marked with the following symbol:

ISO 11140-6 HOLLOW

The symbol shall not be translated.

6.2 Additional labelling requirements for hollow devices

6.2.1 The dimensions and type of chemical indicators with which the hollow device is intended to be used shall be clearly specified by the manufacturer.

6.2.2 The hollow device shall be clearly and permanently marked with the temperature range within which it is intended to be used. This marking shall also be placed on the package label; where this is not possible, this shall be justified and explained in the instructions for use.

6.3 Chemical indicators for use in hollow devices

6.3.1 The instructions for use shall include details of any limitations concerning the design of the hollow device with which the chemical indicator is intended to be used, e.g. capsule dimensions (see also [4.3.1.1](#), [4.3.2.2](#) and [Annex E](#)).

6.3.2 The chemical indicator shall be labelled with a unique product code to enable the correct identification of the chemical indicator to the hollow device.

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Annex A (normative)

Test method for performance of reference hollow indicator system (RHIS)

A.1 Steam exposure apparatus and steam quality for test purposes

A.1.1 General

The steam exposure apparatus for use in this test method has a chamber volume of less than 60 l and is unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm).

The vessel shall be equipped with means of maintaining the internal surface of the chamber walls, other than the endplate and door at a controlled temperature within the range 115 °C to 140 °C with a limit deviation of ±2 K.

The steam exposure apparatus shall be supplied with saturated steam containing up to 2 ml of non-condensable gases collected from 100 ml of steam condensate, when tested as described in EN 285:2015, 21.1.

A.1.2 Leakage test

The steam exposure apparatus shall have an air leakage rate not greater than 0,1 kPa/min when determined by the following method:

With the temperature stabilized and the chamber empty (except for fixed furniture and necessary monitoring sensors) start the test cycle. When the pressure in the chamber has reached or is below the value corresponding to the lowest operating vacuum of the test cycle air removal stages, close all the valves connected to the chamber and stop the vacuum pump. Observe and record the time, t_1 , and the absolute pressure, p_1 . Allow evaporation of condensate in the chamber for 300 s ± 10 s and then observe and record the absolute pressure, p_2 , in the chamber and the time, t_2 . After a further 600 s ± 10 s, again observe and record the absolute pressure, p_3 , and the time, t_3 . The resistometer may be equipped with a test cycle for air leakage that will carry out this procedure automatically and display the air leakage in kPa/min (mbar/min). At the end of the test calculate the rate of pressure rise for the 600 s period.

NOTE 1 If the value of $(p_2 - p_1)$ is greater than 2 kPa (20 mbar), this can be due to the initial presence of excessive condensate in the sterilizer chamber.

NOTE 2 In a closed vessel at 4 kPa pressure, the pressure changes by approximately 0,1 kPa (1 mbar) for each 10 °C change in temperature; over the range 20 °C to 140 °C; at 7 kPa (70 mbar) the change is approximately 0,2 kPa (2 mbar). The test can be compromised if the temperature changes by more than 10 °C during the period in which the chamber pressure is monitored.

The leakage test shall be performed after warming the chamber to the desired exposure temperature.

A.1.3 Apparatus warm-up

After the successful leakage test, perform a further warming cycle to ensure that the inner surfaces are at the desired temperature.

NOTE The warming cycle can be a shorter test cycle which does not have to be identical with the test cycles below.

A.1.4 Instrumentation

A.1.4.1 General

The instrumentation shall conform with ISO 18472.

A.1.4.2 Indicator, controller and recorder sensors

A common system for indication, control and recording may be used provided that:

- a) a minimum of two sensors are employed for each location and variable to be considered;
- b) the system is self-monitoring such that any error in the measured variable in excess of the accuracy specified (see [A.2.1](#) to [A.2.4](#)) shall result in the indication of a fault.

A.1.4.3 Calibration

The equipment used for measurement of temperature and pressure shall be in a known state of calibration which shall be carried out and documented in accordance with ISO 10012.

This shall include verification of calibration before and after each series of tests.

A series of tests shall comprise all the tests required to investigate conformity of a product with this document.

Test results obtained after satisfactory verification of calibration but for which subsequent verification of calibration demonstrates that test equipment was outside specified limits shall not be used for demonstrating conformity with this document.

A.1.5 Cycle control

A.1.5.1 Steam control

Means shall be provided to enable the steam in the vessel to be maintained at the selected operating pressure with a limit deviation of ± 1 kPa.

A.1.5.2 Signals

Means shall be provided to generate signals capable of being used to automatically initiate the operation of ancillary equipment (e.g. air injection apparatus) on attainment of a programmable value for temperature at the reference measurement point of the chamber temperature, chamber pressure, or elapsed time at any chosen point during the air removal, steam admission, or hold stages.

A.1.5.3 Leak valve

To perform a leak test, a test port with direct access to the vessel shall be provided. It is advised to keep the connecting tubes at a total length of 30 cm. At the test port, a valve shall be installed. This valve shall be controlled by the process control of the steam exposure apparatus or a microcontroller.

A.1.6 Operating cycle: Stages and control options required

The automatic controller shall provide means to select and adjust each of the following cycle stages:

- a) Air removal: to effect the initial stages of air removal, a pressure of 5 kPa or less shall be attainable. This shall be followed by alternate steam admission and evacuation of the chamber. The pressure range shall be adjustable to provide both sub-atmospheric and super-atmospheric pulsing. The number of pulses shall be adjustable to provide the option to select between 0 pulse and not less than 6 pulses.

- b) Steam admission: to pre-set exposure conditions (see [A.2.4](#)).
- c) Operating pressure: the pressure shall be controlled throughout the exposure time within ± 2 kPa of the set pressure.
- d) Evacuation: to remove steam (thus ending the indicator reaction) and also to dry the load, an ultimate pressure of 5 kPa or less shall be attainable.
- e) Air admission: to equilibrate the chamber pressure with atmospheric pressure.

A.1.7 Control limits

A.1.7.1 Pressure attained control points shall be capable of being attained reproducibly to a limit deviation of $\pm 0,3$ kPa over the range 4 kPa to 30 kPa and $\pm 1,0$ kPa over the range 30 kPa to 385 kPa.

A.1.7.2 Elapsed time control points shall be capable of being attained reproducibly to a limit deviation of ± 1 s over the range 2 s to 60 min.

A.1.7.3 Temperature attained control points shall be capable of being attained reproducibly to a limit deviation of $\pm 0,5$ K over the range 50 °C to 145 °C.

A.1.8 Steam supply

A.1.8.1 The steam supply shall conform with the requirements of EN 285. Particular attention shall be paid to the levels of non-condensable gases in the steam supply and to ensuring that the moisture content or superheating of the steam is within the specified limits even under the extremes of the steam demand generated by the steam exposure apparatus, and any other equipment connected to the same steam supply.

A.1.8.2 The condensate obtained from steam supplied to the chamber of the steam exposure apparatus shall conform with the following requirements unless the manufacturer can demonstrate that any of the specified contaminants, when present at higher concentrations, do not influence the performance of the indicator or indicator system:

- Conductivity: ≤ 15 $\mu\text{S}/\text{cm}$;
- pH: 5 to 8.

NOTE The pH-value can be monitored by chemical colour indicator as paper strip or solution.

Other interfering substances, e.g. phosphate, chloride, sulfate, oxidizable substances, shall be identified by the manufacturer and stated in the labelling.

A.2 Test cycles

A.2.1 Cycle 1, air removal by sub-atmospheric pulsing, slow

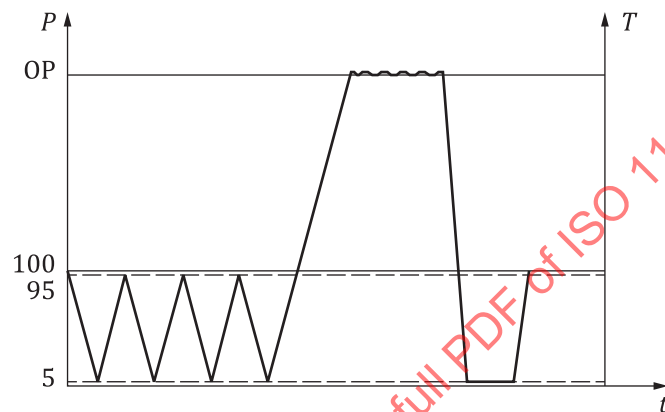
Standard test cycle 1 is shown in [Figure A.1](#) and is adapted from ISO 11140-4:2007, B.1, but with the pressure gradients for both vacuum and steam admission steps limited to 45 ± 1 kPa/min. It shall consist of the following steps:

- a) evacuation of the chamber to 5,0 kPa;
- b) steam admission to 95 kPa;
- c) repetition of steps a) and b) a further three times;
- d) steam admission to set operating pressure;

- e) exposure time;
- f) evacuation to 5,0 kPa with a pressure gradient of at least 250 kPa/min;
- g) evacuation of the chamber to ≤ 5 kPa for 2 min;
- h) air admission.

The actual pressures achieved at the set points shall be determined by the tolerance permitted for the steam exposure apparatus.

The pressure change after the exposure phase shall be as fast as possible (e.g. 400 kPa/min, see ISO 11140-4:2007, A.2.1) in order to prevent belated temperature and steam effects on the detector.



Key

- OP operating pressure
- T temperature
- t time
- P pressure

Figure A.1 — Cycle 1, sub-atmospheric air removal, slow pressure change rate

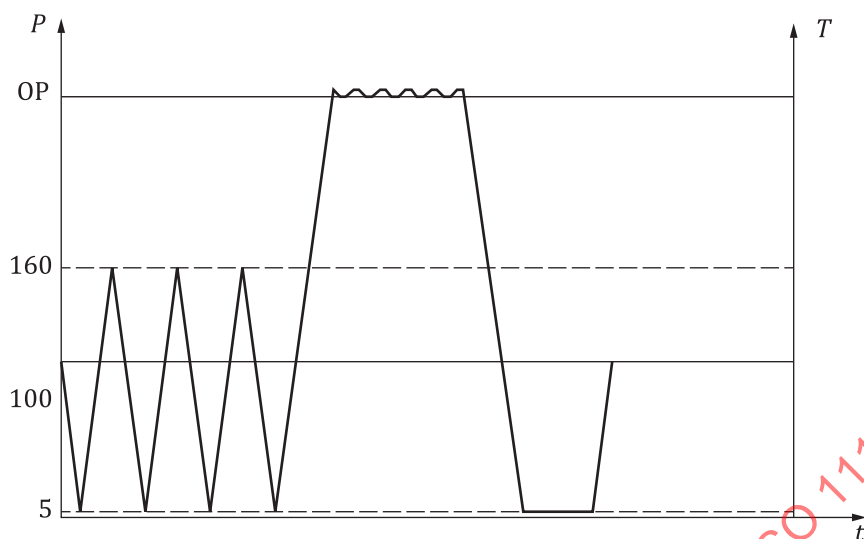
A.2.2 Cycle 2, trans-atmospheric pulsing, fast

The standard test cycle 2 is shown in Figure A.2 for air removal by trans-atmospheric pulsing with the pressure gradients for both vacuum and steam admission steps limited to 250 ± 2 kPa/min. It shall consist of the following steps:

- a) evacuation of the chamber to 5,0 kPa;
- b) steam admission to 160 kPa;
- c) repetition of steps a) and b) a further three times;
- d) steam admission to operating pressure;
- e) exposure time;
- f) evacuation to 5 kPa with a pressure gradient of at least 250 kPa/min;
- g) evacuation of the chamber to ≤ 5 kPa for 2 min;
- h) air admission.

The actual pressures achieved at the set points shall be determined by the tolerance permitted for the steam exposure apparatus.

The pressure change after the exposure phase shall be as fast as possible (e.g. 400 kPa/min, see ISO 11140-4:2007, A.2.1) in order to prevent belated temperature and steam effects on the detector.



Key

OP operating pressure

T temperature

 t time

P pressure

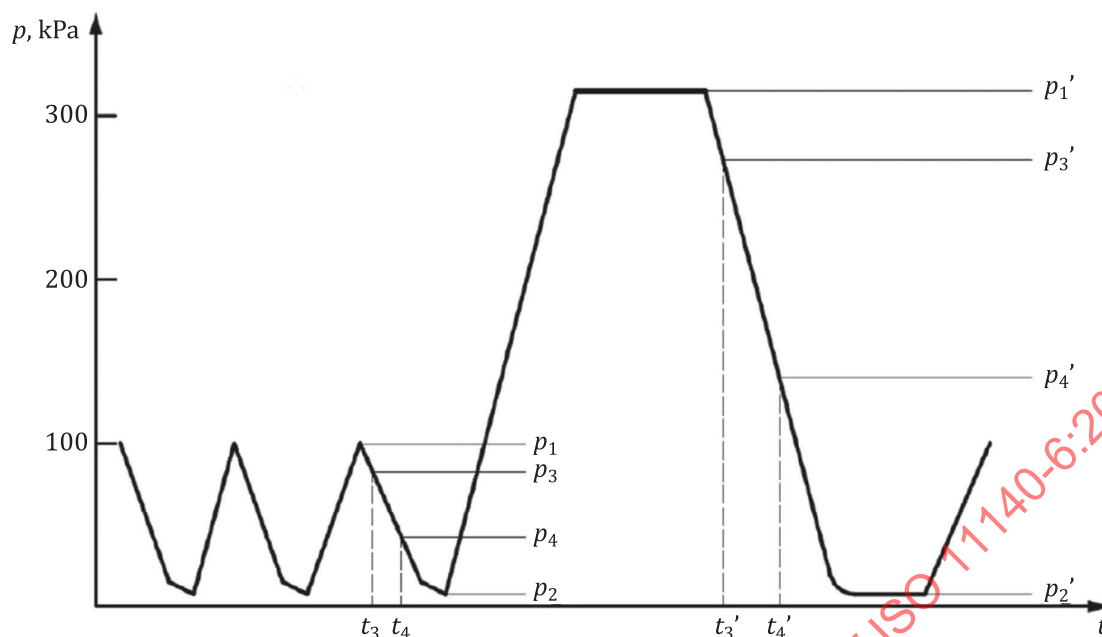
Figure A.2 — Cycle 2, trans-atmospheric fractionation, fast pressure change rate

A.2.3 Cycle 3, air removal by combined sub- and super-atmospheric pulsing

Standard test cycle 3 is shown in [Figure A.3](#) and is adapted from ISO 11140-4:2007, B.3, but with the pressure gradients for both vacuum and steam admission steps limited to 250 ± 2 kPa/min. It shall consist of the following steps:

- evacuation of the chamber to 5,0 kPa;
- steam admission to 95 kPa;
- repetition of steps a) and b) a further two times;
- steam admission to set operating pressure minus 20,0 kPa;
- evacuation of the chamber to 100 kPa;
- repetition of steps d) and e) a further two times;
- steam admission to set operating pressure;
- exposure time;
- evacuation to 5,0 kPa with a pressure gradient of at least 250 kPa/min;
- evacuation of the chamber to ≤ 5 kPa for 2 min;
- air admission.

The actual pressures achieved at the set points shall be determined by the tolerance permitted for the steam exposure apparatus.



Key

OP operating pressure

T temperature

t time

P pressure

Figure A.4 — Acceptance limits during steam admission

A.3 Test methods

A.3.1 Exposure time

A.3.1.1 General

Where 134 °C is used for the exposure temperature / operating temperature, the exposure time shall be 3,5 min.

Other time/temperature combinations specified by the manufacturer may also be tested.

A.3.1.2 Conditioning of reference hollow load device (RHD) and detector

Before every test the hollow device shall be pre-conditioned.

This may be achieved by one of the following methods:

- place all parts of the disassembled hollow device in a vacuum chamber (e.g. desiccator) and evacuate to a vacuum of ≤ 5 kPa;
- draw air between 20 °C and 30 °C and 40 % RH to 60 % RH through it for not less than 15 min.

NOTE Appropriate conditioning of the device is indispensable for repeatable results and the avoidance of false-positive results.

A.3.2 Method for determination of pass conditions

A.3.2.1 Place the inoculated carrier as defined in [4.3.2](#) into the RHD thus creating the RHIS. Three RHISs can be used at a time.

A.3.2.2 Operate the steam exposure apparatus using:

- a) the selected test cycle from [A.2](#) (see [Table 2](#));
- b) the exposure temperature specified in [A.3.1](#);
- c) the exposure time specified in [A.3.1](#).

A.3.2.3 At the end of the cycle recover the RHD from the steam exposure apparatus.

NOTE If the RHD is to be transported to another location for further analysis, means can be provided to ensure recontamination does not occur.

A.3.2.4 Employing aseptic technique, recover the inoculated carrier from the RHD, transfer to growth medium and incubate according to the manufacturer's instructions.

A.3.2.5 The inoculated carriers shall show no growth after the recommended incubation time. If growth of one or more carriers occurs, confirm that this is not due to the presence of surviving indicator organism.

A.3.2.6 Impair the air removal stage of the operational cycle by adjusting the vacuum pressure levels on each of the sub-atmospheric pulses of the test cycle by increments of 5 kPa until at least one inoculated carrier shows growth. Then decrease by increments of 2 kPa until all inoculated carriers show no growth. This process shall be deemed the pass reference cycle if three identical consecutive runs result in 3 × 3 no growth.

A.3.2.7 If growth of one or more inoculated carriers is observed in one repetition, reduce vacuum by 1 kPa increment and repeat the verification in 3 identical consecutive repetitions according to [A.3.2.6](#).

A.3.2.8 Testing shall be conducted in consecutive runs on the same working day.

A.3.3 Method for determination of conditions for fail through modified air removal stage

A.3.3.1 Impair the air removal phase of the reference pass cycle as determined in [A.3.2](#) by adjusting the vacuum pressure levels on each of the sub-atmospheric pulses of the particular test cycle by increments of +5 kPa until all reference inoculated carriers show growth. Then decrease by increments of 2 kPa until at least one inoculated carrier shows no growth. The process with the lowest vacuum set point where all inoculated carriers show growth shall be deemed the fail reference cycle if three identical consecutive runs result in 3 × 3 growth.

A.3.3.2 If no growth of one or more indicator systems is observed in one repetition impair vacuum by +1 kPa increment and repeat the verification in 3 identical consecutive repetitions according to [A.3.3.1](#).

A.3.3.3 Employing aseptic technique, recover the inoculated carrier from the RHD, transfer to growth medium and incubate according to the manufacturer's instructions.

A.3.3.4 All inoculated carriers shall show growth after the recommended incubation time.

Annex B (normative)

Test method for performance of alternative porous indicator system (APIS)

B.1 Apparatus

Steam exposure apparatus in accordance with [A.1](#).

B.2 Pass cycle 1 — Sub-atmospheric air removal

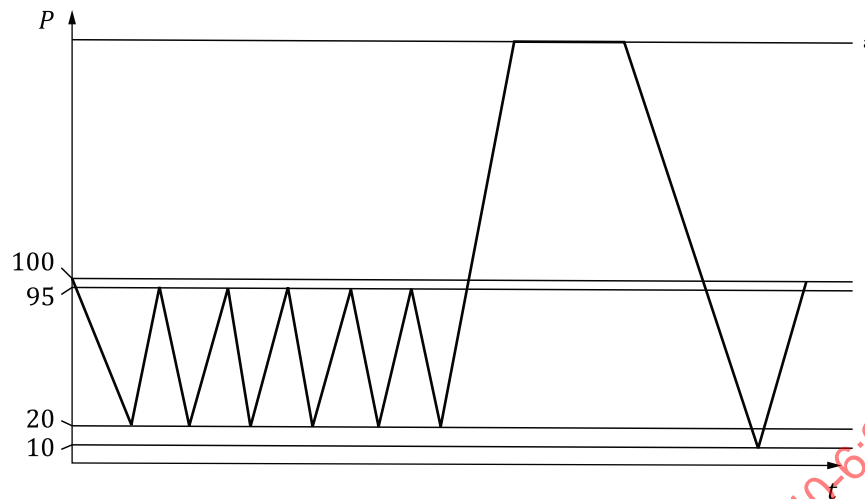
B.2.1 Cycle 1 shown in [Figure B.1](#), sub-atmospheric air removal, shall meet the following requirements:

- a) evacuation to 20 kPa;
- b) steam admission to 95 kPa;
- c) steps a) and b) repeated five more times;
- d) steam admission to exposure pressure;
- e) hold for exposure time;
- f) evacuation to 10 kPa;
- g) air admission to ambient pressure.

B.2.2 The rate of pressure change, during steps [B.2.1](#) a) to b) shall not exceed 50 kPa/min and during step [B.2.1](#) d) shall be within the range 25 kPa/min to 50 kPa/min.

B.2.3 If air injection is being used, it shall take place and be completed during steam admission to the exposure time at a pressure of between 75 kPa and 105 kPa.

NOTE The actual pressures achieved at the set points are determined by the tolerances permitted for the steam exposure apparatus (see [Annex A](#)).

**Key**

- a Operating pressure.
 t time
 P pressure

Figure B.1 — Standard test cycle — Sub-atmospheric air removal (see B.2)

B.3 Pass cycle 2 — Super-atmospheric air removal

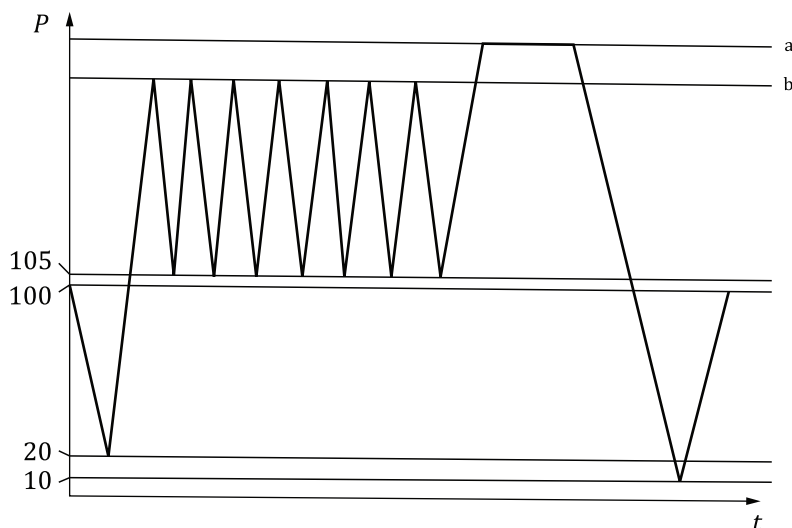
B.3.1 Cycle 2 shown in [Figure B.2](#), super-atmospheric air removal, shall meet the following requirements:

- evacuation to 20 kPa;
- steam admission to set operating pressure minus 20 kPa;
- evacuation to 105 kPa;
- steps b) and c) repeated six more times;
- steam admission to exposure pressure;
- hold for exposure time;
- evacuation to 10 kPa;
- air admission to ambient pressure.

B.3.2 The rate of pressure change during steps [B.3.1](#) a) to c) shall not exceed 50 kPa/min and during step [B.3.1](#) e) shall be within the range 25 kPa/min to 50 kPa/min.

B.3.3 If air injection is being used, it shall take place during steam admission to the exposure time at a pressure of between 120 kPa and 130 kPa.

NOTE The actual pressures achieved at the set points are determined by the tolerances permitted for the steam exposure apparatus (see [Annex A](#)).



Key

- a Set operating pressure.
- b Set operating pressure minus 20 kPa.
- P pressure
- t time

Figure B.2 — Standard test cycle — Super-atmospheric air removal (see B.3)

B.4 Cycle 3 — Impaired sub-atmospheric air removal

Follow the same instructions as Cycle 1 (see B.2) but modify the pressure range, and if necessary, the number of repetitions at step c) until the centre of the RPD performing within the required limits as shown in 4.2.4.2.

The reduction in the pressure range and, if necessary, the number of pulses in the air removal stage, shall be determined by prior trial.

B.5 Cycle 4 — Impaired super-atmospheric air removal

Follow the same instructions as Cycle 2 (see B.3) but modify the pressure range, and if necessary, the number of repetitions at step d) until the centre of the RPD performing within the required limits as shown in 4.2.4.2.

The reduction in the pressure range and, if necessary, the number of pulses in the air removal stage, shall be determined by prior trial.

B.6 Cycle 5 — Air injection

Follow the same instructions as Cycles 1 and 2 (see B.2 and B.3) and then subject to air injection test using an air injection apparatus described in ISO 11140-4:2007, Annex L. Modify air injection until the centre of the RPD performing within the required limits as shown in 4.2.4.2.

Annex C (normative)

Test method for performance of alternative hollow indicator system (AHIS)

C.1 Apparatus

Use a steam exposure apparatus in accordance with [A.1](#).

C.2 Method — Pass cycle

C.2.1 Place the chemical indicator, which has previously been demonstrated to conform with the requirements of [4.4](#), into the alternative hollow device.

C.2.2 Place both the reference indicator system and the alternative indicator system into the steam exposure apparatus.

C.2.3 Operate the steam exposure apparatus using the same test conditions as determined in [A.3.2](#) with the exception that the exposure time shall be set to that required to achieve the chemical indicator endpoint, as specified by the indicator manufacturer.

C.2.4 Upon recovery from the steam exposure apparatus, the indicator shall have reached its chemical indicator endpoint.

C.2.5 Repeat [C.2.1](#) to [C.2.4](#) two more times using separate exposure cycles of the steam exposure apparatus. Carry out the test on three samples for each of three production batches.

C.3 Method — Fail cycle

C.3.1 Place the chemical indicator, which has been previously demonstrated to conform with the requirements of [4.3.3](#), into the alternative hollow device.

C.3.2 Place both the alternative indicator system and the reference indicator system into the steam exposure apparatus.

C.3.3 Operate the steam exposure apparatus using the same test conditions required to generate a fail condition determined in [A.3.3](#), with the exception that the settings required for impaired air removal shall be deeper by 10 % and with the exception that the exposure time shall be set to that required to achieve the chemical indicator endpoint, as specified by the manufacturer.

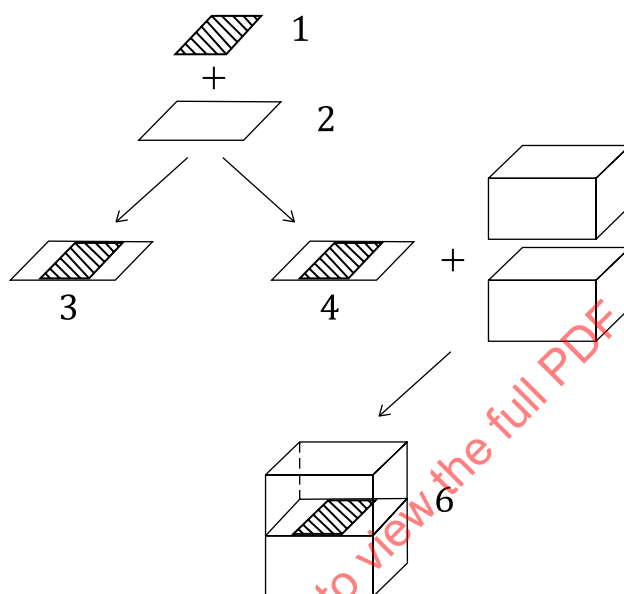
C.3.4 Upon recovery from the steam exposure apparatus, the indicator shall not have reached its chemical indicator endpoint.

C.3.5 Repeat [C.3.1](#) to [C.3.4](#) two more times using separate exposure cycles of the steam exposure apparatus. Carry out the test on three samples for each of three production batches.

Annex D (informative)

Relationship between chemical indicator components

D.1 This document gives requirements for various components of a chemical indicator. These components, and their relationship to other components, are shown in [Figure D.1](#).



Key

- | | | | |
|---|-------------------------------------|---|---|
| 1 | chemical indicator reagent | 4 | chemical indicator to be used only with a specified test load |
| 2 | substrate | 5 | specified test load |
| 3 | chemical indicator to be used as is | 6 | chemical indicator system |

**Figure D.1 — Relationship of chemical indicator components
(from ISO 11140-1:2014, Annex E)**

D.2 This document further sub-divides these components. These can be summarised as follows:

- a) reference porous device = RPD (this is the porous PCD without any detector);
- b) reference porous indicator system = RPIS (this is the RPD plus a detector);
- c) alternative porous device = APD (this is the porous PCD different in design to the RPD without any detector);
- d) alternative porous indicator system = APIS (this is the APD plus a detector);
- e) reference hollow device = RHD (this is the hollow PCD without any detector);
- f) reference hollow indicator system = RHIS (this is the RHD plus a detector);
- g) alternative hollow device = AHD (this is the hollow PCD different in design to the RHD without any detector);
- h) alternative hollow indicator system = AHIS (this is the AHD plus a detector);

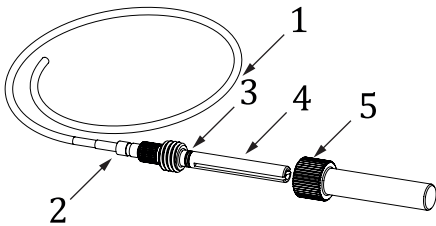
- i) detector = the detector can either be a biological indicator or inoculated carrier, a chemical indicator or a physical measurement system, e.g. thermocouples.

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Annex E
(normative)

Reference hollow device (RHD)

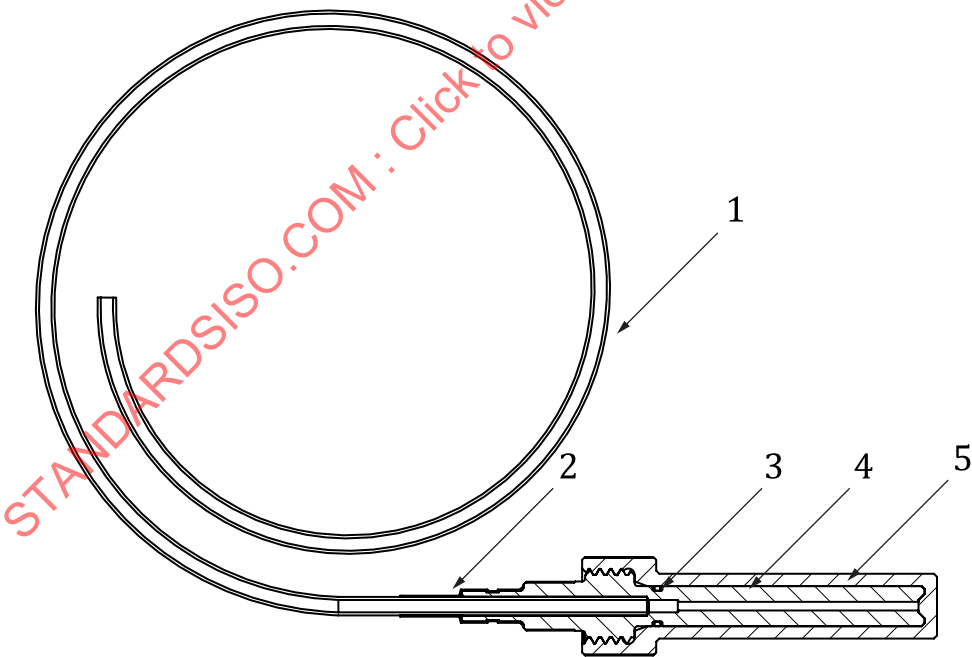
The RHD, its sub-components and dimensions, together with tolerances, are illustrated in [Figures E.1, E.2 and E.3](#).



- Key**
- | | | | |
|---|----------------------|---|----------------|
| 1 | PTFE tubing | 4 | receptacle pin |
| 2 | receptacle connector | 5 | receptacle cap |
| 3 | receptacle seal | | |

NOTE Parts 2, 3, 4 and 5 comprise the capsule.

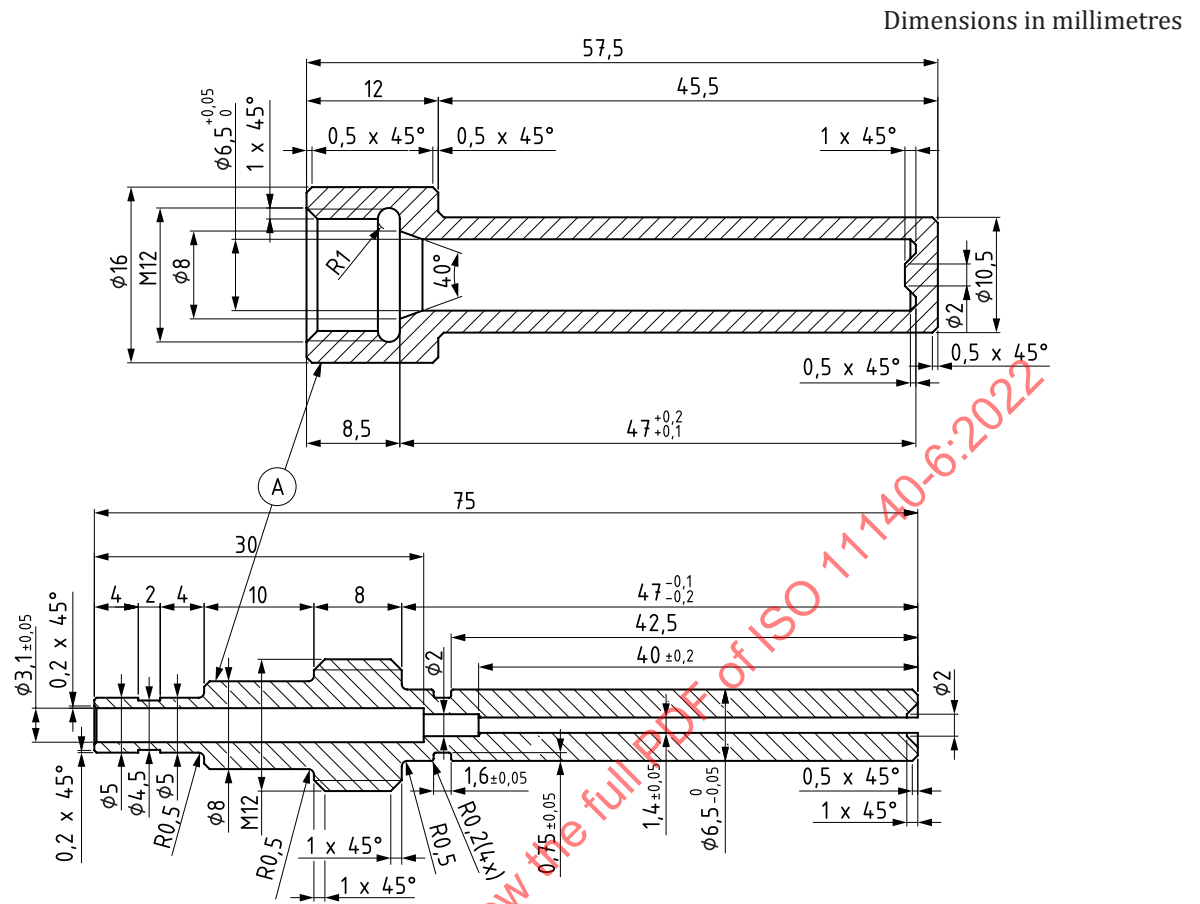
Figure E.1 — Reference hollow device (RHD) with receptacle cap removed



- Key**
- | | | | |
|---|----------------------|---|----------------|
| 1 | PTFE tubing | 4 | receptacle pin |
| 2 | receptacle connector | 5 | receptacle cap |
| 3 | receptacle seal | | |

NOTE Parts 2, 3, 4 and 5 comprise the capsule.

Figure E.2 — Assembled reference hollow device (RHD)



Key

A Knurl, for example type A, with pitch from 0.8 mm to 1.6 mm, according to ISO 13444.

Where not stated, tolerances shall be in accordance with ISO 2768-1.

Figure E.3 — Reference hollow device (RHD) receptacle pin and receptacle cap dimensions

Annex F **(informative)**

Accelerated ageing of test samples

F.1 The testing of the product for determination of the shelf life should be performed in accordance with a written protocol which should be established before the commencement of the study.

F.2 The samples of the product should be stored in their normal packaging at or above the maximum temperature and relative humidity recommended for storage. These conditions should be controlled and monitored.

F.3 All performance requirements should be met during and on completion of the storage period. This should be verified by testing.

F.4 All results of the storage trial should be retained for a period of at least five years from completion of the trial. After this period, a summary report should be retained for as long as the product is commercially available.

NOTE In some cases, this approach is not accepted by regulatory authorities.