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Sterilization of health care products — Chemical indicators —

Part 5: Class 2 indicators for air removal test sheets and packs

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 5: Indicateurs de classe 2 pour draps et paquets prépliés servant à l'essai d'enlèvement d'air

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 11140 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11140-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

— *Part 1: General requirements*

— *Part 2: Test equipment and methods*

— *Part 3: Class 2 indicators for steam penetration test sheets*

— *Part 4: Class 2 indicators for steam penetration test packs*

— *Part 5: Class 2 indicators for air removal test sheets and packs*

Annexes A, B, C, D, E, F, G and H form a normative part of this part of ISO 11140.

Introduction

The air removal test is used to evaluate the efficacy of air removal during the pre-vacuum phase of a pre-vacuum sterilization cycle. Retention of air due to an inefficient air removal stage or the presence of an air leak during the air removal stage are circumstances which can lead to failure of the test. This part of ISO 11140 describes the requirements for Class 2 indicators and systems for air removal test.

For a description of the classes of chemical indicators, see ISO 11140-1.

Because a range of different tests in different countries have historically been named the Bowie-Dick test, no reference to this term is used in ISO 11140-3, ISO 11140-4 or ISO 11140-5.

The difference between the steam penetration test (ISO 11140-3 and ISO 11140-4) and the air removal test (ISO 11140-5) is described in the chemical indicator guidance document (ISO 15882).

Sterilization of health care products — Chemical indicators —

Part 5:
Class 2 indicators for air removal test sheets and packs

1 Scope

This part of ISO 11140 specifies the requirements for an indicator and alternative test system used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles.

Additionally, this part of ISO 11140 includes test methods and equipment used to meet these performance requirements.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11140. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11140 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*.

ISO 11140-1:1995, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*.

IEC 60584-2:1982, *Thermocouples — Part 2: Tolerances*.

IEC 60751:1983, *Industrial platinum resistance thermometer sensors*.

3 Terms and definitions

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

3.1
air removal indicator
indicator to be used in the standard test pack to determine the efficacy of the air removal phase in the steam sterilization process

NOTE See annex E for description of the standard test pack.

3.2
air removal indicator system
specific test load containing an indicator to determine the efficacy of the air removal phase in the steam sterilization process

NOTE The system may be user-assembled or pre-assembled. The test load may be disposable, for limited reuse, or reusable.

3.3
equilibration time
period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature in all parts of the load

4 General requirements

Unless otherwise specified in this part of ISO 11140, the general requirements given in ISO 11140-1 apply.

5 Air removal indicator

5.1 Format

5.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30 % of the test area of the substrate.

NOTE The pattern of indicator agent distribution should allow easy judgement of the uniformity of the colour change.

5.1.2 The indicator shall have an air porosity greater than 0,026 $ml \cdot s^{-1} \cdot mm^{-2}$. Compliance shall be tested in accordance with annex H.

5.1.3 The substrate of the indicator shall have a uniform ground colour which provides a difference in colour density of not less than 0,3 between ground colour and either the changed or the unchanged indicator, as specified by the manufacturer, when the difference in colour density is determined using a reflective densitometer.

Compliance shall be tested in accordance with annex A.

5.1.4 The indicator dimensions shall be (200 ± 20) mm $\times$ (275 ± 25) mm.

5.2 Performance

5.2.1 The indicator shall show a uniform colour change (as specified by the manufacturer) after exposure to saturated steam at 134 °C for 3,5 min $\pm$ 5 s and/or exposure to saturated steam at 121 °C for 15 min $\pm$ 5 s, or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product. In all cases the permitted tolerance on the test temperature shall be $^{+1,5}_{0}$ °C and the time given shall be the time within which the colour change shall occur.

Compliance shall be tested in accordance with annex B.

5.2.2 When placed in the centre of the standard test pack as given in annex E, the indicator shall show a non-uniform colour change when the temperature at the centre of the standard test pack is $\left(2\ ^{+1}_{0}\right)$ °C lower than the temperature of the chamber drain at the beginning of the final 1 min at 134 °C, or at the beginning of the final 5 min of a 15 min cycle at 121 °C of the exposure phase of the steam exposure apparatus. This is the standard fault condition generated by inadequate air removal from the chamber. Any other combination of time and temperature stated by the manufacturer shall exhibit a similar response at the beginning of the final 30 % of the exposure time.

Compliance shall be tested in accordance with annex F.

5.2.3 After exposure to dry heat at (140 ± 2) °C for 30 min, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process.

Compliance shall be tested in accordance with annex C.

5.2.4 Transfer of the indicator agent to the material of the standard test pack in which it is intended to be used, shall not compromise the result of the test.

Compliance shall be tested in accordance with annex D.

NOTE Although some transfer may be possible without adversely affecting the performance of the indicator or test pack, there are currently no test methods available to verify the acceptable limits of indicator agent transfer.

5.2.5 The indicator shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life specified by the manufacturer.

NOTE A documented accelerated ageing procedure may be used in demonstrating compliance.

6 Air removal indicator system

6.1 Format

6.1.1 The indicator agent shall be uniformly distributed on its substrate to cover not less than 30 % of the test area of the substrate.

6.1.2 The substrate of the indicator shall have a uniform ground colour which provides a difference in colour density of not less than 0,3 between ground colour and either the changed or the unchanged indicator agent, as specified by the manufacturer, when the difference in colour density is determined using a reflective densitometer.

Compliance shall be tested in accordance with annex A.

6.2 Performance

6.2.1 The indicator shall show a uniform colour change complying with 6.1.2 both after exposure to saturated steam at $\left(134\ ^{+1,5}_{0}\right)$ °C for 3,5 min ± 5 s and/or exposure to saturated steam at $\left(121\ ^{+1,5}_{0}\right)$ °C for 15 min ± 5 s, or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product. In all cases the permitted tolerance on the test temperature shall be $^{+1,5}_{0}$ °C and the time given shall be the time within which the colour change shall occur.

Compliance shall be tested in accordance with annex B.

6.2.2 After exposure to conditions used to produce a standard fault condition as given in 5.2.2 in the standard test pack as given in annex E, the indicator shall show a non-uniform colour change.

Compliance shall be tested in accordance with annex F.

6.2.3 After exposure to dry heat at (140 ± 2) °C for 30 min, the chemical indicator system shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process. Compliance shall be tested in accordance with annex C.

6.2.4 Transfer of the indicator agent to the chemical indicator system shall not compromise the result of the test.

6.2.5 The indicator shall comply with the requirements of this part of ISO 11140 for the duration of the shelf life specified by the manufacturer.

NOTE A documented accelerated ageing procedure may be used in demonstrating compliance.

7 Packaging and labelling

7.1 The general requirements in ISO 11140-1 apply.

7.2 In addition, each indicator, indicator system and its packaging shall be clearly marked with

AIR REMOVAL

8 Quality assurance

The general requirements in ISO 11140-1 apply.

9 Sampling conditioning

Test samples shall be conditioned for at least 1 h immediately prior to testing in an environment between (23 ± 7) °C with a relative humidity of 30 % to 70 %.

Annex A
(normative)

Determination of the degree of contrast between the colour of the substrate and the indicator agent

A.1 Apparatus

The following equipment is required.

A.1.1 **Steam exposure apparatus**, complying with annex G.

A.1.2 **Reflective densitometer**, complying with ISO 5-4 which has been calibrated and the calibration traceable to a national standard.

A.1.3 **Standard test pack**, as described in annex E and chosen by the manufacturer.

A.2 Method

A.2.1 To determine the degree of contrast between the substrate and the changed indicator agent, the indicator is placed in the centre of a test pack and exposed to a cycle of the steam exposure apparatus at the specified operating temperature required for the indicator to produce uniform colour change.

A.2.2 The difference in colour density between the ground colour of the substrate and that of the changed and/or unchanged indicator agent shall be determined on at least three pairs of locations on the indicator, using a reflective densitometer. Paired readings shall be taken equidistantly over the indicator.

A.2.3 This test shall be repeated five times for each of three separate production batches of the indicator.