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Sterilization of health care products — Chemical indicators —

Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 3: Systèmes d'indicateurs de Classe 2 pour utilisation lors de l'essai de Bowie et Dick de pénétration de la vapeur

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 11140-3 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-3:2000) which has been technically revised.

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

— *Part 1: General requirements*

— *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

— *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

— *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

Introduction

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods and porous loads. As such it is performed during the demonstration of conformance of steam sterilizers to EN 285 and as a routine test of performance in ISO 17665-1. The test method is described in EN 285.

A failure of the Bowie and Dick test is symptomatic of a number of potential problems with the sterilizer that could compromise the uniform sterilization of a load to be processed. This failure is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases and it can be necessary to investigate other causes of failure.

The Bowie and Dick test was conceived as a test for successful air removal from high-vacuum porous-load sterilizers used in the sterilization of health care products [1]. A successful Bowie and Dick test indicates rapid and even penetration of steam into the test pack. The presence of air within the pack, due to an inefficient air removal stage, an air leak during this stage or non-condensable gases in the steam supply, is a circumstance which can lead to failure of the test. The result of the test may also be affected by other factors which inhibit steam penetration. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

A test pack for the Bowie and Dick test consists of two components:

a) a small standardized test load;

b) a chemical indicator to detect the presence of steam.

The Bowie and Dick test as originally described [1] utilized huckaback towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

Because a range of different tests in different countries has historically been termed the Bowie and Dick test, the term “Bowie and Dick-type test” is used in this part of ISO 11140.

Sterilization of health care products — Chemical indicators —

Part 3:
Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test

1 Scope

This part of ISO 11140 specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g. instruments and porous materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

Indicators complying with this part of ISO 11140 are intended for use in combination with the standard test pack as described in EN 285. This part of ISO 11140 does not consider the performance of the standard test pack, but does specify the performance of the indicator systems.

2 Normative references

The following referenced documents are indispensable for the application 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 5-1, *Photography — Density measurements — Part 1: Terms, symbols and notations*

ISO 5-3, *Photography — Density measurements — Part 3: Spectral conditions*

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

ISO 187:1990, *Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

ISO 2248, *Packaging — Complete, filled transport packages — Vertical impact test by dropping*

ISO 5457, *Technical product documentation — Sizes and layout of drawing sheets*

ISO 5636-3, *Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method*

ISO 11140-1:2005, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

ISO/CIE 10526:1999, *CIE standard illuminants for colorimetry*

EN 285:2006, *Sterilization — Steam sterilizers — Large sterilizers*

3 Terms and definitions

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

4 General requirements

4.1 The requirements of ISO 11140-1 apply.

4.2 Test samples shall be conditioned in accordance with ISO 187 prior to testing for performance.

5 Indicator system format

The indicator system format shall meet the following requirements.

a) It shall consist of indicator reagent uniformly distributed on a substrate to cover not less than 30 % of the surface area of the substrate. The distance between adjacent areas of indicator reagent shall not exceed 20 mm. The pattern of indicator reagent distribution should permit easy comparison of the colour change at the margin with the colour change in the central region.

b) It shall have an air porosity not less than 1,7 µm/(Pa·s) when tested in accordance with ISO 5636-3 at an air pressure of 1,47 kPa.

c) It shall have sufficient strength to withstand steam sterilization.

Compliance shall be tested in accordance with Annex A.

d) It shall have a substrate of a colour that is uniform to visual observation.

e) It shall have a difference in reflectance density of not less than 0,3 between the substrate and either the changed indicator or the unchanged indicator as specified by the manufacturer.

Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be of size A4 in accordance with ISO 5457.

6 Performance requirements

6.1 The indicator shall meet the following requirements.

a) It shall show a uniform colour change complying with 5 e) after exposure to dry saturated steam at 134 ($^{+1,5}_{0}$) °C for 3,5 min ± 5 s or after exposure to dry saturated steam at 121 ($^{+1,5}_{0}$) °C for 15 min ± 5 s or both.

Compliance shall be tested in accordance with Annex C.

b) When placed in the centre of a standard test pack, it shall show a non-uniform colour change when the temperature at the centre of the standard test pack is 2 K lower than the temperature of the chamber drain of the steam exposure apparatus (see Annex H).

Compliance shall be tested in accordance with Annex I.

c) It shall show no discernible colour change after exposure to dry heat at (140 ± 2) °C for not less than 30 min.

   Compliance shall be demonstrated in accordance with Annex D.

   With some indicators a slight colour change can occur. This shall be acceptable if the change that occurs is markedly different from that brought about by exposure to steam in accordance with 6.1 a) and within the limits specified by the manufacturer.

d) It shall not visibly transfer indicator reagent to the material of the test load in intimate contact with the indicator during processing.

   Compliance shall be demonstrated in accordance with Annex F.

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

If any change in the indicator occurs during ageing, it shall be different to the change on exposure to dry saturated steam [as described in 6.1 a)], and shall have either inactivated the indicator so that no further change can take place or not affected the performance of the indicator with respect to the requirements of 6.1 a) and 6.1 b).

Compliance shall be tested in accordance with Annex G or by performance testing after accelerated ageing in accordance with Annex E.

7 Packaging and labelling

7.1 Each substrate on which an indicator reagent has been deposited shall be marked with the operating temperature(s) for which the product is designed to be used.

7.2 Each indicator shall be marked with a unique code from which the manufacturing history can be traced.

7.3 Each indicator shall be provided with space for the user to record essential cycle information under the headings:

— department;

— machine No.;

— cycle No.;

— operator;

— date;

— result;

— supervisor.

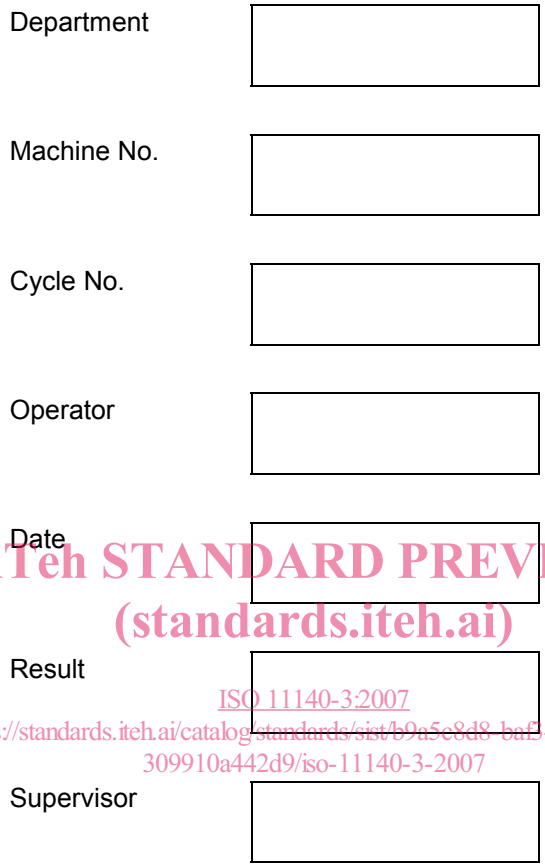
Adjacent to each heading there shall be a clear space not less than 5 mm × 20 mm for the user to enter the required information at the time of use. See Figure 1.

7.4 The product shall be packed in such a way as to allow easy separation of individual units of product and to protect the product from moisture, dust, sunlight and damage in normal transit, to the extent necessary to ensure that the indicator retains its performance throughout the stated shelf life when stored in accordance with the manufacturer's instructions.

The manufacturer shall retain documentary evidence demonstrating compliance.

7.5 The outside of each carton shall be marked with the operating temperature at which the product is suitable for use.

7.6 The information supplied by the manufacturer (see 5.7 and 5.8 of ISO 11140-1:2005) shall include sufficient instruction on the use of the indicator to enable correct interpretation of the test results.



NOTE Other formats may be used.

Figure 1 — Example of a suitable format

8 Quality assurance

8.1 The quality system shall ensure that the performance requirements given in Clause 6 are maintained.

8.2 Suitable records shall be maintained to ensure that, in the event of a defect arising, faulty batches can be recalled from use.

8.3 The manufacturing and distribution records shall be retained for a period of five years or twice the declared shelf life of the product, whichever is less. An example of the requirements for maintaining records is given in ISO 9001 [4].

Annex A
(normative)

Determination of strength after steam sterilization

A.1 Apparatus

A.1.1 **Steam exposure apparatus**, as specified in Annex H.

A.1.2 **Standard test pack**, as specified in Annex K.

A.1.3 **Steam supply**, as specified in EN 285.

A.2 Procedure

A.2.1 Expose the indicator, within a standard test pack, to three successive steam exposures at the stated operating temperature of the indicator system.

A.2.2 Remove the standard test pack from the exposure apparatus and perform a drop test in accordance with ISO 2248 from a height of 1 m on to a firm horizontal surface.

NOTE Concrete or terrazzo surfaces are suitable.

A.2.3 Remove the indicator from the standard test pack and visually examine for damage.

A.2.4 Repeat this test for each of three separate production batches of the indicator system.