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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

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 4: Indicateurs de Classe 2 comme alternative à l'essai de Bowie et Dick pour la détection de la 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 11140-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-4:2001) 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, are circumstances 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 system 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.

Indicators intended as an alternative to the Bowie and Dick test use different materials for the test load and employ indicator systems specifically formulated for use with the defined test load. Because a range of different tests in different countries have historically been termed the Bowie and Dick test, the term “Bowie and Dick-type test” is used in this part of ISO 11140.

This part of ISO 11140 specifies the performance of the indicator system in combination with the test load with which it is intended to be used. The test load may be presented with the indicator system already incorporated and intended for single use, or it may be intended for multiple use with a new indicator system to be inserted prior to each use.

The indicator for which the performance is specified in this part of ISO 11140 is intended to indicate when steam penetration has been inadequate. The performance of the indicator specified in this part of ISO 11140 should be equivalent, but not necessarily identical, to the performance obtained in the Bowie and Dick-type test as described in ISO 11140-3. Equivalence should be regarded as providing a similar response to steam penetration with any differences being predictable and such that the necessary level of assurance of satisfactory steam penetration is provided. An indicator meeting this specification is not intended to identify which of the potential causes of poor steam penetration was responsible for the failure indicated by the test.

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

1 Scope

This part of ISO 11140 specifies the performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick-type test for steam sterilizers for wrapped health care goods (instruments, etc., and porous loads).

NOTE The Bowie and Dick-type test is used for routine testing of steam sterilizers and validation of steam sterilization processes.

An indicator complying with this part of ISO 11140 incorporates a specified material which is used as a test load. This test load may, or may not, be re-usable. This part of ISO 11140 does not specify requirements for the test load, but specifies the performance of the indicator in combination with the test load with which it is intended to be used. The indicator specified in this part of ISO 11140 is intended to identify poor steam penetration but does not necessarily indicate the cause of this poor steam penetration.

This part of ISO 11140 does not include test methods to establish the suitability of these indicator systems for use in sterilizers in which the air removal stage does not include evacuation below atmospheric pressure.

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 10012-1, *Quality assurance requirements for measuring equipment — Part 1: Metrological confirmation system for measuring equipment*

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

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

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

IEC 60584-2/am1:1989, *Amendment 1 — Thermocouples. Part 2: Tolerances*

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

IEC 60751/am1:1986, *Amendment 1 — Industrial platinum resistance thermometer sensors*

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 and the following apply.

3.1
air pocket
concentration of residual, induced or injected air or non-condensable gases in the standard test pack

3.2
chamber reference temperature
temperature measured at a defined reference point within the steam exposure apparatus

NOTE The defined reference point is usually located in the chamber drain or active chamber discharge.

3.3
exposure time
period for which the chamber reference temperature lies within the sterilization temperature band

3.4
pre-assembled pack
indicator in which the indicator system is incorporated into the test load during the manufacturing process and which is supplied ready for use

3.5
reference fault period
period of 30 s commencing when the chamber reference temperature attains the set operating temperature

3.6
sterilization temperature
minimum temperature of the sterilization temperature band

NOTE The use of the word “sterilization” within this and other definitions is not intended to imply that sterilizing conditions will take place under the test cycle conditions.

3.7
sterilization temperature band
range of temperatures from the sterilization temperature to the maximum allowable temperature which may prevail throughout the load during the holding time

NOTE These temperatures are usually stated in whole degrees centigrade.

3.8
temperature depression
thermodynamic temperature difference in kelvin given by (chamber reference temperature, in degrees centigrade) minus (temperature in the standard test pack, in degrees centigrade)

3.9
test equilibration time
time elapsed after the chamber reference temperature attains the set operating temperature until the temperature within the standard test pack is the same as the chamber reference temperature, within the limits of accuracy of the temperature-measuring equipment

3.10
user-assembled pack
indicator in which the user combines the indicator system with the test load prior to use

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.

4.3 Compliance with the requirements of this part of ISO 11140 shall be determined by establishing conformity with the performance requirements of Clause 6.

4.4 The indicator shall have sufficient strength to withstand steam sterilization and subsequent handling.

Compliance shall be tested in accordance with Annex A.

4.5 Test cycles for demonstrating compliance with the requirements of this part of ISO 11140 shall employ sub-atmospheric, trans-atmospheric and super-atmospheric air removal stages (see Table 1 and B.1, B.2 and B.3) except when the indicator, or indicator system, is intended solely for use with one type of air removal system, in which case only the specified air removal system needs to be used during compliance testing.

4.6 A thermometric recording instrument(s) shall be used in conjunction with temperature sensors to record the temperatures measured in the locations specified in the tests described in this part of ISO 11140. The temperature-measuring equipment used in all test methods for demonstrating compliance with this part of ISO 11140 shall meet the following requirements.

a) Temperature sensors shall be either platinum resistance and comply with Class A of IEC 60751:1983 and IEC 60751 Amendment 1:1986 or a thermocouple and comply with one of the tables of tolerance class 1 of IEC 60584-2:1982 and IEC 60584-2 Amendment 1:1989.

b) The performance characteristic of the temperature sensor shall not be affected by the environment in which it is used, e.g. pressure, steam or vacuum.

c) The temperature sensors shall have a response time in water of $\tau_{90} \leqslant 0{,}5$ s.

d) The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known to within $\pm 0{,}1$ K, and within the sterilization temperature band, shall not differ by more than 0,5 K.

e) The recording instrument shall record the temperature from a minimum of 6 sensors. The sampling interval shall not exceed 2,5 s. All data sampled shall be used for the interpretation of results.

f) The scale range shall include 0 °C to 150 °C. For analogue instruments, the minor mark interval shall not exceed 1 K, the resolution shall be not less than 0,5 K and the chart speed shall be not less than 15 mm/min. Digital instruments shall register and record in increments of not more than 0,1 K.

g) The limit of error of the recording instrument between 0 °C and 150 °C (excluding temperature sensors) shall not exceed 0,25 % when tested in an ambient temperature of (20 ± 3) °C. The additional error due to change in the environmental temperature shall not exceed 0,04 K/K.

h) Calibration shall be carried out using a working or reference standard that is traceable to a national standard or a primary standard. The instrument shall have a valid test certificate.

5 Indicator system format

5.1 When the indicator system is one in which the indicator reagent is distributed on a substrate, it shall meet the following requirements.

a) The indicator reagent shall be distributed 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 clear interpretation of the colour change.

b) The substrate shall have a colour which is uniform to visual observation.

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

Compliance shall be tested in accordance with Annex C.

5.2 When the indicator system depends on migration of the indicator reagent to demonstrate change, the pattern of indicator reagent distribution before and after use shall permit clear interpretation of the result.

5.3 When the indicator system is intended for use with a user-assembled pack, the indicator system shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Those markings made before processing shall remain legible after processing.

5.4 When the indicator system is provided by the manufacturer already incorporated into the test load, the material of either the indicator or the indicator system, as appropriate, shall permit writing to be made after processing.

6 Performance requirements

6.1 The indicator, when tested in combination with the test load specified by the manufacturer, shall show a uniform colour change complying with 5.1 c) 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 when the temperature tolerance shall be $\binom{+1,5}{0}$ °C and the time tolerance shall be ± 5 s.

Compliance shall be tested in accordance with Annex D using the steam exposure apparatus. The steam exposure apparatus shall be operated with the standard test cycles described in Annex B as shown in Table 1.

Indicators intended for use only with specific air removal cycles shall be tested with those specific cycles only (see 5.7 of ISO 11140-1:2005).

Indicators intended to be used over a wide range of sterilization temperatures, e.g. both for cycles operating at 121 °C and for those operating at 134 °C, may not give the same depth or intensity of colour change at both temperatures. This should be regarded as in compliance if:

a) all other performance characteristics required by this part of ISO 11140 are met;

b) the nature of the colour change is unambiguously defined in the instructions for use (see 5.8 of ISO 11140-1:2005).

6.2 The indicator shall show no colour change, incomplete colour change, or uneven colour change when exposed to a test cycle previously demonstrated to produce a reference fault condition (a 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, air leak or air injection. The test cycles used to generate the reference fault conditions shall be as shown in Table 1. 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 (see 6.1) when the temperature tolerance shall be $\left(\begin{smallmatrix}+1{,}5\\0\end{smallmatrix}\right)$ °C and the time tolerance shall be ± 5 s.

Compliance shall be tested in accordance with Annex E.

Compliance with the fault condition reproducibility shall be demonstrated in accordance with Annex F.

Table 1 — Schedule of test cycles to be used

Test condition	Standard test cycle of Annex B		
	B.1 **Sub-atmospheric pulsing**	**B.2** **Trans-atmospheric pulsing**	**B.3** **Super-atmospheric pulsing**
“Pass” cycle (see 6.1)	√	√	√
“Fail” cycle – modified air removal stage (see 6.2)	√	√	x
“Fail” cycle – induced leak (see 6.2)	√	x	x
“Fail” cycle – air injection (see 6.2)	√	x	√
√ = test required; x = test not required.			

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

With some indicators, the indicator system can show a slight colour change after exposure to dry heat; this shall be acceptable if the change that occurs is slight or markedly different from that brought about by exposure to steam in accordance with 6.1 and within the limits specified by the manufacturer.

Compliance shall be tested in accordance with Annex G.

6.4 Indicators intended for use only with a sterilization temperature of 121 °C shall be tested by exposure to dry heat at (130 ± 2) °C for not less than 45 min if the indicator will not withstand heating to 140 °C.

Compliance shall be tested in accordance with Annex G.

6.5 Indicator systems intended for use with re-usable user-assembled packs shall not visibly transfer indicator reagent to the material of the test load during processing. Pre-assembled packs and indicator systems intended for use with single-use user-assembled packs shall not transfer indicator reagent to the material of the test load during processing to an extent which impairs the utility of the product.

Compliance shall be demonstrated by visual examination after testing in accordance with the requirements of 6.1 and Annex D.

6.6 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 from the change on exposure to saturated steam (as described in 6.1) and shall either inactivate the indicator system so that no further change can take place or not affect the performance of the indicator system with respect to the requirements of 6.1 and 6.2.

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

7 Packaging and labelling

7.1 Each indicator, or indicator system, shall be marked with:

a) the sterilization temperature(s) at which the product is designed to be used;

b) a unique code from which the manufacturing history can be traced;

c) the expiry date under the specified storage conditions;

d) at least the information summarized in Figure 1.

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 or, if the size of the indicator system does not permit this, each indicator or indicator system shall be supplied with a means of retaining the indicator or indicator system as a permanent record which shall be printed with the information given in Figure 1. The means of retention shall permit writing in permanent ink to be made in association with the indicator.

Cycle No.	Site
Machine No.	Department
Date	Operator
Supervisor	Result

NOTE This is an example of a suitable format. Other formats and/or text can be used.

Figure 1 — Provision for recording information to be provided on or with each indicator

7.2 When the indicator is supplied assembled, i.e. with the indicator system within the test load, the exterior of the test load shall be marked with the sterilization temperature(s) at which the product is suitable for use, the manufacturer's name, batch number and date of manufacture. In addition, either a means of uniquely identifying the individual indicator or an area on the outside of the test load on to which the operator can write the number of the machine tested and date shall be provided.

When a manufacturer provides similar products which are intended only for specific sterilization cycles, the product shall include identification sufficient to enable the user to determine, from the instructions for use, any restrictions on the use of the product. The identification shall be on the indicator or indicator system and, if not visible to the user before use, shall also be on the outside of the test load.

7.3 The transport package shall be such that the product can be removed easily. The package shall protect the product to the extent necessary to ensure that the indicator retains its performance throughout the stated shelf life when stored and transported in accordance with the manufacturer's instructions.

The manufacturer shall retain documentary evidence demonstrating compliance.

7.4 The outside of each package shall be marked with the sterilization temperature(s) at which the product is suitable for use.

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

7.6 When requested by the purchaser, the manufacturer shall supply a certificate of conformity to the requirements of this part of ISO 11140 for each batch of product supplied.

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, if necessary, 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 greater. An example of the requirements for maintaining records is given in ISO 9001:2000 [6].