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Sterilization of health care products — Chemical indicators —

Part 4: Class 2 indicators for steam penetration test packs

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 4: Indicateurs de classe 2 pour paquets prépliés servant à l'essai 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 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 11140-4 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, H, I, J, K and L form a normative part of this part of ISO 11140.

Introduction

The Bowie and Dick test was conceived as a test for successful air removal from high vacuum porous load sterilizers [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 either 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.

Failure of the Bowie and Dick test is not conclusive proof that the fault in the sterilizer is due to air retention, air leakage or non-condensable gases, and it may be necessary to investigate other causes of failure.

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 11134. The test procedure is described in EN 285.

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

a) a small standardized test load and

b) a chemical indicator system to detect the presence of steam (see ISO 11140-3 and ISO 11140-4).

The Bowie and Dick test as originally described [1] utilized huckaback towels as the material for the test load. The test 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. 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 a Bowie and Dick test as described in EN 285. 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 for steam penetration test packs

1 Scope

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

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 system 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 indicate necessarily the cause of this poor steam penetration.

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

NOTE The Bowie and Dick Test is performed to demonstrate conformance of a steam sterilizer for wrapped health care goods to EN 285 and may be used as a routine test of performance of such a sterilizer (see ISO 11134). The test procedure is described in EN 285.

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 5-1, *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, *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 9001:1994, *Quality systems — Model for quality assurance in design, development, production, installation and servicing*.

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

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

IEC 60584-2:1982 + A1:1989, *Thermocouples — Part 2: Tolerances*.

IEC 60751:1983 + A1:1986, *Industrial platinum resistance thermometer sensors*.

EN 285:1996, *Sterilization — Steam sterilizers — Large sterilizers*.

3 Terms and definitions

For the purposes of this part of ISO 11140, the following terms and definitions 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
defined end-point
visible change occurring after exposure to the specified variable(s) at a level equal to or greater than that specified for the indicator

3.4
dry saturated steam
steam with a dryness value between 0,9 and 1,0 and a non-condensable gas content of not more than 3,5 % (volume fraction) when determined by the methods given in EN 285

3.5
exposure time
period for which the chamber reference temperature lies within the sterilization temperature band

3.6
graduated response
progressive visible change, occurring on exposure to one or more process variables, which allows assessment of the level achieved

3.7
indicator
indicator system in the form in which it is intended to be used

3.8
indicator reagent
active ingredient or combination of ingredients before conversion into the indicator

[ISO 11140-1:1995, 3.4]

3.9
indicator system
combination of the indicator reagent and its substrate

3.10
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

3.11
reference fault period
period of 30 s commencing when the chamber reference temperature attains the set operating temperature

3.12
sterilization temperature
minimum temperature of the sterilization temperature band

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

3.13
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 Celsius.

3.14
temperature depression
thermodynamic temperature difference in kelvin given by (chamber reference temperature, in degrees Celsius) minus (temperature in the standard test pack, in degrees Celsius)

3.15
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

3.16
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 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 clauses B.1, B.2 and B.3 respectively in annex B) 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 + A1:1986 or thermocouple and comply with one of the tables of tolerance class 1 of IEC 60584-2:1982 and A1:1989.

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 $\pi_{90} \leqslant 0{,}5$ s.

d) The temperature measured by all temperature sensors when immersed in a temperature source at a temperature known to within ± 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 12 sensors. The sampling duration 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 analog 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 which 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 dry 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 ISO 11140-1).

NOTE 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 and

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

6.2 The indicator shall show no colour change, an incomplete, or an uneven colour change when exposed to a test cycle previously demonstrated to produce a reference fault condition, whether the system used to produce the fault depends on 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 other time/temperature combination specified by the manufacturer (see 6.1) 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 E.

Compliance of 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	B.2	B.3
"Pass" cycle (see 6.1)	✓	✓	✓
"Fail" cycle — modified air removal stage (see 6.2)	✓	✓	×
"Fail" cycle — induced leak (see 6.2)	✓	×	×
"Fail" cycle — air injection (see 6.2)	✓	×	✓
✓ = test required; × = 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 may 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 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 to the change on exposure to dry saturated steam (as described in 6.1) and have either inactivated the indicator system so that no further change can take place or not affected 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

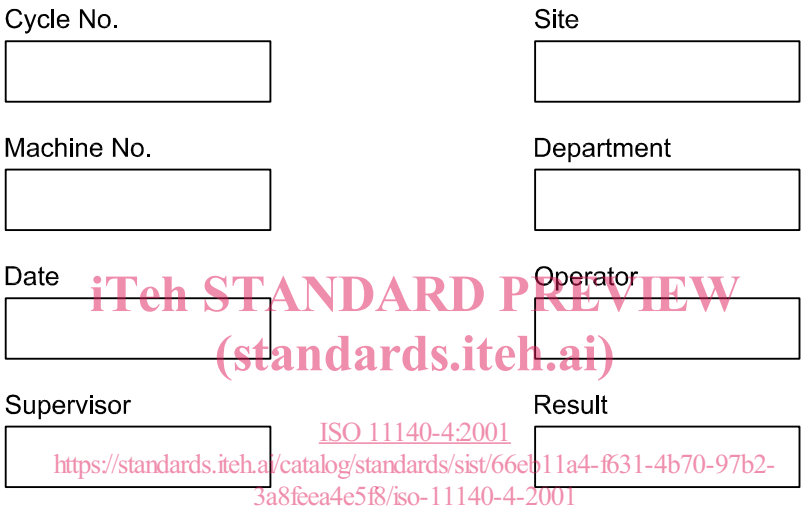
7.1 Each indicator, or indicator system, shall be marked with

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 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.



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 onto which the operator can write the number of the machine tested and the 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 5.6 of ISO 11140-1:1995) 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 manufacturer's quality system shall ensure that an acceptable quality level (AQL) of 1,0 or less is maintained for performance requirements given in clause 6 of this part of ISO 11140. Other statistical control systems which provide equivalent or better assurance of consistent product quality also shall be acceptable.

NOTE The AQL is the maximum number of defects per hundred units that, for the purposes of sampling inspection, can be considered satisfactory as a process average.

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. These records shall be maintained in accordance with the requirements of 4.16 of ISO 9001:1994.