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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 11140-4

Sterilization of health care products — Chemical indicators —

Part 4: Type 2 indicator systems as an alternative to the Bowie and Dick- type test for the detection of steam penetration

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 4: Systèmes d'indicateurs de Type 2 comme alternative à
l'essai de Bowie et Dick pour la détection de la pénétration de la
vapeur*

ICS: 11.080.20

This document is circulated as received from the committee secretariat.

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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*

This third edition cancels and replaces the second edition (ISO 11140-4:2007), which has been technically revised.

The main changes are as follows:

- change of title from class 2 indicator to type 2 indicator to align with ISO 11140-1;
- correct use of the defined terms indicator and indicator system to align with ISO 11140-1;
- updated normative references;
- inserted common [Clause 4](#) for ISO/TC 198 documents, replacing Clause 8;
- added Annex M, modified from ISO 11140-1.

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

The Bowie and Dick test [1] is a test for steam sterilizers for products to be sterilized that are within sterile barrier systems or other 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. 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 sufficient air removal to facilitate rapid and even penetration of steam into the test load. 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 can also be affected by other factors which inhibit steam penetration into the test load. The test does not necessarily demonstrate either achievement of the required temperature or maintenance of that temperature for the required time to achieve sterilization.

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.

Indicators intended as an alternative to the Bowie and Dick test use different materials for the test load and employ indicators 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 document.

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

The indicator system for which the performance is specified in this document is intended to indicate when steam penetration has been inadequate. An indicator system 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:

Type 2 indicator systems as an alternative to the Bowie and Dick-type test for the detection of steam penetration

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 for a Type 2 indicator system 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 system conforming with this document incorporates an indicator together with a specified material which is used as a test load. This test load may, or may not, be re-usable. This document does not specify requirements for the test load, but specifies the performance of the indicator system (the indicator in combination with the test load with which it is intended to be used). The indicator system specified in this document is intended to identify poor steam penetration but does not necessarily indicate the cause of this poor steam penetration.

This document 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 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.

EN 285:2015+A1:2021, *Sterilization — Steam sterilizers — Large sterilizers*

ISO/CIE 11664-2:2022, *Colorimetry — Part 2: CIE standard illuminants*

ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

IEC 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances*

IEC 60751:2022, *Industrial platinum resistance thermometers and platinum temperature sensors*

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
chamber reference temperature

temperature at a specified point within the chamber

Note 1 to entry: The specified point is usually located in the chamber drain or active chamber discharge of the steam exposure apparatus.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.38, modified — Note 1 to entry has been added.]

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 K](#).

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.43, modified — Note 1 to entry has been added.]

3.3
chemical indicator system

combination of a *chemical indicator* ([3.2](#)) and a specific test load

Note 1 to entry: See [Annex K](#).

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.43.1, modified — Note 1 to entry has been added.]

3.4
exposure time

period for which the chamber reference temperature lies within the sterilization temperature band

3.5
pre-assembled pack

indicator system in which the indicator is incorporated into the test load during the manufacturing process and which is supplied ready for use

3.6
reference fault period

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

3.7
sterilization temperature

minimum temperature on which the evaluation of sterilization efficacy is based

Note 1 to entry: This is the minimum temperature of the sterilization temperature band.

Note 2 to entry: 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.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.286, modified — Note 1 to entry and Note 2 to entry have been added.]

3.8
temperature band

range of temperatures expressed as the minimum and maximum temperatures in the usable chamber space during a holding time

Note 1 to entry: These temperatures are usually stated in whole units.

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.293, modified — Note 1 to entry has been added.]

3.9**temperature depression**

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

EXAMPLE 2 K (2 °C).

3.10**test equilibration time**

<indicator> 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

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.297]

3.11**user-assembled pack**

<chemical indicator> combination of the indicator and the test load created at the point of use

[SOURCE: ISO 11139:2018/Amd 1:2024, 3.312]

4 General

4.1 The development, validation and routine control of a sterilization process is a critical element in product realization of health care product. To ensure the consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained. Processes of particular importance in relation to the development, validation and routine control of a sterilization process include but are not limited to:

- control of documentation, including records;
- assignment of management responsibility;
- provision of adequate resources, including competent human resources and infrastructure;
- control of product provided by external parties;
- identification and traceability of product throughout the process; and
- control of non-conforming product.

NOTE ISO 13485 covers all stages of the lifecycle of medical devices in the context of quality management systems for regulatory purposes. National and/or regional regulatory requirements for the provision of health care product can require the implementation of a full quality management system and the assessment of that system by a recognized conformity assessment body.

4.2 A process shall be specified for the calibration of all equipment, including instrumentation for test purposes, used in meeting the requirements of this document.

5 Requirements

5.1 Unless specified otherwise in this document, the requirements of ISO 11140-1 shall apply.

5.2 Test samples shall be conditioned to 23 °C ± 1 °C and 50 ± 2 % RH prior to testing for performance.

5.3 Conformance with the requirements of this document shall be determined by establishing conformity with the performance requirements of [Clause 7](#).

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

5.5 Test cycles for demonstrating conformance with the requirements of this document shall employ sub-atmospheric, trans-atmospheric and super-atmospheric air removal stages (see [Table 1](#) and A.1, A.2 and A.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 conformance testing.

5.6 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 document. The temperature-measuring equipment used in all test methods for demonstrating conformance with this document shall meet the following requirements.

- a) Temperature sensors shall be either platinum resistance and conform with Class A of IEC 60751:2022, 5.2.3.1, or a thermocouple and conform with one of the tables of tolerance class 1 of IEC 60584-1:2013, Clause 5.
- 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 $T_{90} \leq 0,5$ 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 ($\pm 0,1$ °C), and within the sterilization temperature band, shall not differ by more than 0,5 K (0,5 °C).
- 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 (1 °C), the resolution shall be not less than 0,5 K (0,5 °C) 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 (0,1 °C).
- 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 (0,04 °C / °C).
- 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.

6 Indicator format

6.1 When the indicator 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.

NOTE This requirement is intended to apply to indicators that are interpreted by an edge to centre comparison of the indicator.

- b) The pattern of indicator reagent distribution should permit clear interpretation of the colour change.
- c) The substrate shall have a colour which is uniform to visual observation.
- d) The indicator 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 reagent or unchanged indicator reagent as specified by the manufacturer.

Conformance shall be tested in accordance with [Annex B](#).

6.2 When the indicator 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.

6.3 When the indicator is intended for use with a user-assembled pack, the indicator 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.

6.4 When the indicator 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.

7 Performance requirements

7.1 The indicator, when tested in combination with the test load specified by the manufacturer, shall show a colour change, complete colour change or uniform colour change, conforming with [6.1 c\)](#) or complete reagent distribution conforming with [6.2](#) after exposure to a non-fault operating cycle in accordance with ISO 11140-1:2014, 5.8 c), at an exposure time of 3,5 min at 134 °C, or an exposure time of 15 min at 121 °C, or at any other time/temperature combination specified by the manufacturer when the temperature tolerance shall be $+1,5^{\circ}\text{C}$ and the time tolerance shall be ± 5 s.

Conformance 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 A](#) as shown in [Table 1](#).

Indicator systems intended for use only with specific production cycles shall be tested with those specific cycles only (see ISO 11140-1:2014, 5.7).

It is possible that indicator systems 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, will not give the same depth or intensity of colour change at both temperatures. This should be regarded as in conformance if:

- a) all other performance characteristics required by this document are met;
- b) the nature of the colour change is unambiguously defined in the instructions for use (see ISO 11140-1:2014, 5.8).

7.2 The indicator, when tested in combination with the test load specified by the manufacturer, shall show no colour change, incomplete colour change, uneven colour change or incomplete reagent distribution, in accordance with ISO 11140-1:2014, 5.8 c), 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 [7.1](#)) when the temperature tolerance shall be $+1,5^{\circ}\text{C}$ and the time tolerance shall be ± 5 s.

Conformance shall be tested in accordance with [Annex D](#).

Conformance with the fault condition reproducibility shall be demonstrated in accordance with [Annex E](#).

Table 1 — Schedule of test cycles

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

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

With some indicator systems, the indicator 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 [7.1](#) and within the limits specified in the instructions for use (see ISO 11140-1:2014, 5.8).

Conformance shall be tested in accordance with [Annex F](#).

7.4 Indicator systems 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 system will not withstand heating to 140 °C.

Conformance shall be tested in accordance with [Annex F](#).

7.5 Indicators intended for use with reusable user-assembled packs shall not visibly transfer chemical indicator reagent to the material of the test load during processing. Pre-assembled packs and indicators intended for use with single-use user-assembled packs shall not transfer chemical indicator reagent to the material of the test load during processing to an extent which impairs the utility of the product.

Conformance shall be demonstrated by visual examination after testing in accordance with the requirements of [7.1](#) and [Annex C](#).

7.6 The indicator system shall conform with the requirements of this document for the duration of the shelf life specified [see ISO 11140-1:2014, 5.8 j)].

If any change in the indicator occurs during ageing, it shall be different from the change on exposure to saturated steam (as described in [7.1](#)) and shall either inactivate the indicator so that no further change can take place or not affect the performance of the indicator with respect to the requirements of [7.1](#) and [7.2](#).

Conformance shall be tested in accordance with [Annex G](#).

8 Packaging and labelling

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

- the sterilization temperature(s) at which the product is designed to be used (see ISO 11140-1:2014, 5.7);
- a unique code from which the manufacturing history can be traced [see ISO 11140-1:2014, 5.8 k)];
- the expiry date under the specified storage conditions [see ISO 11140-1:2014, 5.8 j)];
- the symbol ISO 11140-4
- at least the information summarized in [Figure 1](#).