



DPC: 25/30497587 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 28 July 2025

Origin: International

Latest date for receipt of comments: 20 September 2025

Project No. 2024/02119

Responsible committee: CH/198 Sterilization and Associated Equipment and Processes

Interested committees:

Title: Draft BS ISO 11140-5 Sterilization of health care products — Chemical indicators. Part 5: Type 2 indicators for Bowie and Dick-type indicators and indicator systems.

Please notify admin.start@bsigroup.com if you are aware of any keywords that might assist in clarifying or identifying the standard or of the content of this standard:

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 20 September 2025

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

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
------------------	------------------------

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 11140-5

Sterilization of health care products — Chemical indicators — Part 5: Type 2 indicators for Bowie and Dick-type indicators and indicator systems

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 5: Indicateurs de type 2 pour indicateurs et systèmes
d'indicateurs de type Bowie et Dick*

ICS: 11.080.20

ISO/TC 198

Secretariat: **ANSI**

Voting begins on:
2025-07-28

Voting terminates on:
2025-10-20

This document is circulated as received from the committee secretariat.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

Reference number
ISO/DIS 11140-5:2025(en)

Full document details: 25/30497587 DC

© ISO 2025



Documents

Document Sharing Hub



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General	2
5 Indicator requirements	3
5.1 General	3
5.2 Format	3
5.3 Performance	3
6 Indicator system requirements	4
6.1 General	4
6.2 Format	4
6.3 Performance	4
7 Packaging and labelling	5
Annex A (normative) Determination of the degree of contrast between colour of the substrate and the indicator reagent	6
Annex B (normative) Method of determining uniform colour change on exposure to saturated steam	7
Annex C (normative) Method for determining indicator colour change on exposure to dry heat	8
Annex D (normative) Method for determining transfer of indicator reagent to standard test pack	9
Annex E (normative) Standard test pack	10
Annex F (normative) Method of determining non-uniform colour change on exposure to a standard fault condition	11
Annex G (normative) Steam exposure apparatus	13
Annex H (informative) Relationship between chemical indicator components	15
Bibliography	16

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 11140-3:2007), 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 H](#), 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 as a routine test 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 steam penetration into a standardised test load in 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. A failure of the Bowie and Dick test is symptomatic of a number of potential problems with the sterilizer that could compromise sterilization of the load. The presence of air within the load may be due to an inefficient air removal stage, an air leak during the air removal stage, or non-condensable gases in the steam supply, are circumstances that can lead to failure of the test. This failure is not conclusive proof that the fault is due to air retention, air leakage or non- condensable gases, and it can be necessary to investigate other causes of failure.

The result of the test can 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.

In this document, the Bowie and Dick test consists of two components:

- a) a small, standardised 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 document. Further information is given in ISO 15882.

