
**Sterilization of health care products —
Chemical indicators —**

Part 3:
**Class 2 indicators for steam penetration
test sheets**

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 3: Indicateurs de classe 2 pour draps 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 11140-3 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 through K form a normative part of this part of ISO 11140.

Introduction

This part of ISO 11140 is based on EN 867-3, *Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test*.

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 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.

A 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 can 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 EN 554. The test method 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 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 have historically been termed the Bowie and Dick test, no reference to this term, other than in this Introduction, is used in this part of ISO 11140.

Sterilization of health care products — Chemical indicators —

Part 3: Class 2 indicators for steam penetration test sheets

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 detail requirements for the standard test pack, but specifies the performance of the indicators.

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 187:1990, *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 drawings — Sizes and layout of drawing sheets.*

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

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

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

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

CIE¹⁾ 15.2–1986, *Colorimetry.*

1) International Commission on illumination, Vienna, Austria.