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

Part 5:
**Class 2 indicators for Bowie and Dick-
type air removal tests**

Stérilisation des produits de santé — Indicateurs chimiques —

*Partie 5: Indicateurs de Classe 2 pour l'essai de Bowie et Dick
d'enlèvement d'air*



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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 11140-5 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-5:2000), 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 air removal test is used to evaluate the efficacy of air removal during the pre-vacuum phase of a pre-vacuum sterilization cycle or during the pulsing stage of positive pulsing cycles if non-condensable gases were present in the steam. Retention of air due to an inefficient air removal stage or the presence of an air leak or non-condensable gases during the air removal stage are circumstances which can lead to failure of the test. This part of ISO 11140 describes the requirements for Class 2 indicators for Bowie and Dick-type air removal test sheets and packs.

For a description of the classes of chemical indicators, see ISO 11140-1.

The difference between the steam penetration test (ISO 11140-3 and ISO 11140-4) and the air removal test (ISO 11140-5) is described in the chemical indicator guidance document (ISO 15882).

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Sterilization of health care products — Chemical indicators —

Part 5:

Class 2 indicators for Bowie and Dick-type air removal tests

1 Scope

This part of ISO 11140 specifies the requirements for Class 2 indicators for Bowie and Dick-type air removal tests used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles.

Additionally, this part of ISO 11140 includes test methods and equipment used to meet these performance requirements.

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 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*

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

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

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

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

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

indicator system

combination of the indicator agent and its substrate subsequently intended to be used in combination with a specific test load

NOTE For the purposes of this document, the specific test load is the standard test pack as defined in Annex E.

3.2

indicator

combination of the indicator agent and its substrate in the final form in which it is intended to be used

See Annex E of ISO 11140-1:2005.

NOTE The indicator may be user-assembled or pre-assembled. The test load may be disposable, for limited re-use or re-usable.