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

Part 5:  
**Class 2 indicators for air removal test  
sheets and packs**

*Stérilisation des produits de santé — Indicateurs chimiques —*

*Partie 5: Indicateurs de classe 2 pour draps et paquets prépliés servant à  
l'essai 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 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 11140-5 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 and H form a normative part of this part of ISO 11140.

## 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. Retention of air due to an inefficient air removal stage or the presence of an air leak 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 and systems for air removal test.

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

Because a range of different tests in different countries have historically been named the Bowie-Dick test, no reference to this term is used in ISO 11140-3, ISO 11140-4 or ISO 11140-5.

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).



# Sterilization of health care products — Chemical indicators —

## Part 5:

## Class 2 indicators for air removal test sheets and packs

### 1 Scope

This part of ISO 11140 specifies the requirements for an indicator and alternative test system 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 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 5-4:1995, *Photography — Density measurements — Part 4: Geometric conditions for reflection density*.

ISO 11140-1:1995, *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 part of ISO 11140, the terms and definitions given in ISO 11140-1 and the following apply.

#### 3.1

##### **air removal indicator**

indicator to be used in the standard test pack to determine the efficacy of the air removal phase in the steam sterilization process

NOTE See annex E for description of the standard test pack.

#### 3.2

##### **air removal indicator system**

specific test load containing an indicator to determine the efficacy of the air removal phase in the steam sterilization process

NOTE The system may be user-assembled or pre-assembled. The test load may be disposable, for limited reuse, or reusable.