

Sterilization of health care products — Chemical indicators —

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

ICS 11.080.01

National foreword

This British Standard was published by BSI. It is the UK implementation of ISO 11140-5:2007.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 May 2007

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ISBN 978 0 580 50705 2

Amendments issued since publication

Amd. No.	Date	Comments

INTERNATIONAL STANDARD

ISO
11140-5

Second edition
2007-03-15

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*



Reference number
ISO 11140-5:2007(E)



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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.

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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).