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

Part 4:

### **Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration**

*Stérilisation des produits de santé — Indicateurs chimiques —*

*Partie 4: Indicateurs de Classe 2 comme alternative à l'essai de Bowie  
et Dick pour la détection de la 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 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 11140-4 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-4:2001) 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*

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## Introduction

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 ISO 17665-1. 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 air removal from high-vacuum porous-load sterilizers used in the sterilization of health care products <sup>[1]</sup>. 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 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 test pack for the Bowie and Dick test consists of two components:

- a) a small standardized test load;
- b) a chemical indicator system to detect the presence of steam.

The Bowie and Dick test as originally described <sup>[1]</sup> utilized huckaback towels as the material for the test load. The test as described in EN 285 uses cotton sheets for this purpose.

Indicators intended as an alternative to the Bowie and Dick test use different materials for the test load and employ indicator systems specifically formulated for use with the defined test load. Because a range of different tests in different countries have historically been termed the Bowie and Dick test, the term "Bowie and Dick-type test" is used in this part of ISO 11140.

This part of ISO 11140 specifies the performance of the indicator system in combination with the test load with which it is intended to be used. The test load may be presented with the indicator system already incorporated and intended for single use, or it may be intended for multiple use with a new indicator system to be inserted prior to each use.

The indicator for which the performance is specified in this part of ISO 11140 is intended to indicate when steam penetration has been inadequate. The performance of the indicator specified in this part of ISO 11140 should be equivalent, but not necessarily identical, to the performance obtained in the Bowie and Dick-type test as described in ISO 11140-3. Equivalence should be regarded as providing a similar response to steam penetration with any differences being predictable and such that the necessary level of assurance of satisfactory steam penetration is provided. An indicator meeting this specification is not intended to identify which of the potential causes of poor steam penetration was responsible for the failure indicated by the test.