

Specification for

**Non-biological sterilization
indicator systems for use in the
Bowie and Dick test with
alternative test loads**

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Laboratory Apparatus Standards Policy Committee (LBC/-) to Technical Committee LBC/35, upon which the following bodies were represented:

Association of British Health Care Industries
 Association of National Health Service Supplies Officers
 Association of Sterilizer and Disinfector Equipment Manufacturers
 British Dental Trade Association
 Central Sterilising Club
 Department of Health
 Health and Safety Executive
 Infection Control Nurses Association
 Institute of Hospital Engineering
 Institute of Purchasing and Supply
 Institute of Sterile Services Management
 Joint Committee of Professional Nursing, Midwifery and Health Visiting
 Associations (England)
 Medical Sterile Products Association
 National Blood Transfusion Service
 Public Health Laboratory Service
 Regional Hospital Boards Engineers' Association
 Royal College of Pathologists
 Royal Pharmaceutical Society of Great Britain
 Society for General Microbiology
 Stainless Steel Fabricators' Association of Great Britain
 Coopted members

The following bodies were also represented in the drafting of the standard, through a subcommittee:

BLWA Ltd. (The Association of the Laboratory Supply Industry)
 Sterilizing Packaging Materials Association

This British Standard, having been prepared under the direction of the Laboratory Apparatus Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on
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Foreword

This British Standard has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee and specifies the requirements for non-biological indicators for particular application in the performance of the Bowie and Dick test.

The non-biological indicators specified in this standard are not intended for use in any process other than that specified. The use of an inappropriate indicator may give dangerously misleading results.

The performance of a non-biological indicator may be affected by the conditions of storage prior to use, the methods of use, and the conditions of storage after exposure to the process. For these reasons, the recommendations of the manufacturer for storage and use should be followed precisely. Non-biological indicators should not be used beyond any expiry date stated by the manufacturer.

The Bowie and Dick test was conceived as a test for air removal from high vacuum porous load sterilizers [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 or an air leak during this stage, or non-condensable gases in the steam supply, are circumstances which can lead to a failure of the test. The results 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 other causes of failure may need to be investigated.

The Bowie and Dick test is a performance test for steam sterilizers for wrapped goods. As such it is performed during the demonstration of conformity of steam sterilizers to EN 285¹⁾ and as a routine test of performance in EN 554¹⁾. The method of carrying out the test is described in EN 285¹⁾.

A test pack for the Bowie and Dick test consists of two components:

- (a) a system or device providing resistance to air removal (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 285¹⁾ uses cotton sheets for this purpose.

Alternative indicator systems for the Bowie and Dick test which use different materials for the test load and employ indicator systems specifically formulated for use within defined test loads are available. This standard describes the requirements for the performance of the indicator system in combination with the test load with which it is intended to be used.

The indicator which is specified in this standard is intended to indicate when steam penetration has been inadequate.

Product certification. Users of this British Standard are advised to consider the desirability of third party certification of product conformity with this British Standard based on testing and continuing product surveillance, which may be coupled with assessment of a supplier's quality systems against the appropriate Part of BS 5750.

¹⁾ In preparation. It is envisaged that British Standards implementing these European Standards will be published in due course.

Enquiries as to the availability of third party certification schemes are forwarded by BSI to the Association of Certification Bodies. If a third party certification scheme does not already exist, users should consider approaching an appropriate body from the list of Association members.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Specification

1 Scope

This British Standard specifies requirements for an indicator system to be used with an alternative test load in the Bowie and Dick test for steam sterilizers for wrapped goods such as instruments and porous loads.

An indicator system conforming to this standard is used in combination with a specified material which is used as a test load. This standard does not specify requirements for the test load but specifies the performance of the indicator system in combination with the test load with which it is intended to be used.

The indicator system specified in this standard is intended to identify poor steam penetration but does not necessarily indicate the cause of this poor steam penetration.

2 References

2.1 Normative references

This British Standard incorporates, by reference, provisions from specific editions of other publications. These normative references are cited at the appropriate points in the text and the publications are listed on the inside back cover. Subsequent amendments to, or revisions of, any of these publications apply to this British Standard only when incorporated in it by updating or revision.

2.2 Informative references

This British Standard refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this British Standard, the following definitions apply.

3.1 graduated response

Progressive visible change occurring on exposure to one or more process variables allowing assessment of the level achieved.

3.2 defined end-point

Visible change occurring after exposure to the specified variable(s) at a level equal to or greater than that specified for the indicator.

3.3 indicator reagent

Active ingredient or combination of ingredients before conversion into the indicator.

3.4 indicator system

Combination of the indicator reagent and its substrate.

3.5 indicator

Indicator system in the form in which it is intended to be used.

3.6 pre-assembled pack

Indicator in which the indicator system is incorporated into the test load during the manufacturing process and which is supplied ready for use.

3.7 process indicator

Indicator intended for use with individual packs of product to demonstrate that the pack has been exposed to the sterilization process.

3.8 user-assembled pack

Indicator for which the user combines the indicator system and the test load prior to use.

3.9 sterilization temperature

Minimum temperature of the sterilization temperature band.

NOTE. The sterilization temperature band is the range of temperatures which may prevail throughout the load during the holding time.

3.10 temperature depression

The thermodynamic temperature in kelvin given by (temperature in degrees Celsius at centre of standard test pack minus temperature in degrees Celsius in active drain).

4 General system requirements

4.1 Documentation

4.1.1 The manufacturer shall establish, document and maintain a formal quality system to cover all operations required by this standard.

NOTE. British Standards of the BS 5750 series and the BS 7501 to BS 7514 series describe requirements for quality systems for manufacture and testing.

4.1.2 Suitable records shall be maintained to ensure that, in the event of a defect arising, faulty batches can be recalled from use.

4.1.3 The manufacturing and distribution records shall be retained for a period of five years, or twice the declared shelf life of the product, whichever is greater. These records shall be maintained in accordance with the requirements of **4.16** of BS 5750 : Part 1 : 1987.