

Autoclaves for sterilization in laboratories —

Part 5: Methods of test for function and performance

Confirmed December 2011

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

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

- Association of Clinical Pathologists
- British Glass Manufacturers' Confederation
- British Laboratory Ware Association
- Copper Development Association
- Institute of Medical Laboratory Sciences
- Manufacturing Science Finance
- Ministry of Agriculture, Fisheries and Food
- Royal Association of British Dairy Farmers
- Society for Applied Bacteriology

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 15 March 1993

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Foreword

This Part of BS 2646 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. It describes methods of testing the function and performance of laboratory autoclaves specified in Part 1 of this standard.

BS 2646 comprises several separate Parts. The other Parts of the standard are as follows.

- *Part 1: Specification for design, construction, safety and performance;*
- *Part 2: Guide to planning and installation;*
- *Part 3: Guide to safe use and operation¹⁾;*
- *Part 4: Guide to maintenance.*

It is anticipated that autoclaves to which this standard applies will be used for the following processes:

- a) liquids sterilization;
- b) make-safe;
- c) equipment and glassware sterilization;

and methods of test are described for each process.

BS 2646-3 will describe the stages of each operating cycle, together with recommended times and temperatures for various processes and safety procedures.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 10, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

¹⁾ In preparation.

Section 1. General

1.1 Scope

This Part of BS 2646 describes the methods of test used to verify compliance with the requirements for design, construction, safety and performance specified in BS 2646-1:1993.

This standard covers laboratory autoclaves for the sterilization of goods and material which could be infected with organisms categorized as Hazard Group 1, 2 or 3²⁾. It does not cover autoclaves for use with material infected with organisms in Hazard Group 4, for which complete containment and sterilization of infected condensate is considered to be essential.

This standard does not apply to sterilizers or disinfectors used for medical, dental, pharmaceutical or veterinary purposes which are directly concerned with patient care, or those used for fabrics subjected to sterilization which are required to be dry at the end of the cycle. These are covered by BS 3970.

1.2 References

1.2.1 Normative references

This Part of BS 2646 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 Part of BS 2646 only when incorporated in it by updating or revision.

1.2.2 Informative references

This Part of BS 2646 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 edition.

1.3 Definitions

For the purposes of this Part of BS 2646, the definitions given in BS 2646-1:1993 apply.

1.4 Test instruments and gauges

1.4.1 General

Test instruments shall be used to check the accuracy of the autoclave instruments to the requirements of BS 2646-1:1993. They shall also be used to indicate or record pressure and temperatures at specified locations within the chamber during performance tests.

Test gauges shall be used to check the accuracy of autoclave pressure and temperature gauges to the requirements of BS 1780:1985 and BS 5235:1975 respectively.

1.4.2 Calibration and verification of test instruments and gauges

1.4.2.1 Calibration of test instruments shall be carried out as follows.

- a) A temperature reference standard shall be used (see 1.4.2.3).
- b) Test instruments shall be calibrated in accordance with the manufacturer's instructions.

1.4.2.2 Test instruments with sensors connected shall be verified on-site using an independent reference standard (see 1.4.2.3).

NOTE Test instruments should not be subjected to rapid variations in ambient temperature.

1.4.2.3 The temperature reference standard shall:

- a) incorporate a reference standard thermometer traceable to a national primary standard³⁾. The thermometer shall include the range 0 °C to 150 °C with minor mark intervals not exceeding 0.2 °C;
- b) incorporate a pocket to accommodate at least three temperature sensors. The temperature gradient through the effective length of each pocket shall not exceed 0.2 °C and the control accuracy shall be ± 0.1 °C in the range 100 °C to 140 °C.

1.4.2.4 The test instrument shall have a manufacturer's valid test certificate.

1.4.2.5 Calibration and verification of gauges shall be carried out in accordance with the manufacturer's instructions.

1.4.3 Test recorders

1.4.3.1 Temperature test recorders shall have the following characteristics:

- a) a scale range which includes 0 °C to 150 °C;
- b) a chart width of not less than 100 mm;
- c) an accuracy of ± 0.5 °C between 120 °C and 130 °C;
- d) be of a continuous recording type with a chart speed of not more than 5 mm/min and not less than 2 mm/min or of a dot recording type with print intervals not exceeding 0.5 mm;
- e) be suitable for use with leads and sensors in accordance with 1.4.6.1.

²⁾ The Hazard Groups of organisms referred to are listed in *Categorization of pathogens according to hazard and categories of containment*, Second Edition, 1990 [1] produced by the Advisory Committee on Dangerous Pathogens, and published by HMSO.

³⁾ Located at the National Physical Laboratory, Queen's Road, Teddington, Middlesex TW 11 0LW