



BS 2646 : Part 1 : 1988

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British Standard

Autoclaves for sterilization in laboratories

Part 1. Specification for design and construction

Autoclaves stériliseurs de laboratoire
Partie 4. Conception et construction — Spécifications

Laborsterilisationsapparate
Teil 4. Bau und Ausführung

British Standards Institution

Foreword

This Part of BS 2646 has been prepared under the direction of the Laboratory Apparatus Standards Committee.

It specifies requirements for the design, construction and performance of laboratory autoclaves for the purpose of sterilization. It does not cover autoclaves for use with material infected with organisms in Hazard group 4 (see dagger footnote to clause 1). This Part of BS 2646 supersedes BS 2646 : 1955 which dealt with cylindrical copper laboratory autoclaves and is now withdrawn. This revision covers horizontal and vertical models with either rectangular or cylindrical chambers.

The revised standard is to be in several Parts.

This Part is a specification for the design and construction of autoclaves.

Further Parts are in preparation dealing with process requirements and functional design, performance testing, installation, use and maintenance.

This Part of BS 2646 specifies requirements for the design and construction of the pressure vessel and also includes details of necessary pressure vessel and electrical safety features. It is intended that in complying with this standard the design and manufacture of autoclave pressure vessels will comply with the relevant requirements of BS 5500.

The section on materials has been expanded to permit the use of a variety of materials in addition to copper and copper alloys for the construction of pressure vessels.

It is acknowledged that copper and copper alloys are not covered by BS 5500, and nor are rectangular pressure

vessels. The design criteria for autoclave pressure vessels constructed of copper or copper alloys and also rectangular chambers are included in this Part of BS 2646.

A section has been included on steam generators heated by electricity where these form part of the autoclave unit.

The maximum permissible working pressure has been increased to 2.4 bar* (35 lbf/in²) from an operating pressure of 25 lbf/in² (1.7 bar) in the 1955 edition.

Autoclaves covered by this standard are not intended for the sterilization of goods or fluids which are directly concerned with patient care nor for fabrics subjected to sterilization which are required to be dry at the end of the cycle. Sterilizers suitable for these applications are covered by BS 3970.

It is intended that consideration will be given, if appropriate, to replacement of the references to BS 3456 : Part 101 in clause 35, relating to electrical safety requirements, by references to BS 4743 when the revision of that standard, currently in progress, is published. The revision of BS 4743 will include safety requirements for various types of laboratory equipment.

Purchasers ordering to this standard are advised to specify in their purchasing contract that the manufacturer operates a quality system as described in BS 5750 : Part 1 to assure themselves that products claimed to comply with this Part of BS 2646 consistently achieve the required level of quality.

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

*1 bar = $1 \times 10^5 \text{ N/m}^2 = 0.1 \text{ N/mm}^2 = 1 \times 10^2 \text{ kPa} = 14.5038 \text{ lbf/in}^2$.

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Section one. General

1 Scope

This Part of BS 2646 specifies requirements for the design and construction of autoclaves operating with saturated steam at temperatures up to 138 °C and pressures not exceeding 2.4 bar* nominal and for operation under vacuum (subject to external pressure).

The standard covers laboratory autoclaves for the sterilization of goods and material which may be infected with organisms categorized as Hazard Group 1, 2 or 3†. 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. These are covered by BS 3970.

NOTE. The titles of the publications referred to in this standard are listed on the inside back cover.

2 Definitions

For the purposes of this Part of BS 2646 the following definitions apply.

2.1 autoclave. A machine, which incorporates a steam pressure vessel, designed to sterilize laboratory materials and equipment.

NOTE. It may also be used for other processes, such as heat disinfection and heat treatment, which may be selected according to the laboratory requirements and the nature of the load.

2.2 maximum permissible working pressure. The maximum internal pressure, not higher than the design pressure, at which the autoclave chamber and/or generator may be operated.

NOTE. To prevent unnecessary lifting of the safety valve there should be an adequate margin between the actual pressure at which the autoclave is operating and the lowest pressure at which the safety valve is set to lift.

2.3 design pressure. The maximum internal pressure, not lower than the safety valve set pressure, that the autoclave chamber and/or generator is designed to withstand and that is therefore used in the design equations.

2.4 safety valve set pressure. The pressure at which a safety valve is set to lift.

2.5 operating pressure. The pressure at which the autoclave operates.

2.6 design temperature. The saturated steam temperature corresponding to the design pressure of the autoclave chamber and/or generator. Its value is used to determine the appropriate nominal design strengths for the selected

materials and is not lower than the actual metal temperature prevailing in service (see 14.1).

2.7 door. The closure of the autoclave chamber. In the case of a top loading autoclave, it is the lid of the chamber.

2.8 purchaser. The individual or organization that buys the completed autoclave for its own use or as an agent for the owner.

2.9 manufacturer. The organization that designs, constructs and tests the autoclave in accordance with this Part of BS 2646 and the purchaser's specification. By agreement the design, construction and testing may be carried out by different organizations (see clause 4).

2.10 Inspecting Authority. The independent body or association appointed to check that the manufacturer's quality system, and the design, materials and construction of the autoclave pressure vessel(s) comply with this Part of BS 2646.

2.11 Regulating Authority. The authority in the country in which the autoclave is to be installed and that is legally charged with the enforcement of the requirements of the law and regulations of that country relating to autoclave pressure vessels.

3 Autoclave types

For the purposes of this Part of BS 2646 autoclaves are classified according to the source of steam as follows.

Type I. Steam from an external source (see 32.1).

Type II. Steam from a generator forming part of the autoclave but capable of being isolated from the autoclave chamber, the generator being heated by means of an electric immersion heater (see 32.2).

Type III. Steam from a generator, as in type II, but without means of isolation from the autoclave chamber (see 32.3).

Type IV. Steam produced from water contained within the autoclave chamber and heated by means of an electric immersion heater (see 32.4).

4 Responsibilities

4.1 Responsibilities of the purchaser

The purchaser shall be responsible for supplying the manufacturer with the information required by 5.1.

If there is a Regulating Authority, it shall be the responsibility of the purchaser to ensure that the Inspecting Authority is acceptable to the Regulating Authority.

NOTE. This should be carried out before the order is placed.

*1 bar = $1 \times 10^5 \text{ N/m}^2 = 0.1 \text{ N/mm}^2 = 1 \times 10^2 \text{ kPa} = 14.5038 \text{ lbf/in}^2$. Pressures referred to are measured from atmospheric and not on the absolute scale.

†The Hazard Groups of organisms referred to are as listed in 'Categorization of pathogens according to hazard and categories of containment', by the Advisory Committee on Dangerous Pathogens, HMSO 1984. Attention is also drawn to the requirements of the Health and Safety (Dangerous Pathogens) Regulations 1981 which apply to those pathogens listed in Schedule 1 of the Regulations.

4.2 Responsibilities of the manufacturer

4.2.1 The manufacturer shall be responsible for the completeness and accuracy of all design calculations and for compliance with all applicable requirements of this Part of BS 2646 for the whole autoclave. During fabrication or design, of the autoclave or pressure vessel, unexpected factors may arise which justify deviations from the specified requirements but which do not affect the safety as intended by this Part of BS 2646. Such deviations shall be submitted to the purchaser for approval and shall be recorded in accordance with 5.2.3(c).

4.2.2 In cases where the design and fabrication functions are carried out by separate organizations, the manufacturer's responsibilities as laid down in this standard shall be discharged in a manner agreed between the parties concerned (see 5.3(a)).

4.2.3 Examinations of a pressure vessel carried out by the Inspecting Authority shall not absolve the manufacturer from his responsibility for compliance with the applicable requirements of this Part of BS 2646.

4.2.4 The manufacturer shall be responsible for supplying the Inspecting Authority with two copies of the informa-

tion required by 5.2.2 for each autoclave pressure vessel or batch of nominally identical vessels serially produced.

4.2.5 The manufacturer shall be responsible for supplying the purchaser with the information required by 5.2.3 which shall also be available to the Inspecting Authority and the Regulating Authority.

4.3 Responsibilities of the Inspecting Authority

The Inspecting Authority shall be responsible for checking the design of the autoclave pressure vessel for compliance with this Part of BS 2646. The Inspecting Authority shall be responsible for inspection and testing as defined in section seven.

4.4 Certificate of compliance

On completion of construction of the pressure vessel the manufacturer shall issue a certificate of compliance (see figure 1) to certify that the vessel has been designed, constructed and tested in every respect in accordance with the requirements of this standard. The certificate of compliance shall be countersigned by the Inspecting Authority if so appointed.

Certificate of Compliance (to be completed for each pressure vessel).*Autoclave type**Vessel description* Boiler/receiver

Approximate internal dimensions

Approved drawing number(s)

Manufacture Year of manufacture

Name of manufacturer

Manufacturer's serial no. or cipher (see note)

Name of Design Organization
(if not above manufacturer) Name of Inspecting Authority,
design approval Name of Inspecting Authority, testing
and inspection (where appointed)*Design* Design pressure (in bar)

Design temperature (in °C)

Construction category

Post-weld heat treatment (where applicable)

Component Temperature (in °C) Holding time (in h)

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Hydraulic pressure test

Location Test pressure Test medium Date

(in bar) and temp. (in °C)

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.....

Deviations and concessions

NOTE 1. The suffix 'XX' is to be added to the serial number of each vessel for which any deviations or concessions have been authorized (see 5.2.3(c)).

Figure 1. Certificate of compliance

<i>Certificate of Compliance (design)</i> We hereby certify that the design of this vessel complies with BS 2646 : Part 1, and has been approved by (Inspecting Authority) Reference of Inspecting Authority, approval For Manufacturer: Date: Position: Name of company:
<i>Certificate of Compliance (construction and testing)</i> We hereby certify that this vessel has been constructed and tested and complies with BS 2646 : Part 1. For Manufacturer: Date: Position: Name of company:
<i>This section to be completed if an Inspecting Authority has been appointed to examine and test this pressure vessel</i> We hereby confirm that the above vessel has been examined and tested and that to the best of our knowledge and belief it complies with BS 2646 : Part 1. For Inspecting Authority: Date: Position: Name of company:

Figure 1 (concluded)

5 Information and requirements to be agreed and to be documented

5.1 Information to be supplied by the purchaser

The following information shall be supplied by the purchaser, if required by the manufacturer, and shall be fully documented. Both the definitive requirements specified throughout this Part of BS 2646 and the documented items shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

- (a) A specification of the normal working conditions of the autoclave together with details of any transient and/or adverse conditions under which the autoclave is required to operate and of any special regulations for in-service inspection.
- (b) Any additional requirements not given in this standard.

(c) Any special statutory or other regulations with which a finished autoclave pressure vessel is required to comply.

(d) The name of the Regulating Authority (if any).

(e) Whether an Inspecting Authority is to be nominated by the purchaser or not (see clause 23).

(f) If an Inspecting Authority is to be nominated by the purchaser, the name of the Inspecting Authority.

5.2 Information to be supplied by the manufacturer

5.2.1 The information listed in 5.2.2 and 5.2.3 shall be supplied by the manufacturer and shall be fully documented. Both the definitive requirements specified throughout this Part of BS 2646 and the documented items shall be satisfied before a claim of compliance with this Part of BS 2646 can be made and verified.

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5.2.2 The manufacturer shall supply the Inspecting Authority with two copies of the following for each autoclave pressure vessel or batch of nominally identical vessels serially produced.

- (a) A fully dimensioned drawing of the vessel, as designed, together with any relevant supporting information as specified in 4.1.1 of BS 5500 : 1988 and which is not covered by the following items (b) to (e) and 5.2.3.
- (b) A list of materials (including welding consumables) used in the construction of the vessel(s) with details of any special heat treatments carried out by the material supplier. For materials specified as complying with a British Standard the date of the standard shall be given.
- (c) Any non-destructive testing specification for the pressure vessel in accordance with clause 28 (for aluminium alloy vessels only).
- (d) The welding procedures used during vessel manufacture (see 24.3).
- (e) Any procedures used for inspection and/or crack detection of welds (see 28.1).

5.2.3 The manufacturer shall supply the purchaser with the following which shall also be available to the Inspecting Authority and Regulating Authority.

- (a) A certificate of compliance for each pressure vessel (see 4.4).
- (b) A facsimile of the marking as required by section ten.
- (c) Records of authorized deviations or concessions as permitted in 4.2.1. The manufacturer shall add the

suffix 'XX' to the serial number of each vessel and autoclave for which any deviation or concessions have been authorized.

(d) Details of any alternative specifications in this standard which require the approval of the purchaser (see 5.3).

(e) Details of the services required on site for the satisfactory operation of the autoclave.

(f) Where an Inspecting Authority is to be nominated by the manufacturer, the name of the Inspecting Authority.

5.3 Requirements to be agreed and documented

The following items to be agreed, as appropriate, between the parties concerned, which are specified in the clauses referred to, shall be fully documented. Both the definitive requirements specified throughout this standard and the documented items shall be satisfied before a claim of compliance with this standard can be made and verified.

(a) The manner in which the manufacturer's responsibilities are to be discharged in cases where the design and fabrication functions are carried out by separate organizations (see 4.2.2).

(b) The use of materials of construction that are not listed in tables 1 or 2 (see 5.2.2(b)).

(c) Whether welder approval tests that have been completed to the satisfaction of another recognized Inspecting Authority are acceptable (see 25.5).

(d) Acceptance criteria for defects revealed by visual examination, including aided visual examination (see 28.1).

Section two. Materials

6 Selection of materials

6.1 General

6.1.1 The selection of the materials of construction for pressure-containing parts and their integral attachments shall take into account the suitability of the material with regard to fabrication and to the conditions under which they will eventually operate. Due attention shall be paid to the effects of galvanic attack and differential expansion when dissimilar metals are used in contact.

6.1.2 The materials used in the manufacture of pressure-containing parts shall be either of the following:

- (a) materials complying with the appropriate British Standard listed in tables 1 and 2;
- (b) other materials subject to agreement with the Inspecting Authority and the purchaser (see 5.3(b)).

6.2 Welding and brazing materials

6.2.1 Welding materials for autoclaves constructed from materials listed in table 1 shall be selected in accordance with 4.3.2 or 4A.3.2 of BS 5500 : 1988.

6.2.2 Brazing materials for the copper and copper alloys listed in table 2 shall comply with clause 22.

7 Nominal design strength

The nominal design strength of every material used in the manufacture of the shell and ends of the autoclave chamber and generator, including the door and frame, shall, as appropriate, be as listed or referred to in tables 1 and 2.