BRITISH STANDARD

BS 2646-5: 1993

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

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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 operation*[1)];

— *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 3[2)]. 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 standard[3)]. 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 OLW

1.4.4 Test pressure gauges

Bourdon tube type test gauges shall be checked for accuracy in accordance with BS 1780:1985.

1.4.5 Test pressure transducers

Pressure transducers for use with recording instruments shall have a limit of error not exceeding 0.2 % when tested in accordance with BS 6253-1:1982 within the range 0 bar to 3 bar[4)].

1.4.6 Temperature sensors

1.4.6.1 Sensor leads shall each be not less than twice the length of a horizontally mounted autoclave chamber (or the height of a vertically mounted autoclave chamber).

1.4.6.2 Thermocouple leads and sensors shall either conform to those requirements of BS 4937-5:1974 that relate to Tolerance class 1 (Type T), or to those requirements of BS 4937-4:1973 that relate to Tolerance class 1 (Type K).

1.4.6.3 Leads shall be twin core, single strand, twisted, unsheathed with a conductor diameter of 0.2 mm to 0.5 mm.

1.4.6.4 Thermocouple hot junctions shall be arc welded or the wires shall be cleaned and twisted together.

NOTE 1 Twisting conductors together may produce an unreliable junction.

NOTE 2 Sensors are introduced into the autoclave chamber through a pressure-tight fitting directly connected to the R_p ¾ threaded entry (see **11.6.4.3** of BS 2646-1:1993).

1.4.7 Timers

Stopwatches used for timing shall be graduated in 0.2 s, with an accuracy over a period of 15 min of ± 1.0 s.

[4)] 1 bar = 10^5 N/m^2 = 10^5 Pa. Pressures referred to are measured from atmosphere and not on the absolute scale.

Section 2. Tests for safe function

NOTE The methods of test described in this section are used to check compliance with the requirements for safety devices specified in BS 2646-1:1993.

2.1 Safety valves (see **9.2** of BS 2646-1:1993)

Gradually increase the pressure in the chamber and/or the generator by using steam, and check that the safety valve(s) lift(s) when the maximum permissible working pressure is reached.

2.2 Tests on door interlocks

2.2.1 Steam to chamber (See item a) of **9.4.2.1** of BS 2646-1:1993 and item a) of **9.4.2.2**)

With the door closed but not locked, check that steam does not enter the chamber when a cycle is initiated.

2.2.2 Door remains in position (quick-opening doors) (see **9.4.2.1** of BS 2646-1:1993)

In turn disable each of the service(s) used to power the door movement as follows:

a) during each stage of a cycle;

b) whilst the door is opening and closing;

c) whilst the door is stationary between cycles.

In each case check that the door stops moving or remains stationary.

2.2.3 Interlock switches (quick-opening doors) (see item h) of **9.4.2.1** of BS 2646-1:1993)

Check that moving parts of switches have a positive movement as the door closes and is secured.

2.2.4 Thermal door interlocks (see **9.5.1** of BS 2646-1:1993)

Where a thermal door interlock is fitted, check that the door securing mechanism is not released until the load has cooled to the set temperature.

2.3 Tests on discharge of chamber contents (see **9.5.2** of BS 2646-1:1993)

With all services connected, disable each service in turn and check that steam, vapour or fluid does not escape from the chamber during a cycle.

2.4 Tests on double door autoclaves

For autoclaves with two doors, check each door for compliance with the tests given in **2.2** above.

In addition, after a fault (see **1.3.30** of BS 2646-1:1993), check that the unloading door cannot be released at the end of the cycle.

Section 3. Tests for performance

3.1 Instrument accuracy, steady state and operating cycle controls: performance tests

3.1.1 Apparatus and materials

Test recorder, which shall have the characteristics listed in **1.4.3.1**, with three input channels, each connected to a theromocouple lead and sensor, which shall meet the requirements listed in **1.4.6**.

3.1.2 Preparation for the test

If a load temperature probe is fitted, place it in the chamber, either in a pocket provided for the purpose or on the load support.

Position the two or three thermocouples, as applicable, as follows:

a) in the chamber drain (or vent), within 100 mm of its connection to the chamber;

b) in the upper half of the chamber;

c) attached to the load temperature probe, if fitted, within 20 mm of its tip.

Ensure that thermocouple junctions are suspended and are not in contact with any surface.

Set the autoclave controller to produce a sterilizing temperature of between 121 °C and 124 °C for 15 min. If such a range is not provided, the nearest temperature to that range shall be used.

3.1.3 Test procedure

Operate the autoclave in accordance with the manufacturer's instructions for a complete operating cycle.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the operating cycle time.

3.1.4 Test result

The accuracy of the autoclave instruments shall be demonstrated to be within the limits specified in BS 2646-1:1993, by checking against the test recorder.

3.2 Liquids sterilization: performance test

(see **12.1** of BS 2646-1:1993)

3.2.1 General

The test measures the performance of the autoclave when processing a standard challenge load of bottled liquid.

Performance is measured in respect of the following.

a) Temperature distribution within the load.

b) Ability to maintain the selected temperature for the set time.

c) Volume changes in the liquid being processed, whether arising from loss of water vapour or as a result of boiling over.

d) The rate of breakage of the specified glass bottles.

e) Overall time taken to complete one operating cycle.

f) The effectiveness of the thermal door interlocks.

3.2.2 Apparatus and materials

3.2.2.1 *Test recorder(s)*, in accordance with **1.4.3**, with twelve input channels each connected to a thermocouple lead and sensor in accordance with **1.4.6**.

3.2.2.2 *Test containers*, comprising glass bottles of nominal capacity 500 ml conforming to BS 5928:1980, with a screw neck of thread conforming to DIN 168-1:1979 [2].

3.2.2.3 *Closures*, being plastics caps made from inert, heat-resistant material moulded to a thread suitable for the test containers.

3.2.2.4 *Test liquid*, comprising bile-salt/agar (MacConkey Agar) solution containing 5 g/l bile salt and 12 g/l agar powder, dissolved in distilled water[5)].

3.2.2.5 *Challenge load*, comprising N test containers holding 400 ml ± 10 ml liquid, as follows:

a) 9 bottles containing the test liquid (**3.2.2.4**), labelled 1 to 9 with a steam resistant marker; and

b) (N – 9) bottles containing tap water.

The total number (N) of bottles shall be calculated as follows:

N = Usable chamber space in litres × 0.2.

NOTE 1 Usable chamber space is defined in **1.3.20** of BS 2646-1:1993.

NOTE 2 This is equivalent to 80 ml liquid load volume per litre chamber capacity.

Place closures (**3.2.2.3**) on the filled containers (**3.2.2.5**). Tighten the closures by hand and then loosen by one complete revolution.

[5)] For information on sources of supply and method of preparation, write to Customer Services, BSI, Linford Wood, Milton Keynes, MK 14 6LE.

3.2.3 Preparation for the test

3.2.3.1 Place the prepared containers (**3.2.2.5**) in the autoclave chamber on load support shelves, the containers being spaced equally, as judged by the eye, one from each other and from the chamber walls.

3.2.3.2 Position the temperature sensors (see **3.2.2.1**) as follows:

a) one in the chamber drain (or vent) within 100 mm of its connection to the chamber;

b) one in the chamber free space;

c) one each in three bottles (containing tap water), known to be the slowest to attain sterilizing temperature;

d) one each in three bottles (containing tap water), known to be the fastest to attain sterilizing temperature;

e) one each in three bottles (containing tap water), known to be the slowest to cool to 80 °C;

f) one in the chamber within 10 mm of, but not touching, the chamber base.

NOTE 1 In order to establish the positions for containers in accordance with items c), d) and e), it will be necessary to conduct preliminary tests.

NOTE 2 The sensor conforming to item f) is to measure the temperature of any liquid present in the chamber at the completion of the operating cycle.

Insert the sensors conforming to items c), d) and e) into the bottles, either using a purpose-made or modified closure and entry gland, or introducing them between the threaded neck and plastics closure.

Locate the sensors conforming to items c), d) and e) in the vertical axis between 20 mm and 40 mm from the base of the bottle, not in contact with any surface but suspended in the liquid.

If a load temperature probe is fitted, place it in one of the bottles conforming to item c) or item d) above and use it to support the sensor.

NOTE 3 It will be necessary to cut a hole in the plastics cap to accept the probe as a tight fit.

3.2.3.3 Weigh the nine bottles containing test fluid individually, recording the mass of each to the nearest gram and locate them adjacent to the containers positioned in accordance with items c), d), and e) of **3.2.3.2**. The contents shall be at a temperature below 50 °C when placed in the chamber.

3.2.3.4 Set the autoclave controller to produce a sterilizing temperature of between 118 °C and 121 °C for 15 min. If such a range is not provided, the nearest to that range shall be used.

3.2.3.5 Set the thermal door interlocks as appropriate for the challenge load.

3.2.4 Test procedure

Operate the autoclave in accordance with the manufacturer's instructions for liquids sterilization.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the operating cycle time.

When the door securing mechanism releases at the end of the operating cycle, if the temperatures recorded by the test sensors conforming to items c), d) and e) of **3.2.3.2** do not exceed 80 °C and the temperatures recorded by the test sensors conforming to items a), b) and f) of **3.2.3.2** do not exceed 95 °C, open the autoclave and remove the load. If necessary, delay opening the autoclave until the above temperatures have been reached. Visually inspect the bottles and note the number of breakages, if any.

When the nine containers of test liquid have cooled to below 50 °C, reweigh them and record the mass of each.

Note if the temperature of any container(s) was above 80 °C or below 65 °C when the door securing mechanism was released.

3.3 Make-safe: performance tests

3.3.1 General

Three tests (A, B and C) are described. Test A shall be performed except that, if the autoclave chamber size or configuration, or the standard challenge load is not appropriate, an alternative test B or test C shall be performed by agreement between the manufacturer and the purchaser (see **12.2** of BS 2646-1:1993).

The tests measure the performance of the autoclave when processing the challenge load, in respect of the following.

a) Ability to reach the selected temperature rapidly in the load.

b) Ability to maintain the selected temperature for the set time.

c) Overall time taken to complete one operating cycle.

d) The effectiveness of the thermal door interlocks.

3.3.2 Make-safe test A

3.3.2.1 ***Apparatus and materials***

3.3.2.1.1 *Test recorder(s)*, in accordance with **1.4.3** with six input channels each connected to a thermocouple lead and sensor in accordance with **1.4.6**.

3.3.2.1.2 *Two discard-containers* (see **1.3.21** of BS 2646-1:1993, with the following dimensions and characteristics.

a) Internal dimensions not less than 250 mm × 280 mm × 210 mm deep.

b) Walls and base of thickness not less than 2.5 mm.

c) Fabricated from polypropylene or other polymer which will withstand the autoclaving process, with thermal conductivity not more than 0.15 W/(m·K).

3.3.2.1.3 *Bottles*, of capacity 5 ml approximately.[6) 7)]

3.3.2.1.4 *Test container and closure*, containing 400 ml ± 10 ml tap water (see **3.2.2.2**, **3.2.2.3** and **3.2.2.5**).

3.3.2.1.5 *Challenge load,* comprising:

a) the discard-containers (**3.3.2.1.2**), filled with clean, dry, uncapped bottles (**3.3.2.1.3**), randomly distributed such that at least 550 bottles are used;

b) the test container (**3.3.2.1.4**).

3.3.2.2 ***Preparation for the test***

3.3.2.2.1 Position the temperature sensors, as follows:

a) one in the chamber drain (or vent), within 100 mm of its connection to the chamber;

b) one in the chamber free space;

c) one inside an inverted bottle (**3.3.2.1.3**), placed centrally at the lowest level in each discard-container (**3.3.2.1.2**);

d) one in the test container (**3.3.2.1.4**), located in the vertical axis between 20 mm and 40 mm from the base of the container, not in contact with any surface but suspended in the liquid;

e) one in the chamber within 10 mm of, but not touching, the chamber base.

Insert the sensor conforming to item d) into the bottle, either using a purpose-made or modified closure and entry gland or introducing it between the threaded neck and plastics closure.

NOTE 1 The sensor conforming to item e) is to measure the temperature of any liquid present in the chamber at the completion of the operating cycle.

Place the two discard-containers, containing the bottles (see item a) of **3.3.2.1.5**, in the autoclave chamber on load support(s), one in the upper half of the chamber and the other in the lower half of the chamber, each at the centre.

Place the test container on a load support adjacent to the lower box.

If a load temperature probe is fitted, place it in its holder or on a load support.

NOTE 2 It will be necessary to cut a hole in the plastics cap to accept the probe as a tight fit.

3.3.2.2.2 Set the controller to produce a sterilizing temperature of between 130 °C and 126 °C for 10 min. If such a range is not provided, the nearest temperature to that range shall be used.

3.3.2.2.3 Set the thermal door interlock as appropriate for a 500 ml capacity container of 400 ml water.

3.3.2.3 ***Test procedure***

Operate the autoclave in accordance with the manufacturer's instructions for make-safe.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the duration of the equilibration time;

3) the operating cycle time.

When the door securing mechanism releases at the end of the operating cycle, if the temperature recorded by the test sensor conforming to item d) of **3.3.2.2.1** does not exceed 80 °C, and the temperature recorded by the test sensor conforming to item e) of **3.3.2.2.1** does not exceed 95 °C, open the autoclave and remove the load. If necessary, delay opening the autoclave until the above temperatures have been reached.

Note if the temperature of the test container was above 80 °C when the door securing mechanism was released.

3.3.3 Make-safe test B

3.3.3.1 ***Apparatus and materials***

3.3.3.1.1 *General.* Use the apparatus described in **3.3.2.1.1**, **3.3.2.1.3 and 3.3.2.1.4**, together with the following.

[6)] For information on availability, write to Customer Services, BSI, Linford Wood, Milton Keynes MK 14 6LE.

[7)] Known as $\frac{1}{1}$ oz glass bijou bottles.

3.3.3.1.2 *Discard-containers*, (see **1.3.21** of BS 2646-1:1993), designated, designed and/or supplied by the autoclave manufacturer.

3.3.3.1.3 *Challenge load*, comprising:

a) sufficient discard-containers (**3.3.3.1.2**) to fill the usable chamber space, each containing a number, as specified by the manufacturer, of clean, dry, uncapped bottles (**3.3.2.1.3**) randomly distributed;

b) the test container and closure (**3.3.2.1.4**).

3.3.3.2 ***Preparation for the test***

3.3.3.2.1 Position the temperature sensors, as follows:

a) one in the chamber drain (or vent), within 100 mm of its connection to the chamber;

b) one in the chamber free space;

c) one inside an inverted bottle (**3.3.2.1.3**), placed centrally at the lowest level in each discard-container (**3.3.3.1.2**) where one or two discard-containers are used. Where more discard-containers are used, select the two discard-containers known to be slowest to attain sterilizing temperature;

d) one in the test container (**3.3.2.1.4**), located in the vertical axis between 20 mm and 40 mm from the base of the discard-container, not in contact with any surface but suspended in the liquid;

e) one in the chamber within 10 mm of, but not touching, the chamber base.

Insert the sensor conforming to item d) into the bottle, either using a purpose-made or modified closure and entry gland, or introducing it between the threaded neck and plastics closure.

NOTE 1 In order to establish the positions for discard-containers in accordance with item c), it may be necessary to conduct preliminary tests.

NOTE 2 The sensor conforming to item e) is to measure the temperature of any liquid present in the chamber at the completion of the operating cycle.

Insert the thermocouple into the test container either using a purpose-made or modified closure and entry gland, or between the threaded neck and plastics cap.

Place the discard-containers containing the bottles (see item a) of **3.3.3.1.3**) in the autoclave chamber on load supports, in accordance with the manufacturer's instructions.

Place the test container (see item b) of **3.3.3.1.3**) on a load support at the lowest possible level in the chamber adjacent to or inside a discard-container.

If a load temperature probe is fitted, place it in its holder or on a load support.

NOTE 3 It will be necessary to cut a hole in the plastics cap to accept the probe as a tight fit.

3.3.3.2.2 Set the controller to produce a sterilizing temperature of between 130 °C and 126 °C for 10 min. If such a range is not provided, the nearest to that range shall be used.

3.3.3.2.3 Set the thermal door interlock as appropriate for a 500 ml capacity container of 400 ml water.

3.3.3.3 ***Test procedure***

Operate the autoclave in accordance with the manufacturer's instructions for make-safe.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the duration of the equilibration time;

3) the operating cycle time.

When the door securing mechanism releases at the end of the operating cycle, if the temperature recorded by the test sensor conforming to item d) of **3.3.3.2.1** does not exceed 80 °C, and the temperature recorded by the test sensor conforming to item e) of **3.3.3.2.1** does not exceed 95 °C, open the autoclave and remove the load. If necessary, delay opening the autoclave until the above temperatures have been reached.

Make a note if the temperature of the test container was above 80 °C when the door securing mechanism was released.

3.3.4 Make-safe test C

3.3.4.1 ***Apparatus and materials***

3.3.4.1.1 *General*. Use the test container and closure described in **3.3.2.1.4**, together with the following.

3.3.4.1.2 *Test recorder(s)*, in accordance with **1.4.3** with twelve input channels each connected to a thermocouple lead and sensor in accordance with **1.4.6**.

3.3.4.1.3 *Discard-containers*, (see **1.3.21** of BS 2646-1:1993), designated, designed and/or supplied by the autoclave manufacturer.

3.3.4.1.4 *Culture plates*, comprising plastics Petri dishes, type A, of 90 mm nominal size, vented or unvented (conforming to BS 611-2:1990), containing 19 ± 1 ml of agar gel. The agar gel concentration shall be 12 g to 13 g of agar per litre of water and shall be prepared by adding agar powder to tap water and heating to between 100 °C and 126 °C until the powder is melted. It shall then be cooled to below 80 °C before being added to the Petri dish.

3.3.4.1.5 *Challenge load*, comprising:

a) sufficient discard-containers (**3.3.4.1.3**) to fill the usable chamber space, each containing a number, as specified by the manufacturer, of culture plates (**3.3.4.1.4**) stacked in piles.

b) the test container and closure (**3.3.2.1.4**).

3.3.4.2 ***Preparation for the test***

3.3.4.2.1 Position the temperature sensors, as appropriate, as follows:

a) one in the chamber drain (or vent) within 100 mm of its connection to the chamber;

b) one in the chamber free space;

c) inside each discard-container, in culture plates, under the agar gel, as follows:

1) one in the geometric centre of the discard-container;

2) one in a culture plate located as the third from the bottom of a stack and;

3) one in a culture plate located as the third from the top of a stack;

4) one in the space between its base and its contents;

d) one in the test container (**3.3.2.1.4**), located in the vertical axis between 20 mm and 40 mm from the base of the container, not in contact with any surface but suspended in the liquid;

e) one in the chamber within 10 mm of, but not touching, the chamber base.

Insert the sensor conforming to item d) into the bottle, either using a purpose-made or modified closure and entry gland, or introducing it between the threaded neck and plastics cap.

Place the discard-container(s) (**3.3.4.1.3**), containing the culture plates, (**3.3.4.1.4**) in the autoclave chamber on load supports, in accordance with the manufacturer's instructions.

Place the test container with closure (**3.3.2.1.4**) on a load support at the lowest possible level in the chamber adjacent to or inside a discard-container.

If a load temperature probe is fitted, place it as recommended by the manufacturer for make-safe.

3.3.4.2.2 Set the controller to produce a sterilizing temperature of between 130 °C and 126 °C for 10 min. If such a range is not provided, the nearest to that range shall be used.

3.3.4.2.3 Set the thermal door interlock for a 500 ml capacity bottle containing 400 ml water.

3.3.4.3 ***Test procedure***

Operate the autoclave in accordance with the manufacturer's instructions for make-safe.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the duration of the equilibration time;

3) the operating cycle time.

When the door securing mechanism releases at the end of the operating cycle, if the temperature recorded by the test sensor conforming to item d) of **3.3.4.2.1** does not exceed 80 °C, and the temperature recorded by the test sensor conforming to item e) of **3.3.4.2.1** does not exceed 95 °C, open the autoclave and remove the load. If necessary, delay opening the autoclave until the above temperatures have been reached.

Note if the temperature of the test container was above 80 °C when the door securing mechanism was released.

3.4 Equipment and glassware sterilization: performance tests

3.4.1 General

Two tests (A and B) are described. Test A shall be performed except that, if the autoclave chamber size or configuration, or the standard challenge load is not appropriate, the alternative test B shall be performed, by agreement between the manufacturer and the purchaser (see **12.3** BS 2646-1:1993).

The tests measure the performance of the autoclave, when processing the challenge load, in respect of the following.

a) Ability to reach the selected temperature rapidly in the load.

b) Ability to maintain the selected temperature for the set time in the load.

c) Overall time taken to complete one operating cycle.

d) Ability to dry the load.

3.4.2 Equipment and glassware sterilization test A

3.4.2.1 ***Apparatus and materials***

3.4.2.1.1 *Test recorder(s)*, in accordance with **1.4.3**, with five input channels each connected to a thermocouple lead and sensor in accordance with **1.4.6**.

3.4.2.1.2 *Two boxes as described for discard-containers* (see **3.3.2.1.2**)

3.4.2.1.3 *Bottles* (see **3.3.2.1.3**).

3.4.2.1.4 *Challenge load,* comprising the boxes (**3.4.2.1.2**) filled with clean, dry, uncapped bottles (**3.4.2.1.3**), randomly distributed (such that at least 550 bottles are used).

3.4.2.2 ***Preparation for the test***

3.4.2.2.1 Position the temperature sensors, as follows:

a) one in the chamber drain (or vent), within 100 mm of its connection to the chamber;

b) one in the free chamber space;

c) one inside an inverted bottle (**3.4.2.1.3**), placed centrally at the lowest level in each box (**3.4.2.1.2**);

d) one in the chamber within 10 mm of, but not touching, the chamber base.

NOTE The sensor conforming to item d) is to measure the temperature of any liquid present in the chamber at the completion of the operating cycle.

Ensure that temperature sensors are suspended and are not in contact with any surface.

Place the two boxes, containing the bottles, (see **3.4.2.1.4**) in the autoclave chamber on load support(s), one in the upper half of the chamber and the other in the lower half of the chamber, each at the centre.

If a load temperature probe is fitted, place it in its holder or on a load support.

3.4.2.2.2 Set the controller to produce a sterilizing temperature of between 129 °C and 126 °C for 10 min. If such a range is not provided, the nearest to that range shall be used.

3.4.2.3 ***Test procedure***

Operate the autoclave in accordance with the manufacturer's instructions for equipment and glassware sterilization.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the operating cycle time.

Visually inspect the bottles and the internal surfaces of the boxes and note the extent of any condensate.

3.4.3 Equipment and glassware sterilization test B

3.4.3.1 ***Apparatus and materials***

3.4.3.1.1 *General*. Use the apparatus described in **3.4.2.1.1** and **3.4.2.1.3** together with the following.

3.4.3.1.2 *Load-containers*, designated, designed, and/or supplied by the autoclave manufacturer.

3.4.3.1.3 *Challenge load*, comprising sufficient load-containers (**3.4.3.1.2**) to fill the usable chamber space, each containing a number, as specified by the manufacturer, of clean, dry, uncapped bottles (**3.4.2.1.3**) randomly distributed.

3.4.3.2 ***Preparation for the test***

3.4.3.2.1 Position the temperature sensors, as follows:

a) one in the chamber drain (or vent), within 100 mm of its connection to the chamber;

b) one in the free chamber space;

c) one inside an inverted bottle (**3.4.2.1.3**), placed centrally at the lowest level in each load-container (**3.4.3.1.2**), where one or two load-containers are used. Where more load-containers are used, select the two known to be slowest to attain sterilizing temperature;

d) one in the chamber within 10 mm of, but not touching, the chamber base.

NOTE 1 In order to establish the positions of load-containers in accordance with item c), it may be necessary to conduct preliminary tests.
NOTE 2 The sensor conforming to item d) is to measure the temperature of any liquid present in the chamber at the completion of the operating cycle.

Ensure that sensors are suspended and are not in contact with any surface.

Place the load-containers, containing the bottles, (see **3.4.3.1.3**) in the autoclave chamber on load support(s), in accordance with the manufacturer's instructions.

If a load temperature probe is fitted, place it in its holder or on a load support.

3.4.3.2.2 Set the controller to produce a sterilizing temperature of between 129 °C and 126 °C for 10 min. If such a range is not provided, the nearest temperature to that range shall be used.

3.4.3.3 ***Test procedure***

Operate the autoclave in accordance with the manufacturer's instructions for equipment and glassware sterilization.

During each stage of the operating cycle:

a) monitor the temperatures recorded by the test recorder;

b) monitor and record the autoclave instrument readings;

c) measure, independently of the autoclave controller, and record:

1) the duration of the holding time;

2) the operating cycle time.

Visually inspect the bottles and the internal surfaces of the load-containers and note the extent of any condensate.

List of references (see 1.2)

Normative references

BSI standards publications

BRITISH STANDARDS INSTITUTION, London

BS 611, *Petri dishes.*
BS 611-2:1990, *Specification for plastics Petri dishes for single use.*
BS 1780:1985, *Specification for bourdon tube pressure and vacuum gauges.*
BS 2646, *Autoclaves for sterilization in laboratories.*
BS 2646-1:1993, *Specification for design, construction, safety and performance.*
BS 4937, *International thermocouple reference tables.*
BS 4937-4:1973, *Nickel-chromium/nickel-aluminium thermocouples. Type K.*
BS 4937-5:1974, *Copper/copper-nickel thermocouples. Type T.*
BS 5235:1975, *Specification for dial-type expansion thermometers.*
BS 5928:1980, *Specification for bottles for laboratory use.*
BS 6253, *Electrical measuring transducers for converting a.c. electrical quantities into d.c. electrical quantities.*
BS 6253-1:1982, *Method for specifying general purpose transducers.*

Other references

[2] DIN 168, *Round screw threads, especially for glass containers.*
DIN 168-1:1979, *Screw thread sizes.*

Informative references

BSI standards publications

BRITISH STANDARDS INSTITUTION, London

BS 2646, *Autoclaves for sterilization in laboratories.*
BS 2646-2:1990, *Guide to planning and installation.*
BS 2646-3, *Guide to safe use and operation*[8)].
BS 2646-4:1991, *Guide to maintenance.*
BS 3970, *Sterilizing and disinfecting equipment for medical products.*
BS 3970-1:1990, *Specification for general requirements.*
BS 3970-2:1991, *Specification for steam sterilizers for aqueous fluids in sealed rigid containers.*
BS 3970-3:1990, *Specification for steam sterilizers for wrapped goods and porous loads.*
BS 3970-4:1990, *Specification for transportable steam sterilizers for unwrapped instruments and utensils.*
BS 3970-5:1990, *Specification for low temperature steam disinfectors.*
BS 3970-6:1990, *Specification for sterilizers using low temperature steam with formaldehyde*[8)].

Other references

[1] *Categorization of pathogens according to hazard and categories of containment*, 2nd edition. HMSO, 1990.

[8)] In preparation.

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