BS 3970-4:1990

Sterilizing and disinfecting equipment for medical products —

Part 4: Specification for transportable steam sterilizers for unwrapped instruments and utensils

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/14, upon which the following bodies were represented:

Associated Offices Technical Committee
Association of British Health-Care Industries
Association of British Sterilizer Manufacturers
Association of Clinical Pathologists
Association of National Health Service Supplies Officers
British Dental Trade Association
British Surgical Trades Association
Central Sterilising Club
Department of Health
Guild of Hospital Pharmacists
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 Engineer's Association
Royal College of Pathologists
Royal Pharmaceutical Society of Great Britain
Scottish Home and Health Department
Stainless Steel Fabricators' Association of Great Britain

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Contents

Foreword

It is recommended that this foreword be read in conjunction with the foreword to BS 3970-1.

This Part of BS 3970 has been prepared under the direction of the Health Care Standards Policy Committee. It forms part of BS 3970, which specifies the requirements for a range of sterilizing and disinfecting equipment intended for medical and related uses.

The general requirements applicable to all the sterilizers and disinfectors covered by this standard are given in Part 1. Those requirements that are not common to most types of sterilizer or disinfector are specified in subsequent Parts of BS 3970. These Parts giving particular requirements should be read in conjunction with BS 3970-1 which they supplement or modify. The titles of these Parts are expected to be as follows:

— *Part 3: Specification for steam sterilizers for wrapped goods and porous loads;*

— *Part 5*[1)]*: Specification for low-temperature steam disinfectors;*

— *Part A*[1)]*: Specification for steam sterilizers for fluids in sealed rigid containers;*

— *Part B*[1)]*: Specification for steam sterilizers for fluids in unsealed vented containers;*

— *Part C*[1)]*: Specification for steam sterilizers for fluids in sealed non-rigid containers;*

— *Part D*[1)]*: Specification for steam sterilizers using low-temperature steam with formaldehyde;*

— *Part E*[1)]*: Specification for steam sterilizers using ethylene oxide or ethylene oxide mixtures.*

This Part of BS 3970 specifies safety and performance requirements for portable, electrically-heated steam sterilizers intended for the sterilization of unwrapped instruments and utensils which are used for medical purposes, e.g. general medical and veterinary practices, dentistry and acupuncture, or used in circumstances where they are likely to come into contact with human blood, e.g. implements used by beauty therapists, tattooists and hairdressers. As these machines are designed to require no plumbing or permanent connection to an electrical supply and as their maximum mass has been specified, they can be considered transportable. Carrying handles, although not specified, are not precluded.

Steam is raised within the vessel by electrical heaters and, in general, the water used should be distilled water or deionized water.

NOTE The use of mains supply water may cause scaling and subsequent impairment of the performance of the sterilizer.

Gas-heated equipment is not covered by this Part of BS 3970.

Air removal prior to attainment of sterilizing conditions is achieved only by displacement with steam. The absence of a forced air removal stage and a post-sterilization vacuum drying stage precludes the use of such machines for wrapped instruments or porous goods, e.g. dressings and fabrics.

Guidance on the operation, monitoring and maintenance of steam sterilizers is given in Health Technical Memorandum (HTM) 10 “Sterilizers”, published by the Department of Health and Social Security.

This Part of BS 3970 specifies sterilizers that provide a single operating cycle pre-selected from the options given in Table 1 (see clause **12**). The operating cycle proceeds automatically after energizing the heaters until completion of the sterilizing stage. Some sterilizers may also be equipped to provide other optional operating cycles but the selection of the cycle will not be available to the operator.

[1)] In preparation; each Part will be allocated a number in its respective order of publication.

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

Enquiries as to the availability of third party certification schemes will be 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.

Alternatively, users of this British Standard may wish to consider the desirability of assessment and registration of a supplier's quality systems against the appropriate Part of BS 5750 by a third party certification body.

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 to iv, pages 1 to 8, 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.

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1 Scope

This Part of BS 3970 specifies particular requirements for transportable, unjacketed electrically-heated steam sterilizers, fitted with a single manually-operated door, and designed for the sterilization of unwrapped instruments and utensils for use in clinics, in medical and dental surgeries and in non-medical applications. These requirements apply in addition to the general requirements specified in BS 3970-1.

The sterilizer, which has a mass not exceeding 75 kg, is specified to withstand a design pressure not exceeding 2.65 bar[2)] and to operate fully automatically for one pre-determined cycle selected from within the temperature range 115 °C to 138 °C (see Table 1).

NOTE 1 Sterilizers complying with this specification may not be suitable for operation in zones of risk associated with the use of flammable materials.

NOTE 2 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 3970, the definitions given in BS 3970-1 apply, together with the following:

2.1
door

a lid or similar device provided as a means of closing and sealing the chamber

2.2
transportable

requiring no permanent connections or installation, and capable of being moved manually from one site to another without lifting tackle

2.3
water charge

the volume of the water which is admitted to the vessel and from which the steam for the operating cycle is generated

3 General requirements

3.1 Transportable steam sterilizers for unwrapped instruments and utensils shall comply with the requirements of BS 3970-1, with the exception of **4.1, 5.4, 6.1.7, 6.2, 6.4, 7.2.1, 7.2.3, 7.2.4, 11.2.1, 11.3.2, 11.6.1, 11.6.2**, clause **12, 13.1.3, 13.1.5. 13.1.6, 13.2.1, 13.2.2, 13.2.4, 13.2.5, 13.3, 14.1** c), clause **15**, clause **16**, **17.1** and **17.2** c) of that standard. Clauses **4** to **17** shall replace or supplement the requirements specified in BS 3970-1.

NOTE Users of this Part of BS 3970 are advised that reference should be made to the Electrical Supply Code for Hospital Laboratory Equipment (ESCHLE) as certain of its requirements are specified in BS 3970-1.

3.2 Unless otherwise stated in this British Standard, compliance with this Part of BS 3970 shall be checked by visual inspection and, where practicable, by direct measurement.

4 Chamber size

NOTE This clause replaces **4.1** of BS 3970-1.

The combined volume of the chamber, including any ancillary vessel which is in direct connection with the chamber and which is used to generate the steam for the sterilizing process together with any inter-connecting pipework, shall not exceed 50 L and shall not exceed 170 % of the usable chamber space.

5 Vessel and its components

NOTE This clause replaces **5.4** of BS 3970-1.

5.1 The vessel shall not be fitted with a jacket.

NOTE The vessel may be fitted with a vented case (see **8.5**) to protect the operator from direct contact with the vessel.

5.2 For the purposes of testing the sterilizer, the vessel shall be fitted with at least one thermocouple entry connection, terminating in a female thread complying with G ¼ A of BS 2779, closed with a sealing plug.

5.3 With each sterilizer vessel, the manufacturer shall issue a certificate of compliance as specified in **5.7** of BS 3970-1.

If a pressure vessel, which had originally been constructed in accordance with BS 1746, has been modified for use as a sterilizer chamber, the sterilizer manufacturer shall, in addition, supply a certificate from the original pressure vessel manufacturer claiming the chamber's compliance with BS 1746.

Each sterilizer shall also be supplied with a performance certificate (see clause **15**).

6 Door and controls

NOTE This clause replaces **6.1.7, 6.2** and **6.4** of BS 3970-1.

6.1 The chamber shall be provided with only one door.

6.2 The door shall be manually operated. Power-operated doors shall not be fitted to sterilizers complying with this Part of BS 3970.

6.3 When a "fault" is indicated, the door shall remain locked until a defined manual operation, different from the manual operation required at the end of a satisfactory cycle, is carried out.

[2)] 1 bar = 10^5 N/m^2 = 10^5 Pa.

7 Over-pressure protection devices

NOTE This clause replaces **7.2.1, 7.2.3** and **7.2.4** of BS 3970-1.

7.1 Each vessel shall be fitted with an over-pressure protection device complying with BS 6759-1, except that, if the source of pressure or heat is external to the vessel and is such that the maximum permissible working pressure cannot be exceeded, a protection device need not be fitted.

NOTE If two or more vessels are connected together without any intervening valve, a single over-pressure protection device may be fitted.

7.2 The over-pressure protection device shall be mounted in an upright vertical position unless the sterilizer manufacturer can demonstrate that a different orientation of the device would not impair its correct functioning. Records of any tests carried out by the sterilizer manufacturer to demonstrate this shall be available to the purchaser on request (see item f) of **17.1**).

NOTE The over-pressure protection device should be directly connected to the vessel by the shortest practicable length of pipe.

7.3 The over-pressure protection device shall be fitted to the vessel so that either:

a) the discharge from the device is enclosed; or

b) the device discharges into an outer case surrounding the sterilizer (see **8.5**).

If item a) applies, each discharge shall be individually piped to the atmosphere and should terminate in a position that does not cause a safety hazard. If the discharge from the protection device is not visible from the sterilizer, the discharge pipe shall be provided with a small-bore pipe terminating at the sterilizer to give a visible indication of the discharge.

NOTE If item b) applies, see the requirements of **11.4**.

8 Construction

8.1 The overall dimensions of the sterilizer shall not exceed a height of 500 mm, a breadth of 800 mm and a depth of 650 mm.

8.2 The maximum mass of the sterilizer, excluding the load but otherwise complete and ready to operate with the chamber, any ancillary vessel and any water reservoir filled with water to the level recommended by the manufacturer, shall not exceed 75 kg.

8.3 When operated in accordance with the manufacturer's instructions, the water charge shall not come into direct contact with the load.

8.4 A sterilizer that is manually charged with water shall be equipped with means by which the operator can verify that the water in the chamber is at the correct level.

NOTE For example, the water charge may be checked by means of a water level mark in the chamber or a sight glass.

8.5 Any casing shall be vented to prevent it becoming pressurized. Vents shall be placed on at least two different surfaces of the casing.

9 Water reservoir

If a water reservoir is fitted to provide the charge of water to the vessel, the following shall apply.

a) The reservoir and associated pipework shall be fitted with a valve or other device to allow the reservoir to be drained.

b) The reservoir shall be capable of containing sufficient water to enable at least 12 consecutive operating cycles to be performed with no load in the chamber.

c) Means shall be provided to indicate that the water charge is at the correct level required for an operating cycle.

NOTE For example, the water charge may be checked by means of a water level mark in the reservoir or a sight glass.

d) If, during the cooling stage, the air vent and/or the chamber drain discharge into the water reservoir, the temperature of the water in the reservoir after 12 consecutive operating cycles with an empty chamber shall not exceed 98 °C.

Compliance is checked as follows. Carry out 12 consecutive operating cycles with the chamber empty except for any fixed furniture. Ensure that not more than 2 min elapses between completion of one cycle and starting the next. Carry out the test at an ambient air temperature of between 20 °C and 25 °C. Check the temperature of the water in the reservoir immediately after the twelfth cycle.

e) The reservoir shall be vented and the closure device shall be removable to facilitate cleaning, inspection and filling of the reservoir.

f) Any pipe connecting the reservoir to the vessel shall be so constructed that it shall prevent the discharge of boiling water or any steam jet above the plane of the top surface of the reservoir.

Compliance is checked as follows. With the reservoir containing the minimum volume of water for one complete operating cycle (see item a) of **17.1**) and with the reservoir closure device removed, operate the sterilizer. When the vessel is at the operating pressure, open the filling valve and check that there is no visible discharge about the plane of the top surface of the reservoir.

10 Steam control

NOTE This clause replaces clause **12** of BS 3970-1.

Means shall be provided to enable the steam in the chamber to be maintained at the stated operating pressure to ± 50 mbar (see Table 1).

11 Electrical requirements

NOTE This clause applies in addition to clause **11** of BS 3970-1. Subclauses **11.2.1, 11.3.2, 11.6.1** and **11.6.2** of BS 3970-1 do not apply.

11.1 The machine shall be operable from a 13 amp, single-phase 50 Hz supply at 220 V to 240 V.

11.2 The machine shall be equipped with a mains connection lead of length not less than 1.4 m and not more than 1.5 m. This lead shall be supplied with a 13 amp plug complying with BS 1363/A fitted with the appropriate replaceable cartridge fuse complying with BS 1362.

11.3 The electrical supply shall be connected to the sterilizer by means of a double pole on/off switch complying with BS 816 which shall be fitted to the front panel.

11.4 If the discharge from the safety valve or any other over-pressure protection device is within the same casing as the electrical connections and/or the automatic controller, they shall be encapsulated, shrouded or otherwise treated to prevent the ingress of moisture.

Compliance is checked as follows. Operate the machine with a continuous discharge from the over-pressure protection device for a period of not less than 5 min and check the functioning of the electrical components during this period and for the subsequent 10 min.

11.5 If the sterilizer has one or more outlets providing an electrical supply to other equipment or parts, the voltage of the outlets shall not exceed 30 V and the rated output of each outlet socket shall be marked.

If the sterilizer is fitted with a recording thermometer (see **13.5**), it shall not be connected via a switch or similar disconnecting device.

11.6 The water charge shall be heated by either surface mounted or immersion heating elements.

NOTE Whichever heating element is used, it should be easily replaceable.

Each immersion heating element shall be covered to the depth stated by the sterilizer manufacturer when the minimum water charge is admitted to the vessel (see item i) of **17.1**) and when so covered shall be capable of operation up to the design pressure of the chamber.

Each surface mounted heating element shall be arranged to maintain permanent thermal contact with the surface to which it is attached.

Compliance is checked as follows. Operate the machine for a complete operating cycle and then, by the use of a feeler gauge, check that the heater has not separated from the surface by more than 100 μm.

12 Operating cycle

12.1 The sterilizer shall be supplied with only one of the options listed in Table 1 available to the operator (see foreword).

If controls within the sterilizer can be adjusted to permit an alternative option for the operating cycle, access to these controls shall be available only after removal of the facia or side panel. It shall only be possible to make such adjustments by means of a special tool which is not to be available to the operator (see item f) of clause **16**).

12.2 After adding to the chamber or the steam generator at least the stated minimum volume of water for one complete operating cycle (see item a) of **17.1**), the automatic controller of the sterilizer shall be capable of carrying out the following sequence of operations.

Stage 1. Heating the water and generating steam in order to vent the air from the chamber until the sterilizing temperature is attained (see Table 1).

Stage 2. Maintaining the sterilizing temperature within the limits specified in Table 1 for not less than the minimum hold time.

Stage 3. After completion of stage 2, exhausting the steam from the chamber and/or condensing it within the chamber (see note 1).

NOTE 1 Initiation of this stage of the operating cycle may be achieved by manual operation.

NOTE 2 The addition of water may be part of the controlled sequence, or may be achieved by manually filling to a marked level from a separate container (see also clause **9** above).

12.3 At the completion of a satisfactory cycle, "CYCLE COMPLETE" shall not be indicated until the temperatures in the air vent or the coolest part of the chamber and of any liquid remaining in the vessel are below the boiling point of the liquid in the vessel, in respect of the local atmospheric pressure.

12.4 The total cycle time for one successful cycle shall not exceed the maximum cycle time given in Table 1.

Compliance is checked as follows. Carry out a test on a pre-heated sterilizer, i.e. immediately after at least one cycle with the chamber empty except for the chamber furniture specified in **14.1**. Measure the cycle time from the time the heaters are energized to the time that "CYCLE COMPLETE" is first indicated.

Table 1 — Operating cycle conditions (see 12.1)

Option	Sterilizing temperature			Approximate operating pressure	Minimum hold time	Maximum overall cycle time with chamber empty
	Nominal	Range				
		Minimum	Maximum			
	°C	°C	°C	bar	min	min
A	136	134	138	2.25	3	20
B	127.5	126	129	1.5	10	30
C	122.5	121	124	1.15	15	40
D	116.5	115	118	0.75	30	50

13 Instrumentation and controls

NOTE This clause replaces **13.1.3, 13.1.5, 13.1.6, 13.2.1, 13.2.2, 13.2.4, 13.2.5** and **13.3** of BS 3970-1.

13.1 A bourdon tube pressure gauge shall indicate the pressure within the sterilizer chamber and shall comply with BS 1780. The gauge shall have a scale range of 0 bar to at least 2.5 bar, unless the sterilizer is to operate under option A of Table 1, when the scale range shall be 0 bar to at least 4.0 bar.

13.2 A bimetallic-type indicating thermometer shall not be fitted.

13.3 A thermometer shall indicate the temperature within the chamber and shall have a scale range from at least 100 °C to 140 °C. The instrument error over this scale range shall not exceed ± 1.5 °C. The thermometric sensing element shall be sited either:

a) within (at) the coolest part of the chamber; or

b) within the active air vent from the chamber.

If item a) applies, the manufacturer shall state [see **17.1** j)] the location of the coolest part of the chamber.

The sensing element shall not be used for any control function.

13.4 The scale length of analogue instruments shall be not less than 40 mm.

13.5 If a temperature recorder is provided, it shall comply with **13.3.2, 13.3.3** and **13.3.4** or BS 3970-1 and with **13.3** of this standard.

NOTE The sensor for the temperature recorder may also be that used for temperature indication (see **13.3**).

If a temperature recorder is provided, its sensing element shall not be used for any control function.

13.6 Digital display instruments shall register in increments of 0.5 °C or less and shall comply with measuring class index 1 of BS 5164 over a temperature scale range of 10 °C to 160 °C.

If a sensor is broken, the instrument shall indicate an error message.

13.7 The timing of the sterilization stage shall be independent of other timing devices and shall not be initiated by the action of a pressure sensor.

The timing of the sterilization stage shall be initiated by the attainment of the sterilizing temperature in the chamber and shall be dependent on the maintenance of this temperature for the remainder of the timing stage. The temperature shall be continuously monitored from a sensor located in the coolest part of the chamber or the active air vent from the chamber. If the sensor is located in the coolest part of the chamber, the manufacturer shall identify to the purchaser the location of the coolest part of the chamber (see clause **17**).

Except for micro-processor controlled sterilizers, the temperature sensor shall be independent from other sensors used for monitoring, control or indicating functions. Failure of this sensor shall cause a fault to be indicated. However, if the temperature sensor is also to be used to control the heating device(s) of a sterilizer controlled by means of a micro-processor, the measuring systems for the indication and control of temperature shall be fully independent of each other. In addition, a system shall be provided to continuously compare the temperatures indicated by those two systems and if, during the sterilizing stage, a difference greater than 0.5 °C is detected between the two, a fault shall be indicated. The software for the comparing system shall have been developed under a quality assessment system in accordance with BS 5750-1.

13.8 An over-temperature protection device shall prevent the temperature of the heating element(s) exceeding 250 °C and shall prevent the design temperature of the chamber being exceeded. The device shall operate by isolating the power supply to the heating element(s).

The over-temperature protection device shall be independent of the automatic controller. The primary over-temperature protection device shall not be a fusible link and a manual operation shall be required to reset the device.

14 Load supporting and handling equipment

NOTE This clause replaces clause **16** of BS 3970-1.

14.1 Load containers

Not less than two instrument load containers, which may be in the form of trays or cradles, shall be provided (see note 1).

Sterilizers that are fitted with a vertical door, i.e. a horizontal chamber, shall be provided with load trays. The base of each tray and, if fitted, each lid shall be perforated (see **14.2**). Each tray shall be self-supporting when withdrawn to one-half its length from the chamber.

Sterilizers that are fitted with a horizontal door, i.e. a vertical chamber, shall be provided with load cradles. The vertical surfaces (see note 2) of each cradle shall be perforated (see **14.2**).

Each instrument load container shall be fully removable, self-draining and provided with means to keep its under-surface not less than 5 mm from a plane horizontal supporting surface.

NOTE 1 At least two containers are specified so that one may be in use in the sterilizer whilst the second is being loaded prior to a subsequent sterilizing cycle.

NOTE 2 The vertical surfaces are those surfaces which are in the vertical plane when the cradle is loaded into the sterilizer.

14.2 Load container perforations

The area of the perforations on each instrument load container shall be not less than 10 % of surfaces to be perforated. The perforations shall be uniformly distributed and each shall have an area of not less than 20 mm^2.

14.3 Lifting device

A separate lifting device shall be provided capable of removing the instrument load containers when carrying the maximum load stated by the manufacturer (see clause **17**).

NOTE The containers and the perforations should be so designed that, when placed in the sterilizer, they do not prevent the drainage of the condensate from, and the penetration of steam into, the container.

14.4 Container supports

The load container supports within the chamber shall be removable.

15 Performance

When tested as described in Appendix B, the sterilizer shall comply with the following.

a) During the whole of stage 2 of the operating cycle (see clause **12**), the temperature measured by the sensor attached to the load shall not differ by more than 2 °C from the temperature measured by the sensor in the active chamber discharge. Both the temperatures measured shall be within the temperature range for the cycle pre-selected from those shown in Table 1.

b) The temperature indicated by the indicating thermometer (see **13.3**) during stage 2 shall be within the specified range for the pre-selected option (see Table 1).

c) The duration of stage 2 of the operating cycle shall exceed the minimum time specified in Table 1 for the pre-selected option.

d) The temperature of any liquid remaining in the chamber at completion of the cycle and when the door can be opened shall be less than the boiling point of the liquid, at the local atmospheric pressure.

NOTE The records obtained as a result of the tests described in Appendix B, are required for use with the performance certificate (see **17.2**).

16 Marking

NOTE This clause applies in addition to clause **18** of BS 3970-1.

In addition to the requirements of clause **18** of BS 3970-1, the sterilizer shall be permanently and legibly marked with the following information. The marking shall be clearly visible from the operating position.

a) The statement “DO NOT PROCESS WRAPPED GOODS OR FLUIDS IN THIS STERILIZER”.

b) The manufacturer’s instructions for safe operation of the sterilizer including any restrictions, e.g. “Not to be used in zones of risk associated with flammable anaesthetics”.

c) If appropriate, the statement “DO NOT USE TAP WATER”.

d) The manufacturer’s name, postal address and the telephone number to be used when seeking advice on operation, servicing or repair of the sterilizer.

e) The nominal operating cycle conditions, unless two or more of the options specified in Table 1 can be pre-selected (see **12.1**), when the marking shall include all of the available operating cycle conditions. In these latter circumstances, the manufacturer shall provide a system by which the pre-set option will be indicated.

17 Information to be supplied by the manufacturer

NOTE This clause replaces **17.1** and item c) of **17.2** of BS 3970-1.

17.1 The manufacturer shall supply, with the sterilizer, the following information.

a) Whether the sterilizer may be operated with tap water or whether distilled (or deionized water) is to be used (see foreword and item c) of clause **16**), and the minimum volume of water required for one complete operating cycle (see item f) of clause **9**, **12.2** and **B.3.1**).

b) If appropriate, the pre-set sterilizing temperatures (see Table 1) and the corresponding maximum cycle times.

c) The volume of the chamber or the dimensions of the chamber (see clause **4**).

d) Whether the vessel complies with **5.1.1** or **5.1.2** of BS 3970-1.

e) The certificate of compliance (see **5.3**).

f) The attitude of the safety valve if not mounted vertically and, at the request of the purchaser, records of any tests carried out by the manufacturer to demonstrate the correct functioning of the over-pressure protection device (see **7.2**).

g) The point of discharge of the over-pressure protection device (see **7.3**).

h) The appropriate replacement cartridge fuse (see **11.2**).

i) Whether the water charge is heated by surface mounted or immersion heating elements and, with the minimum water charge, the depth of water covering the elements (see **11.6**).

j) If appropriate, the coolest part of the chamber (see item a) of **13.3** and **13.7**).

k) The maximum mass of the load for each instrument load container (see **14.3**).

l) The mass of the maximum load (see **B.2.3**).

m) The name of the Inspecting Authority referred to in **5.6.1** of BS 3970-1.

n) The facsimile of the marking on the vessel (see clause **16**).

17.2 In addition the manufacturer shall supply, with the sterilizer, a performance certificate which shall include the following information.

a) The sterilization conditions (see Table 1) which the sterilizer is intended to achieve, for example 134 °C to 138 °C for 3 min.

b) The total cycle time (see **12.4**).

c) The maximum load which the sterilizer is designed to accommodate, including the mass of any removable chamber furniture (see clause **14**).

d) The maximum design temperature.

e) The temperature at which the over-temperature protection device isolates the power supply to the heater (see **13.8**).

f) The pressure at which the over-pressure protection devices operate (see clause **7**).

g) The maximum temperature to which the load may be subjected following a single fault condition.

Each performance certificate shall be accompanied by an individual temperature record (or a copy), obtained during the manufacturer's tests on the particular sterilizer (see Appendix B).

The record shall include the test, the serial number of the sterilizer and the name of the operator.

Appendix A Information to be supplied by the purchaser

The purchaser should provide the manufacturer with the following information.

a) The maximum size and mass of the load that is to be processed in any one operating cycle.

b) The expected number of loads to be processed during a stated period of maximum use.

c) The nominal sterilizing temperature chosen from the four options listed in Table 1. If the purchaser fails to advise the manufacturer of the nominal sterilizing temperature required, it should be assumed that a sterilizer capable of providing option A is to be supplied.

Appendix B Performance tests

B.1 Principle

The performance of the sterilizer is assessed by carrying out an operating cycle at the pre-set sterilizing temperature both with a load and with the chamber empty except for the normal chamber furniture (see clause **14**).

B.2 Apparatus

B.2.1 *Temperature recorder*, capable of receiving inputs from a minimum of three sensors, and with the following characteristics:

a) a scale range of at least 0 °C to 150 °C;

b) a limit of error between 0 °C and 150 °C (excluding that of the temperature sensors) not exceeding ± 0.25 °C when tested at an ambient temperature of 20 ± 3 °C;

c) an accuracy of T ± 0.25 °C, where T is the nominal sterilizing temperature specified in Table 1 for the option selected.

B.2.2 *Temperature sensors*, three.

B.2.3 *Test load*, comprising a number of stainless steel rods, with diameters not less than 8 mm and not greater than 16 mm, and with a mass equal to the maximum load recommended by the manufacturer (see item l) of **17.1**).

B.3 Full load test

B.3.1 Add to the chamber or the steam generator sufficient water for at least one complete operating cycle.

NOTE The minimum amount of water required for a complete operating cycle will be given in the manufacturer's instructions (see item a) of **17.1**).

B.3.2 Place the test load (**B.2.3**) in the chamber and locate the three sensors (**B.2.2**) as follows:

a) one sensor either in the active chamber discharge or, if there is no active chamber discharge, in the coolest part of the chamber space;

b) one sensor in contact with the load;

c) one sensor in the water charge within the chamber.

Connect the sensors to the temperature recorder (**B.2.1**).

B.3.3 Carry out a complete operating cycle. Examine and retain the temperature records. Check that the requirements specified in clause **15** have been attained.

B.4 Test with an empty chamber

B.4.1 Add to the chamber or the steam generator sufficient water for at least one complete operating cycle.

B.4.2 With the chamber containing only the furniture specified in clause **14**, locate the three sensors (**B.2.2**) as described in **B.3.2**, except for placing sensor b) in contact with a tray or container. Connect the sensors to the temperature recorder (**B.2.1**).

B.4.3 Carry out a complete operating cycle. Examine and retain the temperature records. Check that the requirements specified in clause **15** have been attained.

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Publications referred to

BS 816, *Specification. Requirements for electrical accessories.*

BS 1362, *Specification for general purpose fuse links for domestic and similar purposes (primarily for use in plugs).*

BS 1363, *Specification for 13A plugs, switched and unswitched socket-outlets and boxes.*

BS 1746, *Specification for domestic pressure cookers.*

BS 1780, *Specification for bourdon tube pressure and vacuum gauges.*

BS 2779, *Specification for pipe threads for tubes and fittings where pressure-tight joints are not made on the threads (metric dimensions).*

BS 3970, *Sterilizing and disinfecting equipment for medical products.*

BS 3970-1, *Specification for general requirements.*

BS 5164, *Specification for indirect-acting electrical indicating and recording instruments and their accessories.*

BS 5235, *Specification for dial-type expansion thermometers.*

BS 5750, *Quality systems.*

BS 5750-1, *Specification for design/development, production, installation and servicing.*

BS 6759, *Safety valves.*

BS 6759-1, *Specification for safety valves for steam and hot water.*

The Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE), Health Equipment Information (HEI) No. 158, DHSS, SHHD, Welsh Office and DHSS (Northern Ireland), August 1986[3)].

Health Technical Memorandum (HTM) No. 10 "Sterilizers", DHSS, 1981[4)].

[3)] Available from DHSS (Leaflets) PO Box 21, Stanmore, Middlesex, HA5 1AY.

[4)] Available from HMSO, 49 High Holborn London WC1 for personal callers, or by post from HMSO, PO Box 276, London SW5 5DT.

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