

Washer-disinfectors for medical purposes —

Part 1: Specification for general requirements

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 a subcommittee:

- BLWA Ltd. (The Association of the Laboratory Supply Industry)
- Healthcare Sanitary Systems Association
- Hospital Infection Society
- National Health Service Regional Engineers' Association
- Water Research Centre

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Foreword

This Part of BS 2745 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. Together with BS 2745-2 and BS 2745-3 it supersedes BS 2745:1966 which is withdrawn.

The first edition of BS 2745, which was published in 1956, with a second edition in 1966, applied to bed pan and urine bottle washers operating on a choice of any one of three specified washing sequences. However, in this revision, the structure of BS 2745 has been changed so that the general requirements applicable to all washer-disinfectors are now given in this Part. The requirements of this Part of BS 2745 apply to all washer-disinfectors specified in subsequent Parts of BS 2745, except insofar as they may be modified or added to by a subsequent Part, in which case the requirements of the particular Part will apply. Those requirements that are not common to most types of washer-disinfectors are given in subsequent Parts of the standard, which have the following titles.

— *Part 2: Specification for human-waste container washer-disinfectors;*

— *Part 3: Specification for washer-disinfectors except those used for processing human-waste containers and laundry.*

It is essential that the equipment is used only for washing and disinfecting the type of goods for which it is designed. In selecting the appropriate washer disinfectant, reference should be made to these Parts. The choice of type of washer-disinfectant, operating cycle or quality of the services provided may be inappropriate for a particular load and means cannot necessarily be provided to detect an incorrect choice or a misuse.

Other British Standards related to disinfecting equipment include the following.

BS 2646, *Autoclaves for sterilization in laboratories.*

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

The United Kingdom statutory requirements given in Section 6 of the Health and Safety at Work etc. Act 1974 [1] are applicable to washer-disinfectors and the practice of disinfection. That section describes the general duties of manufacturers, etc., regarding articles and substances for use at work and covers the design, manufacture, import and supply of any articles for use at work. However, in the case of washer-disinfectors that are classed as steam boilers or steam receivers, there are additional legal requirements which are set out in Sections 32 to 35 of the Factories Act 1961 [2].

On 1 July 1994, Sections 32 to 35 of the Factories Act 1961 [2] will be repealed, and replaced by the Pressure Systems and Transportable Gas Container Regulations 1989 [3]. These Regulations, together with their associated Approved Code of Practice and Guidance Note and the requirements of the Health and Safety at Work etc. Act 1974 [1], will provide a regime, the aim of which is to ensure the safety of pressure systems. In particular, regulation 4 of these Regulations sets out requirements for the design, construction, repair and modification of any pressure system. In the context of this standard, these Regulations apply to steam pressure systems at any pressure, and for hot-water systems operating at greater than 0.5 bar above atmospheric pressure.

In addition, Health Technical Memorandum (HTM) 10 *Sterilizers* [4], published by the Department of Health and Social Security, contains further information on installation and maintenance as well as on the subsequent use of sterilizers.

This standard specifies washer-disinfectors in which the load remains within the machine until the cycle is completed. All such machines within the scope of this standard are required to include a heat disinfection stage during the cleansing cycle. This heat disinfection stage raises all parts of the maximum permitted load to a specified temperature and maintains that temperature for a specified period of time. Thermal disinfection is achieved by use of hot water or steam in direct contact with all potentially contaminated surfaces after the complete removal of soil.

If the specified temperature is not reached or is not held for the required time, this has to be clearly indicated and it has to be ensured that it will not be possible to remove the contents without appreciating that such a failure has occurred, even when the operator is unfamiliar with the machine. The specified disinfection temperature and holding time should have a lethality sufficient to reduce the number of viable micro-organisms in a load but which may not necessarily inactivate some viruses and bacterial spores (see **3.11**, **3.12** and **3.13**).

In addition, the machine's washing sequence should remove all visible evidence of any soiling likely to have occurred during the normal use of each item of a load or any soil deposited on the chamber walls during the process, provided that the total load does not exceed the specified maximum. This specification should ensure that a machine is safe to operate and conforms to any relevant existing standards, taking account of all legal requirements given in the Acts and documents detailed in this foreword. This standard avoids unnecessary restrictions on size, shape and materials to be used.

BS 2745 has been prepared on the basis that every individual washer-disinfector will be subjected to functional performance tests. Unless otherwise stated in this standard, conformity to the performance requirements is checked by visual inspection or direct measurement.

Reference is also made to the *Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE)* [5]¹⁾, to some provisions of which washer-disinfectors are required to conform. While references to *ESCHLE* are being retained, it is recognized that, in due course, reference will need to be made instead to the appropriate Part(s) of IEC 1010 or, if implemented by CENELEC, of BS EN 61010. It is envisaged that a Part of IEC 1010 will be prepared specifying particular requirements for washer-disinfectors, which amend or supplement the requirements of IEC 1010-1.

The test methods and requirements of this British Standard are equally applicable for assessing the functional performance of the washer-disinfector throughout its life.

This standard is not applicable to equipment used to process goods contaminated with dangerous pathogens in Hazard Group 4, as given in the Report of the DHSS Advisory Committee on Dangerous Pathogens²⁾, because additional precautions are then needed in the design of the drainage and ventilation systems to protect both users and the environment.

Attainment of disinfection conditions should be assured by validation procedures. Disinfection using hot water or steam can be validated by measuring certain specified physical conditions because sufficient data exists to substantiate this approach.

Attention is drawn to the need for washer-disinfector installations and machines to conform to the local water byelaws (see Annex A). Without adequate protective measures against backflow, the direct connection of equipment of this type to a mains water supply would pose very serious risks to the water supplies as well as to other connected services within the building in which the washer disinfector is installed. As a consequence, this Part of BS 2745 specifies the incorporation of a type "A" air gap in each disinfector; this is in accordance with the "Water Undertakers" Byelaws 1989 [8].

¹⁾ *ESCHLE* is published as Health Equipment Information (HEI) No. 158 by the United Kingdom Department of Health [5], and is available from HMSO.

²⁾ The Hazard Groups are listed in *Categorization of pathogens according to hazard and categories of containment*, produced by the Advisory Committee on Dangerous Pathogens [6]. Attention is also drawn to the requirements of the Health and Safety (Dangerous Pathogens) Regulations 1981 [7] applying to those pathogens listed in Schedule 1 of the Regulations.

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

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

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 24, 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 Scope

This Part of BS 2745 specifies general requirements for washer-disinfectors that are intended to be used for washing and thermal disinfection of articles contaminated by human or animal-waste products generated in medical, dental, pharmaceutical and veterinary establishments. It specifies materials, certain design features, such as inclusion of a thermal disinfection stage, and dimensions, as well as the construction and performance of washer-disinfectors.

NOTE There are two broad categories of washer-disinfector. These are as follows.

- a) cabinet machines;
- b) continuous process machines.

This Part of BS 2745 does not allow for additional gas or oil firing equipment to be incorporated and, when required, control/safety requirements should be specified in addition to this standard.

2 References

2.1 Normative references

This Part of BS 2745 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 page 22. Subsequent amendments to, or revisions of, any of these publications apply to this Part of BS 2745 only when incorporated in it by updating or revision.

2.2 Informative references

This Part of BS 2745 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 page 24, but reference should be made to the latest editions.

3 Definitions

For the purposes of this Part of BS 2745 the following definitions apply.

3.1

washer-disinfector (WD)

machine intended to clean and make microbiologically safe, by a process of thermal disinfection (3.30), articles contaminated by human or animal-waste products generated in medical, dental, pharmaceutical and veterinary establishments

NOTE This type of machine does not include those designed specifically to wash linen or clothing. Machines intended to sterilize or designated as "sterilizers" are specified in BS 3970 or BS 2646.

3.2

calorifier

a vessel conforming to BS 853:1990. A closed cylindrical vessel, in which water is indirectly heated under a pressure greater than atmospheric, for the supply of hot water services, for central heating purposes and for industrial applications. The water is heated by tubular primary heaters, with hot water, steam or oil as the heating medium, or electrical immersion heating elements

3.3

chamber

that part of the WD (3.1) in which the load (3.20) is processed

NOTE The chamber does not include steam generators, pipework and fittings from which it can be isolated.

3.4

chamber diameter

for a cylindrical chamber, the minimum internal diameter, excluding functional protrusions, of the chamber (3.3) or of the door opening, whichever is the smaller

3.5

chamber height and breadth

for a rectangular chamber, the minimum internal dimensions of the chamber (3.3), measured along an axis which passes through the geometric centre of the chamber or door opening (whichever is the smaller) but excluding corner radii

3.6

continuous process machine

a machine which automatically transports the load through each stage of the operating cycle (3.25)

3.7

controller

a device that, in response to pre-determined cycle variables (3.9), operates the WD sequentially through the required stages of the process

3.8

cycle complete

recognition by the controller (3.7) that the pre-set values for the cycle variables (3.9), necessary for a successful operating cycle (3.25), have been attained

3.9

cycle variables

the physical properties (e.g. times, temperatures, pressures and flows) that influence the efficacy of the washing and disinfection (3.11) process

3.10
design pressure

the maximum internal gauge pressure (3.18) which the chamber (3.3) is designed to withstand and which is used in the design calculations

3.11
disinfection

process used to reduce the number of viable micro-organisms in a load but which may not necessarily inactivate some viruses and bacterial spores

3.12
disinfection temperature

the temperature measured in a part of the washer system and which is used to provide assurance that all parts of the load (3.20) attain the temperature at which disinfection (3.11) is to be achieved

3.13
disinfection time

the time period during which the temperature of the load is maintained at or above the disinfection temperature

3.14
disinfector

equipment designed to achieve the disinfection (3.11) of a load (3.20) by means of heat

3.15
double-ended WD

a WD (3.1) with a chamber (3.3) incorporating separate doors for loading (3.21) and unloading (3.31)

3.16
fail-safe

an attribute of machine design whereby failure of any component or its associated services does not create a safety hazard (3.28)

3.17
fault

the recognition by the controller (3.7) that the pre-set cycle variables (3.9) for the operating cycle (3.25) have not been attained and that the processing of the load has been jeopardized

3.18
gauge pressure

pressure measured from atmospheric pressure

3.19
Inspecting Authority

the independent body or association appointed by the manufacturer or the purchaser to carry out the duties in accordance with BS 5500:1991 and with this standard

3.20
load

a collective term used to describe all the goods, equipment and materials that are put into a WD at any one time for the purpose of processing it by an operating cycle (3.25)

NOTE Various devices may be necessary to carry and manipulate the load. These devices (see clause 18) are usually provided by the manufacturer of the WD.

3.21
loading door

the door or curtain in a double-ended WD (3.15) through which the load enters the chamber (3.3) prior to disinfection (3.11), i.e. processing

3.22
loading height

the minimum height to which the underside of the load or load container has to be raised for it to enter the loading door (3.21)

3.23
maximum permissible working pressure

the maximum gauge pressure (3.18) at which a vessel may be operated (see clause 6)

3.24
monitoring

a function of the controller (3.7) to check the attainment or otherwise of the pre-set cycle variables (3.9) essential to the efficacy of the operating cycle (3.25)

3.25
operating cycle

the complete set of stages of the process that is carried out in the sequence as regulated by the controller (3.7)

3.26
operating pressure

the gauge pressure (3.18) at which the vessel is operated during normal use

3.27
override

the system by which the operating cycle (3.25) can be interrupted or modified as necessary

3.28
safety hazard

a potentially detrimental effect on persons or the surroundings arising directly from either the WD or its load

3.29**steam generator**

vessel designed to contain water and a heating system (usually a fully immersed electric element), which is used to heat the water to its vapour state

3.30**tank**

a process vessel, integral to the WD, designed to hold solutions during processing

3.31**thermal disinfection**

disinfection (3.11) achieved by means of heat (see 13.1)

3.32**unloading door**

the door in a double-ended WD (3.15) which is only opened at the end of a successful operating cycle (3.25) to withdraw the load from the chamber (3.3)

3.33**usable chamber space**

the maximum dimensions of a load which the chamber (3.3) is designed to accommodate, with any necessary allowance for the jet nozzles within the chamber

3.34**validation**

obtaining, documenting and interpreting information needed to provide assurance that processes and procedures will consistently render the results required

3.35**warning pipe**

overflow pipe so fitted that its outlet, whether inside or outside the building, is in a conspicuous position, where the discharge of water can be readily seen

3.36**waste outlet**

the point from which the chamber (3.3) discharges the waste fluids

4 Testing for conformity

Unless otherwise stated, conformity to this standard shall be checked by visual inspection and, where practicable, by direct measurement.

NOTE Testing is commonly part of a quality control system which requires the manufacturer to issue the purchaser with test results and certificates of compliance. If the quality system conforms to BS 5750, this will reduce, and may eliminate, the need for the purchaser to witness the works and commissioning tests.

5 Construction**5.1 General**

5.1.1 The WD shall be so constructed as to enable easy access for maintenance and changing components without dismantling parts of the machine (see also 5.4).

5.1.2 The material of construction of connectors and the chamber integral attachments shall be chosen with due regard to the fabrication process, and the conditions under which they will operate.

5.1.3 All components and surfaces shall be free from sharp edges, burrs, etc.

Where plastics material is used as an alternative to stainless steel, it shall be in accordance with 5.2.

5.1.4 All chamber seams, joints and connections shall be bonded or fusion welded and finished smooth. The chamber shall be self draining, and

- a) be formed, pressed or mould designed with a continuous form line and with the radius of internal corners not less than 6 mm; or
- b) be fabricated.

5.1.5 Carriers shall be provided to locate the load during the washing and disinfection process. If interchangeable load carriers/baskets are provided, each load carrier shall be capable of being fitted and removed from the WD without the use of tools.

NOTE The type and quantity of load carriers (see clause 18) are items to be specified by the purchaser (see Annex A).

5.1.6 Means shall be provided to enable temperature sensors to be inserted into the chamber. This shall be either by means of a dedicated thermocouple entry connection or, if practicable, by use of an existing chamber orifice. Insertion shall not be via the door seal(s).

5.2 Materials

Those parts of the WD which come into contact with the load shall be manufactured from a material(s) which has corrosion and abrasion resistance properties not less than those specified for the 304 series of stainless steel (see BS 1449-2:1983).

NOTE In the selection of the materials of construction, due attention should be paid to the effects of galvanic attack, vibration and differential expansion when dissimilar metals are used in contact.

5.3 Fatigue life

The chamber shall be designed to withstand the number of operating cycles calculated from the equation:

$$\text{Number of operating cycles} = \frac{25\,000}{t}$$

where

t is the minimum operating cycle time (in h).

5.4 Frame and panels

The base of floor mounted WDs shall be complete with feet with adjustments to compensate for irregular surfaces.

NOTE 1 External surfaces of the WD should be finished smooth, with an easy clean surface.

NOTE 2 Due regard should be given to the means of access for component maintenance and general cleaning. Panels should be easily removed and reinstalled. Information supplied by the purchaser (see Annex A) should indicate if the machine's location restricts access to the machine, e.g. it is located against a wall.

6 Integral steam generators designed to operate at gauge pressures exceeding 200 mbar

NOTE Reference should also be made to the requirements of 5.1.

6.1 General

6.1.1 Steam generators with a volume of not greater than 5.5 l shall be designed and manufactured to conform to section 3, section 4 and annex AA, section 4, of BS 5500:1991. Materials and design stresses shall conform to section 2 and Annex AA, section 2, of BS 5500:1991 and, in the case of copper and copper-based alloys, shall conform to Annex B of this Part of BS 2745.

6.1.2 Steam generators with a volume of 5.5 l or greater shall conform to BS 5500:1991.

6.2 Components

Pipes and pipe fittings for steam generators shall conform to the appropriate standard given in Table 1.

Table 1 — Standards for pipes and pipe fittings for steam generators

Pipes	Pipe fittings
BS 806:1990	BS 1740-1:1971
BS 1306:1975	BS 1965-1:1963
BS 1387:1985	BS 4504-3.1:1989, BS 4504-3.2:1989 and BS 4504-3.3:1989
BS 2871-2:1972	BS 4865-1:1989 and
BS 3059-2:1990	BS 4865-2:1989
BS 3601:1987	
BS 3604-1:1990 and BS 3604-2:1991	
BS 3605	
BS 6362:1990	

6.3 Manufacturer's inspection

Steam generators manufactured in accordance with 6.1.1 shall be inspected, either by the manufacturer or by his agent on behalf of the manufacturer, to ensure that:

- the steam generator has been manufactured within a quality system which is acceptable to the Inspecting Authority (e.g. in accordance with BS 5750); and
- the steam generator is marked in accordance with clause 20.

6.4 Certificate of compliance

On completion of the construction and inspection of the steam generator (see 6.1), the manufacturer shall issue a certificate of compliance to certify that the steam generator has been designed, constructed and tested in accordance with this Part of BS 2745. The certificate shall be countersigned by the Inspecting Authority (see 6.3) as evidence that it has been so designed, constructed and tested.

NOTE Information about the appointment of an Inspecting Authority is given in the foreword.

For steam generators constructed in accordance with 6.1.1, a certificate of compliance (see Figure 1) shall be issued. For vessels constructed in accordance with BS 5500:1991 (see 6.1.2), the certificate of compliance shall be as shown in 1.4.4 of BS 5500:1991.

6.5 Over-pressure protection devices

6.5.1 The steam generator shall be fitted with an over-pressure protection device (safety valve) conforming to BS 6759-1:1984.

6.5.2 The over-pressure protection device shall be set to operate at a pressure not higher than the maximum permissible working pressure and shall be of a size that will ensure, in the event of failure to control the supply pressure, that the pressure within the steam generator will not exceed the maximum permissible working pressure by more than 10 %.

Testing shall be carried out as follows. The steam supply pressure, i.e. the pressure at which the steam is supplied to the pressure vessel, measured in the steam supply pipe, shall be raised to the maximum acceptable level, as stated by the manufacturer.

NOTE The maximum acceptable steam supply pressure will commonly be set at a value between the maximum permissible working pressure and the design pressure.