

Washer-disinfectors for medical purposes —

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

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

This British Standard, having been prepared under the direction of the Laboratory Apparatus Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 November 1993

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First published, as BS 2745, May 1956
Second edition February 1966
Third edition, as BS 2745-3, November 1993

The following BSI references relate to the work on this standard:
Committee reference LBC 35
Draft for comment 91 52186 DC

ISBN 0 580 21545 8

Amendments issued since publication

Amd. No.	Date	Comments

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Foreword

It is recommended that this foreword be read in conjunction with the foreword to BS 2745-1.

This Part of BS 2745 has been prepared under the direction of the Laboratory Apparatus Standards Policy Committee. It is published simultaneously with BS 2745-1 and BS 2745-2. Together with Part 1 and Part 2 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. 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 Part 1, while requirements for washer-disinfectors used to treat human-waste containers are given in Part 2 of the standard.

For successful washing and disinfection, it is necessary first to clean and secondly to disinfect the load. Disinfection may be impaired if soil remains on the load. The load should be carefully installed in the machine to ensure all parts are subject to the thermal disinfection process for the required time, and this may involve the use of special carriages which form part of the distribution system for the process medium. Drying may be an integral part of the washer-disinfector when requested by the purchaser.

Washer-disinfectors conforming to this standard are intended for a wide variety of loads. The purchaser should give careful consideration to the implication of installing general purpose machines or those designed for processing a specific load, e.g. anaesthetic equipment. The purchaser should discuss specific requirements with the manufacturer.

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 and ii, pages 1 to 16, 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 particular requirements for washer-disinfectors intended to be used for washing and thermal disinfection of all goods except human-waste containers and laundry. Solvent drying systems are excluded from this standard.

These requirements apply in addition to the general requirements specified in BS 2745-1:1993.

Ventilation ducting is outside the scope of this Part of BS 2745, but as it is an essential part of a total system, guidance for the purchaser has been included in Annex E of BS 2745-1:1993.

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

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

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 the inside back cover. 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 the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this Part of BS 2745 the definitions given in BS 2745-1:1993 apply, together with the following.

3.1

cabinet machine

a machine in which all stages of the operating cycle are carried out sequentially in one chamber

3.2

de-gassing

the removal of sufficient gas present within the solution to prevent impairment of the process

3.3

de-wetting

a chemical agent to assist in the displacement of water from the surface of the load

4 De-wetting agents, detergent and load lubrication

4.1 General

When de-wetting agents, detergent and load lubrication are specified by the purchaser, see Annex A, a means shall be provided to control the volume, which shall be adjustable and deliver within $\pm 10\%$ of the set volume with a resolution of not greater than 10 cm^3 or 10 g , as applicable.

4.2 De-wetting agents

Unless not required because a treated rinse water is specified, de-wetting agents shall be injected automatically. The de-wetting agent shall give a surface tension of not greater than 0.035 N/m .

NOTE De-wetting agents will not normally be required when a specifically treated rinse water, e.g. distilled water, is specified.

4.3 Detergent

Detergent shall be injected automatically.

4.4 Load lubrication

Load lubricant shall be injected automatically. The lubricant used shall be clinically acceptable.

NOTE A white mineral oil conforming to purity values given in European and British Pharmacopoeias, is considered to be clinically acceptable.

5 Load handling and supports

5.1 Automatic load transport systems

5.1.1 The load transport system shall pause when:

- a) no load is being processed in the washer-disinfector (WD) and the loading conveyer is empty;
- b) the preset temperature and time for disinfection are not being achieved (see 13.1 of BS 2745-1:1993);
- c) the unloading conveyer is full.

NOTE Loads in the WD may continue to be processed to completion to wait for a space on the unloading conveyer.

5.1.2 Failure of any sensing device shall not cause a safety hazard.

5.1.3 When the WD load handling system pauses for the reasons stated in item a) or item c) of 5.1.1, it shall automatically restart when:

- a) a load is presented on the loading conveyer; or
- b) a space is available on the unloading conveyer.

5.1.4 With the exception of continuous process machines (see 12.4), when a disinfection fault occurs, it shall only be possible to restart the WD manually using a special key, code or tool.

5.2 Stop buttons for transport systems

Where a motorized external transport system is provided, emergency stop buttons of the type described in BS 5304:1988 shall be incorporated. In the interface between the external and internal load transport systems the following shall apply.

- a) All external motorized conveyers and rollers shall be fitted with stop buttons. The stop buttons shall stop the external load transport system but not the WD's internal load transport system. A separate manual restart button shall be provided for each system.
- b) When the WD's internal load transport system is stopped, the external system shall also stop.

5.3 Additional requirements for WDs with overhead transport system

NOTE When not in use, the transport system should be located in the start position over the loading conveyer.

Vapours from the WD shall not cause the transport system to malfunction.

Testing shall be carried out as follows. After the WD has been run with the transport system held stationary over each section of the WD which emits vapour, in turn, for 15 min, the transport system shall operate under automatic control without a fault.

6 Venting and drainage systems

6.1 Exhaust system

Aqueous solution tanks, operating at 80 °C and above, not contained within an enclosure shall be provided with a means of connecting ductwork for vapour extraction (see 17.1 of BS 2745-1:1993).

6.2 System closedown

6.2.1 Means shall be provided such that, when the WD is closed down, the extract system continues to operate to remove residual vapour. The extract system operating after the machine is closed down shall be stopped by an automatic control. If this automatic control is operated by means of an adjustable timer, the timer shall have restricted access in accordance with 14.1.3 of BS 2745-1:1993.

6.2.2 Where the extract system is supplied and/or fitted by a party other than the manufacturer of the WD, connections shall be fitted to the control system to enable the extract system to overrun in the event of WD system close down.

7 Process information

The washer disinfectant shall conform to clause 13 of BS 2745-1:1993, except that, for machines using ultrasonic cleaning, the first wash (see 13.1 of BS 2745-1:1993) shall be optional.

Where special rinse water and/or additional rinses are required, the quality of the water, and the number of rinses shall be as stipulated by the purchaser (see Annex A).

8 Instrumentation and controls

8.1 Start up

The automatic control shall prevent the WD's operating cycle commencing until the predetermined operating parameters have been achieved.

8.2 Monitoring

The automatic control shall cause a fault to be indicated when the data obtained is not within the limits stated for a particular process.

NOTE Time-temperature relationships for thermal disinfection are given in 13.2 of BS 2745-1:1993.

8.3 Recording instruments

8.3.1 Where a recording instrument is specified (see Annex A), it shall record the time and temperature for each disinfection period.

If a common system is used for indication, recording and control, the following shall apply.

- a) A minimum of two sensors shall be fitted.
- b) The system shall be capable of detecting an error in the measured temperature greater than 1 °C.
- c) The system shall indicate a fault at the end of the cycle when the error in temperature measurement exceeds 1 °C.

8.3.2 The recording instrument shall include one of the following.

- a) A strip chart recorder, having a temperature range of 20 °C to 120 °C, a chart width of 100 mm (minimum) and a chart speed of 1 cm/5 min.
- b) An alpha numeric printer, of minimum 40 columns width (see also 14.3.4 of BS 2745-1:1993). The printer shall have a resolution of 1 K and an accuracy of 0.5 °C over the range 60 °C to 100 °C. Data which are not within the specified limits and which cause a fault to be indicated shall be printed in a different colour (preferably red) and/or a distinctively different typeface.

8.4 Adjustment of disinfection temperature and disinfection time controls

The disinfection temperature control and the disinfection time control shall be adjustable only by means of a code, key or tool.

NOTE It is essential that the temperature/time combination required for thermal disinfection is achieved (see 13.2 of BS 2745-1:1993).

9 Power sources

NOTE 1 This clause replaces 4.8 of the *Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE)*[1].

Means shall be provided for isolating the electrical equipment simultaneously from all poles of the main supply. An emergency stop button or switch that will disconnect the electricity supply to the WD shall be fitted within 1 m of each loading and unloading position.

NOTE 2 See also clause 14 of *ESCHLE* [1].

Testing shall be carried out as follows. Each stop button or switch shall be operated in turn and the equipment tested to determine whether it has been disconnected from the power supply.

10 Drying

10.1 General

When specified by the purchaser, integral drying shall be provided (see Annex A).

10.2 Hot air drying adjustment

Where hot air drying is to be used, a means shall be provided to vary the temperature and time of the drying process, adjustments being possible only by means of a code, key or tool. The control shall provide a temperature within $\pm 5^\circ\text{C}$ of the set temperature, reached within $\pm 5\%$ of the set time. Set values for any other variables, e.g. humidity, shall be met to within $\pm 5\%$.

The recommended settings for the loads to be processed shall be stated (see 14.1).

NOTE 1 When adjusting the drying time on a continuous process machine, caution may be necessary to avoid adversely affecting the disinfection and other stages.

NOTE 2 Requirements to restrict the escape of vapour and heat are given in 12.5.

NOTE 3 The maximum operating temperature of the dryer should be stated, in order to facilitate monitoring of the operating cycle (see 14.1).

11 Ultrasonic cleaning system

11.1 Bonding and housing

The substrate used to mount the ultrasonic transducers shall have an erosion allowance of not greater than 25 %.

The material enclosing ultrasonic transducers and the material on which the transducers are bonded shall not leak during an operating period of 5 years.

Testing shall be carried out as follows. The tank containing the transducers shall be filled with water to the normal operating level. The assembly, which shall be watertight, shall be operated continuously for 12 months under this condition.

NOTE Interruptions due to emergencies and/or power failures are excepted, up to a maximum of 168 h.

After this time the assembly shall be checked and shall conform to the following criteria.

- a) It shall be fully operational and no fixings or components shall have become loose.
- b) It shall not leak.
- c) Deterioration of the substrate surface shall not occur over more than 60 % of the surface area.
- d) Erosion shall not exceed 25 % of the metal thickness at any point.

11.2 Transducer fault

The automatic control system shall cause a fault to be indicated if one or more transducer assemblies are not operating within the limits stated by the manufacturer.

Testing shall be carried out as follows. Each transducer or group of transducers (not exceeding 50 % of the total number) shall be disconnected in turn and the WD shall then be run. When tested in this way, in each case a fault shall be indicated.

11.3 Maintenance of transducers

Means shall be provided for replacing individual transducers or groups of transducers without dismantling or replacing other systems of the WD.

11.4 De-gassing

The de-gassing stage of the operating cycle shall be completed before the load enters the tank.

When tested by the method given in Annex B, the test piece shall have a similar erosion pattern to the reference.

12 Continuous process machines

12.1 General

Means shall be provided for automatically transporting the load through the washing, disinfection and, if specified, the drying process (see Annex A).

12.2 Removing loads

Baskets and loads that are stalled shall be easily removed from the machine.

NOTE This may be by means of access doors suitably positioned along the WD.

When the load transport system is stopped in turn at a series of points corresponding to 10 % intervals along the length of the WD, it shall be possible for the operator to remove the basket from each position without having to climb into the machine.