

Sterilizing and disinfecting equipment for medical products —

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

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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

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 July 1990

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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 disinfectant 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 5¹⁾: Specification for low-temperature steam disinfectors;*
- *Part A¹⁾: Specification for steam sterilizers for fluids in sealed rigid containers;*
- *Part B¹⁾: Specification for steam sterilizers for fluids in unsealed vented containers;*
- *Part C¹⁾: Specification for steam sterilizers for fluids in sealed non-rigid containers;*
- *Part D¹⁾: Specification for steam sterilizers using low-temperature steam with formaldehyde;*
- *Part E¹⁾: 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.