

Sterilizing and disinfecting equipment for medical products —

Part 5: Specification for low temperature steam disinfectors

Confirmed
December 2011

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 Engineers' Association
- Royal College of Pathologists
- Royal Pharmaceutical Society of Great Britain
- Scottish Health Services
- 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 28 September 1990

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The following BSI references relate to the work on this standard:
Committee reference HCC/14
Draft for comment 85/53989 DC

ISBN 0 580 18508 7

Amendments issued since publication

Amd. No.	Date of issue	Comments

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Foreword

It is recommended that this foreword be read in conjunction with the foreword of 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 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 3970-1:1990 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 4: Specification for transportable steam sterilizers for unwrapped instruments and utensils;*
- *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 sterilizers using low-temperature steam with formaldehyde;*
- *Part E¹⁾: Specification for sterilizers using ethylene oxide or ethylene oxide mixtures.*

This Part specifies requirements, in addition to those specified in BS 3970-1, for equipment operating at sub-atmospheric pressures and designed to disinfect heat sensitive products by using saturated steam at low temperature in the absence of formaldehyde (see note). The process described achieves disinfection only. The equipment specified in this Part of BS 3970 is intended for treating both wrapped or unwrapped instruments and for those materials unsuitable for treatment at temperatures above 80 °C. Only one operating cycle is specified; process control is fully automatic.

It is necessary to ensure that the walls of the chamber are heated prior to commencing stage 2 in order to minimize condensation and to achieve the correct conditions for disinfection. Also, for successful disinfection, it is usual to have an efficient vacuum system both to ensure steam penetration during stage 5 of the operating cycle and to ensure that the pressure during stage 6 is sufficiently reduced to enable the moisture to be removed from the load (see clause 5).

NOTE Although this practice is deprecated, the operating cycle specified in this standard is usually provided as an alternative operating cycle on equipment designed for sterilization by low temperature steam with formaldehyde. It is for this reason that this Part is included in BS 3970. The Part of BS 3970 specifying low temperature steam sterilizers using formaldehyde is being considered at the time of publication of this Part of BS 3970.

Attention is drawn to the fact that the production of dry packs is assisted by the use of suitable absorbent packaging materials. Guidance in the treatment of wet loads is given in Health Technical Memorandum (HTM) 10 “Sterilizers”, published by the Department of Health and Social Security.

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.