

Sterilizing and disinfecting equipment for medical products —

**Part 2: Specification for steam
sterilizers for aqueous fluids in sealed
rigid containers**

Confirmed
December 2011

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:

- Associated Offices Technical Committee
- Association of British Health-care Industries
- Association of British Sterilizer Manufacturers
- Association of National Health Service Supplies Officers
- British Dental Trade Association
- British Surgical Trades 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 body was also represented in the drafting of the standard, through subcommittees and panels:

Guild of Hospital Pharmacists

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 30 September 1991

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The following BSI references relate to the work on this standard:
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Amendments issued since publication

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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 Laboratory Apparatus Standards Policy Committee. This Part and BS 3970-1:1990 together supersede BS 3970-2:1966, which is withdrawn.

Parts 1 and 2 of the first edition of BS 3970 were both published in 1966 and covered two specific types of sterilizer. However, in this revision the structure of BS 3970 has been changed so that general requirements are now given in the revised (1990) edition of Part 1. Those requirements that are not common to most types of sterilizer are specified in subsequent Parts of this standard. 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 given in Part 1.

When aqueous fluids in sealed rigid containers are heated, the increased pressure within them becomes a source of danger, especially when temperatures above 80 °C are reached. Hence it is a requirement of this standard that the load in the chamber of the sterilizer shall remain inaccessible to the operator unless the temperature of all the contents of the load has become lower than 80 °C. Appropriate interlocks on the door-controlling mechanisms are specified, together with appropriate temperature detectors.

There are two accepted principles of exposing the load to a sterilization cycle that gives an adequate level of lethality, each involving the attainment of an adequate temperature for an adequate time. In Table 1 a preferred combination of time and temperature is given, this being entirely acceptable for thermo-stable products. Additionally with thermo-labile products the user may choose to use the F_0 principle in which other times and temperatures are employed. In this case the onus is on the User to determine the nature of the bioburden in the product(s) and also to determine that the proposed cycle will ensure that the probability of survival of microorganisms does not exceed 10^{-6} . The F_0 control function may be incorporated into the automatic controller.

With thermo-labile products it will normally be appropriate to employ assisted cooling in order to limit thermal damage.

It is also the responsibility of the user to provide a suitable container which will withstand the physical conditions and remain intact and sealed both during and after the process in order to prevent adulteration of the contents of the container during the process itself or any possible subsequent microbial contamination.

The purchaser may have to adjust the timing of the stages of the process when sterilizing a fluid with viscosity markedly higher than that of water.

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 10, 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 3970 specifies particular requirements for sterilizers intended to be used for the sterilization of aqueous fluids in sealed rigid containers in which the heat transfer is effected by saturated steam under phase-boundary conditions, having a steady-state equilibrium during the holding phase. These requirements apply in addition to the general requirements specified in BS 3970-1.

NOTE 1 Recommendations for the information to be supplied by the purchaser to the manufacturer are given in Appendix A.

NOTE 2 The attention of both the sterilizer manufacturer and the user is drawn to the hazards associated with processing fluids in sealed rigid containers described in Appendix H.

NOTE 3 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

acceptable temperature band

the temperature range within which all parts of the load are to be maintained throughout the holding time (see 2.8) of the operating cycle, there being a minimum acceptable temperature (see 2.13) and a maximum acceptable temperature

2.2

air ballasting

a process whereby the chamber pressure is maintained at or near the pressure obtaining in the chamber during the steady-state stage (see 2.12) of the operating cycle either during the whole of the cooling stage or during the initial part of it

NOTE Although called air ballasting gases other than air may be suitable.

2.3

cooling stage

the period of the operating cycle, after the holding time (see 2.8) has been completed, during which the load remains in the chamber, while the load cools to a temperature of 80 °C or below

2.4

natural cooling mode

a method of cooling in which the steam supply to the chamber is cut off and the sterilizer and its load allowed to cool to the required temperature by natural heat loss. This may take several hours to complete and is only suitable for loads with high thermal stability

2.5

assisted cooling

any method of cooling in which, after the steam supply to the chamber has been shut off, the rate of heat loss from the load is increased significantly above the rate of natural cooling

2.6

rapid cooling

assisted cooling in which stage 4 of the operating cycle is completed in not more than 45 min when conducted with a fully loaded chamber

NOTE A short period of natural cooling may precede assisted cooling or rapid cooling in stage 4.

2.7

equilibration time

the period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature (see 2.13) at all points of the load

2.8

holding time

the stage during which all parts of the chamber, load and any coolant fluid are at a temperature within the acceptable temperature band (see 2.1)

2.9

simulator

a temperature-detecting device so constructed that its temperature relates to the thermal characteristics of a stated load container over part or all of the operating cycle

NOTE Sterilizers may be fitted with more than one simulator.

2.10

simulator safety system

a system or device incorporating a simulator that prevents the operator opening the chamber door when the temperature of the load within the chamber exceeds 80 °C

2.11

simulator control system

a system or device that incorporates a simulator and that controls the equilibration time (see 2.7) so that the load achieves the necessary acceptable temperature band (see 2.1) for the required holding time (see 2.8)

2.12

steady-state stage

the period that includes the equilibration time (see 2.7) and the holding time (see 2.8)