
British Standard

Sterilizing and disinfecting equipment for medical products

Part 3. Specification for steam sterilizers for
wrapped goods and porous loads

Matériels de stérilisation et de désinfection des produits médicaux

Partie 3. Stérilisateurs pour produits enveloppés et charges poreuses - Spécifications

Sterilisier- und Desinfiziergeräte für medizinische Erzeugnisse

Teil 3. Sterilisatoren für verpackte und poröse Waren

Foreword

It is recommended that this foreword be read in conjunction with the foreword to BS 3970 : Part 1.

This Part of BS 3970 has been prepared under the direction of the Health Care Standards Policy Committee. It is published simultaneously with BS 3970 : Part 1 and, together, they supersede BS 3970 : Part 1 : 1966, which is withdrawn.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 applicable to all the sterilizers and disinfectors are now given in Part 1. Those requirements that are not common to most types of sterilizer are specified in subsequent Parts of BS 3970. These Parts, giving particular requirements, should be read in conjunction with BS 3970 : Part 1, which they supplement or modify. The titles of these Parts are expected to be as follows:

- Part 4. Specification for transportable steam sterilizers for unwrapped instruments and utensils
- Part 5. Specification for low-temperature steam disinfectors
- *Part A. Specification for steam sterilizers for fluids in sealed rigid containers
- *Part B. Specification for steam sterilizers for fluids in unsealed vented containers
- *Part C. Specification for steam sterilizers for fluids in sealed non-rigid containers
- *Part D. Specification for sterilizers using low-temperature steam with formaldehyde
- *Part E. Specification for steam sterilizers using ethylene oxide or ethylene oxide mixtures
- *Part F. Specification for steam sterilizers for unwrapped utensils, instruments and holloware.

NOTE. BS 3970 : Part 5 : 1968 'Electrically heated steam generators for use with hospital sterilizers' no longer forms Part of BS 3970, and has been withdrawn.

For successful sterilization of wrapped goods and porous loads it is usual to have an efficient vacuum system both to ensure steam penetration during stage 3 of the operating cycle and to ensure that the pressure during stage 4 is sufficiently reduced to enable the moisture to be removed from the load (see clause 4). A heated jacket is generally used to prevent condensate from forming on the chamber walls and to assist drying of the load in stage 4.

When a mixed load of porous and non-porous items having a large heat capacity, e.g. a load containing metallic materials, is to be sterilized, the load should be prepared so that the condensate either is allowed to drain freely or is retained in the proximity of the non-porous items to facilitate re-evaporation during stage 4. Failure to consider this may result in a wet load at the end of the operating cycle. 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.

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.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

*In preparation; each Part will be allocated a number in its respective order of publication.