



BSI Standards Publication

**Packaging for terminally-sterilized
medical devices — Method for
determination of methylene blue
particulate penetration**

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Summary of pages

This document comprises a front cover, and inside front cover, pages i to iv, pages 1 to 27, an inside back cover and a back cover.

Foreword

Publishing information

This British Standard is published by BSI Standards Limited, under licence from The British Standards Institution, and came into effect on 31 January 2021. It was prepared by Technical Committee CH/198, *Sterilization and Associated Equipment and Processes*. A list of organizations represented on this committee can be obtained on request to its committee manager.

Supersession

This British Standard supersedes [BS 6256:1989](#), incorporating amendment 1, which is withdrawn.

Information about this document

[BS 6256:1989](#) specified requirements for materials, performance, marking and packaging for paper used in the manufacture of steam sterilization paper bags, pouches and reels. These requirements have been superseded by the adoption as British Standards of European Standards in the EN ISO 11607 series and EN 868 series (see Bibliography).

Annex C to [BS 6256:1989](#) provided a test method for determination of methylene blue particulate penetration of packaging material. This test method is referenced in BS EN ISO 11607-1 but has not been incorporated into that standard nor into the BS EN 868 series. This British Standard contains only the test method from the 1989 edition of BS 6256 and retains the same BS identifier in order to maintain the integrity of the reference from BS EN 11607-1.

Annex C to [BS 6256:1989](#) normatively referenced [BS 2577:1955](#) and [BS 3431:1961](#), which have been withdrawn. The necessary content of these standards has therefore been incorporated into this new edition.

Presentational conventions

The provisions of this standard are presented in roman (i.e. upright) type. Its methods are expressed as a set of instructions, a description, or in sentences in which the principal auxiliary verb is “shall”.

Commentary, explanation and general informative material is presented in smaller italic type, and does not constitute a normative element.

The word “should” is used to express recommendations of this standard. The word “may” is used in the text to express permissibility, e.g. as an alternative to the primary recommendation of the clause. The word “can” is used to express possibility, e.g. a consequence of an action or an event.

Notes and commentaries are provided throughout the text of this standard. Notes give references and additional information that are important but do not form part of the recommendations. Commentaries give background information.

Where words have alternative spellings, the preferred spelling of the Shorter Oxford English Dictionary is used (e.g. “organization” rather than “organisation”).

Where websites and webpages have been cited, they are provided for ease of reference and are correct at the time of publication. The location of a webpage or website, or its contents, cannot be guaranteed.

Contractual and legal considerations

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

0 Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavour. The device components and the packaging system need to be combined to create a product that performs efficiently, safely, and effectively in the hands of the user. The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, intended sterilization methods(s), intended use, expiry date, transport and storage all influence the packaging system design and choice of materials. The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device.

BS EN ISO 11607-1 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices, while considering the wide range of potential materials, medical devices, packaging system designs and sterilization methods.

BS EN ISO 11607-2 describes the validation requirements for forming, sealing and assembly processes.

[BS EN 868](#) Parts 2 to 10 specify particular requirements for a range of commonly used materials. Compliance with [BS EN 868](#) Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of BS EN ISO 11607-1.

BS EN 11607-1 requires that porous materials provide an adequate microbial barrier to microorganisms in order to provide integrity of the sterile barrier system and product safety. It continues by noting that there is no universally accepted method of demonstrating microbial barrier properties. Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates under a set of test conditions which specify the flow rate through the material, challenge to the sample and duration of the test. The microbial barrier properties of the material, under these specified test conditions, are determined by comparing the extent of bacterial or particulate penetration through the material with that of the original challenge. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. As validated microbial challenge methods for materials and sterile barrier systems become available, they will be considered for inclusion in future editions of BS EN ISO 11607-1.

BS EN ISO 11607-1:2009+A1:2014, Annex B lists standardized test methods and procedures that may be used to demonstrate compliance with the requirements of BS EN ISO 11607-1. The method described in this British Standard is listed as one of the possible methods of demonstrating microbial barrier properties. This method is based on a test method described in [BS 2577](#) (withdrawn) that was developed to assess the protection afforded by respirator cannisters containing a filtering medium against particulate clouds.

1 Scope

This British Standard describes methods of demonstrating the performance of the microbial barrier of porous material used in a sterile barrier system by penetration of particles of methylene blue.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes provisions of this document¹⁾. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

BS EN 20187, *Paper, board and pulps – Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples*

3 Terms and definitions

No terms and definitions are listed in this document.

NOTE ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- a) ISO Online browsing platform: available at <https://www.iso.org/obp>; and
 - b) IEC Electropedia: available at <http://www.electropedia.org/>.
-

4 Principle

COMMENTARY ON CLAUSE 4

The layout of the apparatus is illustrated in [Figure 1](#) and [Figure 2](#).

The atomizer, working under a constant pressure and flow of compressed air, disperses a solution of methylene blue into a mist at a uniform rate. The mist passes into the evaporation tube (E) where it is diluted to a total volume of 30 dm³/min by dry air entering at (B). The droplets of solution evaporate before reaching the control cock (C), leaving a residue of solid particles of methylene blue. When the control cock (C) is in the test position, the test cloud passes to the test circuit which contains the sample under test and the filter paper.

When the control cock is turned to the central or air position, the cloud is diverted to the by-pass circuit and at the same time air is drawn through the test circuit. In the off position of the control cock, the cloud remains diverted to the by-pass circuit, but there is no flow through the test circuit. The rates of flow in the circuits are adjusted to 30 dm³/min by means of the air valves V₂ and V₃.

To test a sample, the control cock is first turned to the off position and the sample and filter paper are inserted into their respective holders. The test cloud is then passed to the sample for a predetermined time, following which air is passed for a further period of 2 s in order to sweep out the residual cloud from the test circuit. The control cock is then turned to off and the filter paper removed. Finally, the test stain is developed with steam and the penetration assessed by comparing the stain with the standard stains.

¹⁾ Documents that are referred to solely in an informative manner are listed in the Bibliography.

Figure 1 — Circuit diagram of apparatus for methylene blue particulate penetration test

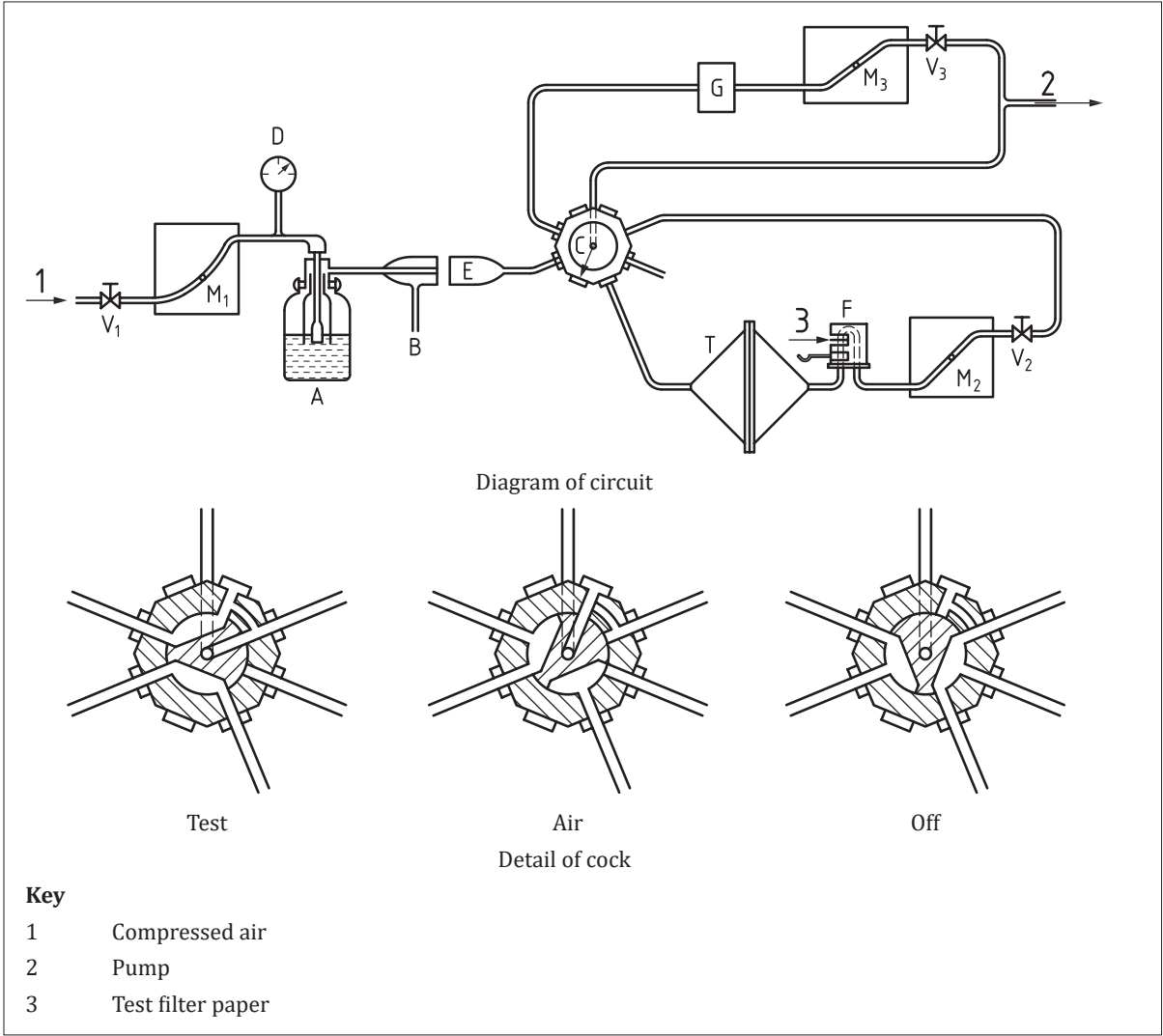
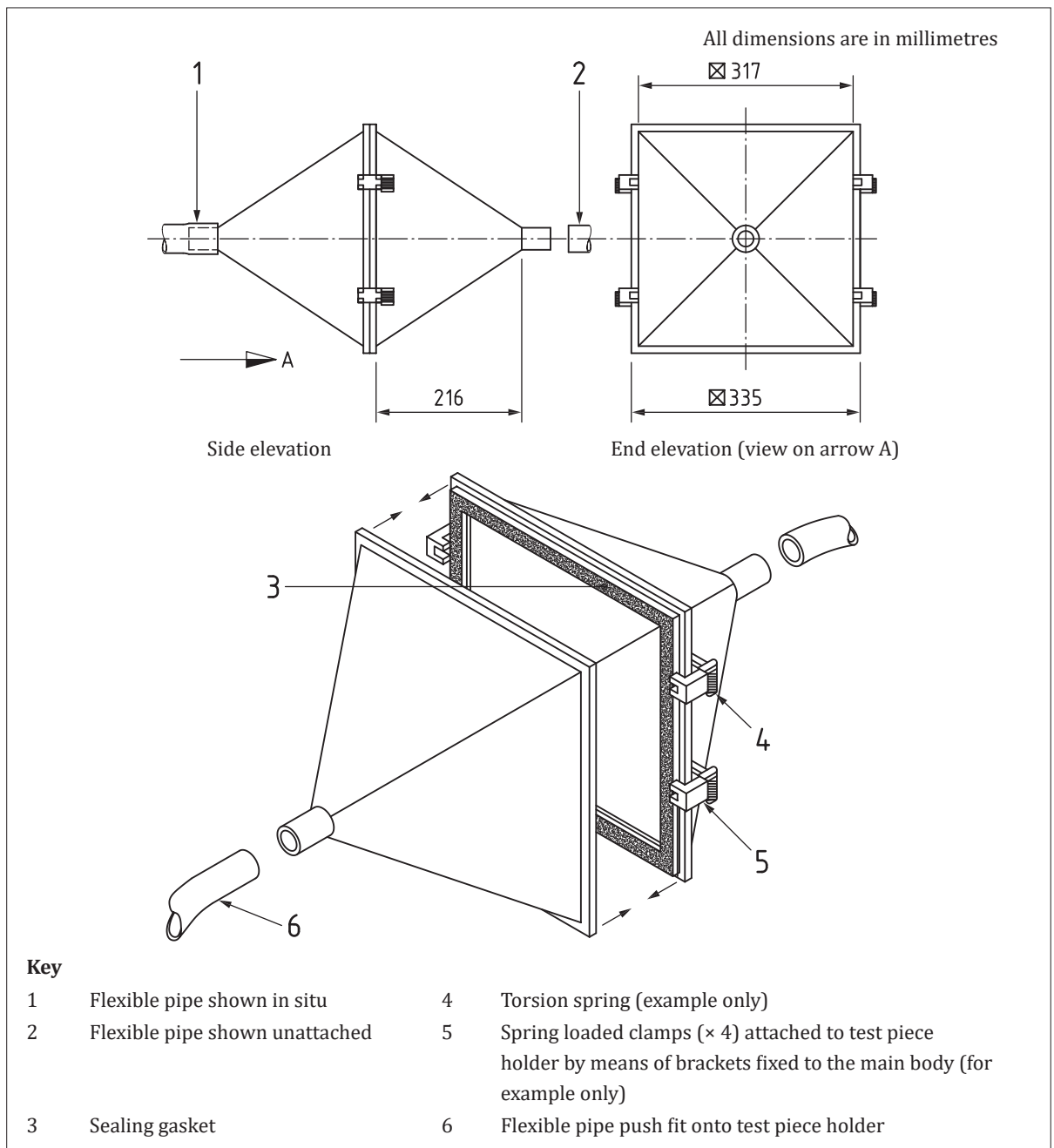


Figure 2 — Test piece holder for methylene blue particulate penetration test

5 Apparatus, components and layout

NOTE See [Annex A](#) and [Figure 1](#).

- 5.1 *Test cloud generator*, comprising the atomizer (A), needle valve (V_1), pressure gauge (D), compressed air flowmeter (M_1) and evaporation tube (E).
- 5.2 *Control cock* (C).
- 5.3 *Test circuit*, comprising test piece holder (T), test paper holder (F), flowmeter (M_2) and control valve (V_2).
- 5.4 *Bypass circuit*, comprising the filter (G), flowmeter (M_3) and control valve (V_3).
- 5.5 *Filter paper* (3).

5.6 Rotary suction pump.

5.7 Air drier.

6 Procedure

6.1 Preliminary

6.1.1 Fill the atomizer with a 1% methylene blue solution up to a level 6 mm below that of the spray orifice: approximately 500 ml of solution are required.

6.1.2 After a maximum of 8 h operation, discard the methylene blue solution and replace with a fresh 1% solution of methylene blue.

NOTE The methylene blue solution in the atomizer with the standard nozzle is consumed at a rate of approximately 10 ml per hour. This loss is due in part to the atomization of the solution and in part to the evaporation of water from the main bulk of the liquid. The concentration of the solution in the reservoir therefore increases steadily during the operation of the apparatus. The volume of the reservoir is chosen so that the change in concentration, and loss of volume, of the solution during a period of 8 h operation or less, will not cause an appreciable change in the concentration of the test cloud.

6.2 Start-up instructions

6.2.1 Start up the apparatus as follows.

- a) Turn the control cock (C) to OFF.
- b) Switch on the suction pump.
- c) Close and clamp the unloaded test piece holder (T).
- d) Clamp the unloaded test paper holder (F) firmly closed.
- e) Turn the control cock (C) to TEST.
- f) Adjust the air valve (V_2) to give a flow of 30 dm³/min through the bypass circuit.
- g) Turn the control cock (C) to OFF.
- h) Adjust control valve (V_3) to give a flow of 30 dm³/min through the test circuit.
- i) Turn on the compressed air to the atomizer and adjust the needle valve (V_1) until the pressure gauge (D) registers 205 kPa. The ball in the compressed air flowmeter (M_1) should now rise to the calibration mark. If the air flow is insufficient, turn off the compressed air and clear the atomizer jets.

NOTE 1 Steps e) to h) establish the nominal air valve settings to give the required flow rates in subsequent operations. Minor adjustments only from these settings can be made.

NOTE 2 For details of maintenance, see [Clause 8](#).

6.2.2 Maintain the air pressure at a constant of 205 kPa. The air pressure is not to be increased to bring the air flow up to the correct value.

6.3 Preparation of standard stains

Prepare the standard stains as follows.

- a) Close and clamp the unloaded test piece holder.
- b) Clamp a short piece of filter paper in the test paper holder.
- c) Turn the control cock (C) to TEST for 20 s. During this period check, and adjust if necessary, the air valve (V_2) in the test circuit to give a flow rate of 30 dm³/min.