

Environmental cleanliness in enclosed spaces — Guide to test methods

ICS 13.040.30

NO COPYING WITHOUT BSI PERMISSION EXCEPT AS PERMITTED BY COPYRIGHT LAW



Document Sharing Hub

Committees responsible for this Published Document

The preparation of this Published Document was entrusted to Technical Committee LBI/30, Cleanroom technology, upon which the following bodies were represented:

- AEA Technology
- Association of British Health-Care Industries
- British Textile Technology Group
- Chartered Institution of Building Services Engineers
- Chilled Food Association
- Department of Health — Medical Devices Agency
- Guild of Hospital Pharmacists
- Heating, Ventilating and Air Conditioning Association
- Institute of Mechanical Engineers
- Institute of Sterile Services Management
- Parenteral Society
- Pharmaceutical Microbiology Interest Group (Pharmig)
- Scottish Society for Contamination Control
- Society of Environmental Engineers
- Sterilised Suture Manufacturers' Association
- Surgical Dressings Manufacturers' Association

This Published Document, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 July 2000

© BSI 07-2000

ISBN 0 580 33170 9

Amendments issued since publication

Amd. No.	Date	Comments

Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
1 Scope	1
2 Measurement of pressure difference	1
3 Measurement of filter performance	1
4 Measurement of particulate contamination by microscopic sizing and counting	3
Annex A (informative) Reproduction from BS 5295-1:1989 (withdrawn) of appendix B: Method of test for the determination of pressure differences	7
Annex B (informative) Reproduction from BS 5295-1:1989 (withdrawn) of appendix C: Method of test for the determination of filter installation leaks	7
Annex C (informative) Reproduction from BS 5295-1:1989 (withdrawn) of appendix F: Method of test for the determination of particulate contamination by microscopic sizing and counting	9
Bibliography	13
Figure 1 — Diagrammatic representation of aerosol filter testing requirements of BS 5295-1:1989 (withdrawn)	4
Figure 2 — Schematic diagram of aerosol challenge to air handling unit	5
Figure 3 — Typical aerosol output versus operating pressure of hot generated aerosol	6
Figure F2 — Calibration of the measuring eyepiece	10
Figure F3 — Reduced unit area	11

Foreword

This Published Document has been prepared by Technical Committee LBI/30. It supersedes PD 6609:1996 which is withdrawn.

BS 5295-1:1989 was replaced in 1999 by BS EN ISO 14644-1:1999. However, BS EN ISO 14644-1:1999 does not contain test methods equivalent to all those given in BS 5295-1. Most test methods will be given in ISO 14644-3, currently in preparation. Meanwhile this revision of PD 6609 reproduces test methods from the withdrawn BS 5295-1:1989, for use where necessary in the interim period (approximately two years).

This revision of PD 6609 also includes the supplementary guidance, given in the first edition, on arrangements and test equipment for in situ HEPA filtration testing.

A British Standard does not purport to include all 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 13 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

1 Scope

This Published Document provides information supplementary to the provisions of BS EN ISO 14644-1:1999, pending the publication of further parts of the ISO 14644 series of standards. In particular it gives recommendations and explanatory guidance in respect of the determination of pressure differences, the determination of filter performance and the determination of particulate contamination by microscopic sizing and counting.

2 Measurement of pressure difference

Where a difference in air pressure is to be maintained between adjacent areas of different classification, this should be measured in accordance with appendix B of BS 5295-1:1989 (withdrawn), which is reproduced in annex A of this Published Document.

3 Measurement of filter performance

3.1 General

Where filter installation leaks are to be measured, this should be carried out in accordance with appendix C of BS 5295-1:1989 (withdrawn), which is reproduced in annex B of this Published Document.

3.2 Requirements prior to installation

In order to maintain the cleanliness level by filtration of all air before it enters the clean space, careful consideration needs to be given to the choice of filter medium, its housing and the frame into which it is installed. These should be well defined at the time of ordering.

BS 3928 is a volumetric test method commonly used in the United Kingdom for testing high efficiency filters. However, this test is not equivalent to the in situ tests described in BS 5295 and indeed filters certified by this method may not be suitable for the intended application or ensure the protection required. The BS 3928 test uses a sodium chloride aerosol, which may contaminate products.

BS 5295 only refers to single leaks found in applying the scan method. For this purpose, the magnitude of a leak is defined as the ratio between the downstream aerosol concentration and the upstream aerosol concentration expressed as a percentage for any single leak at the filter face.

Care and attention is therefore required when considering:

- a) filter leakage and penetration;
- b) filter test requirements (see **D.3** of BS 5295-2:1989);
- c) filter sealing arrangement;
- d) filter sizes and forms of construction;
- e) regulatory requirements.

These requirements should be clearly identified on all requisitions or orders to ensure compatibility with application and to avoid inappropriate filters being specified.

When specifying a filter size, it is a commonly accepted practice to quote "height by width by depth". Failure to observe this system can often result in a filter of inappropriate dimensions being supplied.

With regard to the measurement of pressure difference across filters or banks of filters, the HEPA filter differential pressure gauge may for most purposes be assumed to indicate the upstream pressure.

A general rule of thumb is to change a filter when its differential pressure increases to 2.5 to 3 times its initial differential pressure.

Whilst HEPA filtration can be operated at a range of discharge velocities and although some applications may require a lower velocity, 0.45 m/s is generally accepted as standard. Most filter manufacturers refer to this velocity when providing data on their products. An average differential pressure necessary to achieve a 0.45 m/s discharge velocity from a volumetrically tested filter found to be equal to or greater than 99.997 % efficient at 0.3 μm nominal particle size will be in the region of 120 Pa to 130 Pa. Similarly, for a HEPA filter working at an efficiency of equal to or greater than 99.9998 % at 0.12 μm , a differential pressure of about 165 Pa to 170 Pa will be needed.

A higher face velocity will require a higher upstream pressure.

NOTE An increase in differential pressure may affect the filter penetration.

The velocity criterion will affect the design of the higher pressure zones between fan and filter; and the fan selection. It should be noted, however, that the high pressure zone may experience pressures between 375 Pa and 510 Pa (or higher, should the initial face velocity be greater than 0.45 m/s) in the period prior to a filter change.

With regard to the testing of installed high efficiency filters with a test aerosol in accordance with appendix C of BS 5295-1:1989 (withdrawn), the test facilities required to create an aerosol test are:

- a) aerosol injection point or port;

NOTE 1 A port should be of sufficient size to enable the entry of the requisite challenge aerosol to achieve the required upstream concentration.

- b) upstream concentration measurement port;

NOTE 2 Items a) and b), if directly into ductwork, will require to be sealed when not in use.

- c) clear access to the filter face and filter seals and any ductwork that may be exposed within the clean area.

The aim of an aerosol test is to ensure that leakage through the filter installation(s) does not exceed that required according to table 3 of **C.6** of BS 5295-1:1989 (withdrawn).

Important. All air should pass through the HEPA filtration system before entering the clean air space. Aerosol testing of HEPA filters is addressed in **3.3** below.

3.3 Requirements for testing — Considerations with respect to appendix C of BS 5295-1:1989

3.3.1 Aerosol injection (see figure 1)

3.3.1.1 It is essential that the aerosol is injected on the dirty side of the filter sufficiently far upstream to ensure good mixing. The test relies on a homogeneous distribution of aerosol across the whole filter face.

For ducted systems, typical distances for good mixing in straight ducts are 15-20 duct diameters from the filter face. Where this cannot be achieved, the aerosol should be distributed evenly across the intake using an injection grid and blower.

3.3.1.2 The upstream aerosol challenge should be measured as close as possible to, and ideally not more than 50 mm from the front of the filter, to be sure of a sufficient upstream concentration for the test. This should be between 50 µg and 100 µg/l.

Systems which do not have the facility to measure this upstream concentration cannot be tested as described herein unless some other provision is made to accurately establish the upstream concentration.

3.3.1.3 Equipment claimed to be in accordance with the provisions of this Published Document should be fitted with appropriate upstream sample ports. Where applicable in ducted systems, suitable injection ports may also be fitted. When used, it is essential that injection ports allow sufficient aerosol to be injected into the system under test.

Aerosols introduced into ducted systems may result in uneven distribution to individual filters. In these cases upstream sample ports are the only method of ensuring correct upstream challenge.

Care is essential when injecting into long ducted systems with distribution legs along the main duct (see figure 2). Good mixing will not occur unless distance D is about 20 duct diameters. In practice, the first filters will receive considerably less aerosol challenge than those further down the system, if sufficient mixing has not occurred.

The test results in cases of inadequate upstream concentration sampling may be such that some filters pass while other filters fail what the tester believes to be a common test.

3.3.1.4 Where aerosol challenge is fed into the intakes of an air conditioning unit, it should be checked that the air handler unit has its refrigeration, heating and humidification circuits switched off to avoid attenuation of the aerosol challenge.

3.3.1.5 The aerosol should not be pre-filtered. Any pre-filters between the injection point and the HEPA filter(s) should therefore be removed prior to test.

3.3.2 Aerosol challenge (see figure 2)

3.3.2.1 Each filter requires an upstream aerosol challenge of between 50 µg and 100 µg per litre of air passing through the filter.

To calculate the aerosol generator output to achieve this upstream concentration for each filter, the flowrate (Q) of air passing through each filter, in m³/hour, needs to be calculated, as follows:

$$Q = V \times A \times 3600$$

where

A is the area of the filter in m²;

V is the average velocity in m/sec.

Then the air flow rate, in l/min, Q_L , needs to be calculated as follows:

$$Q_L = Q \times 1000/60$$

The concentration (C) of aerosol in the air, in µg/l, is then determined from the following equation.

$$C = \frac{M_g \times 10^6}{Q_L}$$

where

M_g is the aerosol generator output in grams per minute.

Thus the required aerosol generator output may be calculated as follows.

$$M_g = \frac{C \times Q_L}{10^6}$$

Where more than one filter is used, the total aerosol challenge is determined by summing M_g for all filters.

3.3.2.2 After checking against the aerosol generator output curve/graph (see figure 3), adjust the generator output controls to the settings calculated. Should the aerosol generator not have an output graph, its controls should be adjusted in increments from the minimum to the maximum setting, allowing approximately 60 s between adjustments and upstream sampling carried out after each adjustment. Using a photometer calibrated in µg/l to sample the upstream concentration, the aerosol generator can be adjusted until the correct upstream aerosol challenge is established.

NOTE 1 When monitoring the upstream challenge with the aerosol photometer, sampling times should be no longer than 10-15 s, with 15 s between samples. If the photometer is exposed to high aerosol concentrations for long periods, its accuracy may be impaired.