

In situ aerosol testing of HEPA filtration

An explanatory supplement to BS 5295 : Part 1 : 1989

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

This Published Document has been prepared by Technical Committee LBI/30.

BS 5295 : Part 1 : 1989 specifies arrangements and test equipment for in situ HEPA filtration testing. However, it does not fully explain the application, possible areas of error and methods of ensuring accurate repeatability of testing.

Publication of this document was deemed necessary to reduce the incidence of incorrect specification of HEPA filters, seals and housings and incorrect testing. The document should enable an end user to create a test procedure which ensures repeatability of testing.

To facilitate its use, clause 5 and appendix C of BS 5295 : Part 1 : 1989 are reproduced within this Published Document.

Guide

Introduction

In situ HEPA filtration testing requires a complete understanding of the test method and how it can be applied to the testing of the installed systems.

This document is intended to eliminate some of the irregularities of practice and variability of results that occur with on site testing during different inspections.

This document does not, however, remove from the specifier or the specifier's purchasing agent(s) the requirement for correct selection of filter media and test requirements.

1 Scope

This Published Document provides information supplementary to the provisions of BS 5295 : Part 1. In particular it gives explanatory guidance on meeting the requirements of clause 5 of BS 5295 : Part 1.

2 Requirements prior to installation — Considerations with respect to clause 5 of BS 5295 : Part 1 : 1989

NOTE. Clause 5 of BS 5295 : Part 1 : 1989 is reproduced in annex A.

2.1 Subclause 5.1 : requirement for filtration

Subclause 5.1 appears self explanatory and is the leading requirement for creating the quality of the clean air found in the clean space. Careful consideration therefore 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 also D.3 of BS 5295 : Part 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.

2.2 Subclause 5.2 : requirement for provision of pressure differential indication across HEPA filter

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.

2.3 Subclause 5.3 : requirement for testing facilities for installed filters

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.

