SLOVENSKI STANDARD
SIST EN 13328-1:2002

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Sistem dihalnih filtrov za anestezijsko in dihalno uporabo ï 1. del: Preskusna metoda s soljo za ocenitev uļ inkovitosti filtracije

Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance

Filter für Atemsysteme zur Anwendung bei Anästhesie une Beatmung - Teil 1: Prüfverfahren mit Salzpartikeln zur Bewertung der Filterleistung

Filtres des sytemes respiratoires utilsés en anesthésie et soins respiratoires - Partie 1: Méthode d'essai avec une solution saline pour l'évaluation des performances de filtration

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ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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EUROPEAN STANDARD

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English version

Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance

This European Standard was approved by CEN on 29 June 2001.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2002, and conflicting national standards shall be withdrawn at the latest by June 2002.
This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this standard.

EN 13328 consists of the following parts under the general title *Breathing system filters for anaesthetic and respiratory use :*

— *Part 1 : Salt test method to assess filtration performance*

— *Part 2 : Non-filtration aspects*

EN 13328-1 gives a test method for the assessment of the filtration performance of breathing system filters (BSFs) for anaesthetic and respiratory use. The method is based on the USA National Institute for Occupational Safety and Health (NIOSH) method for Respiratory Protective Devices (42 CFR Part 84) [1] and uses sodium chloride particles.

Annex A is normative and forms part of this European Standard. Annexes B, C and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard gives a method of test for assessing the filtration performance of breathing system filters (BSFs).

BSFs are used to reduce the number of particulates, including micro-organisms, in gases delivered to, and exhaled from, patients.

BSFs are exposed to various levels of humidity during clinical use. Exposure of the BSF to humidified air to simulate clinical use forms part of this method (see Annex A), as it is possible that such exposure can influence the filtration performance of the BSF.

In the test, the BSF is challenged with sodium chloride particles of the particle size range that is considered to be the most penetrating i.e. 0,1 µm to 0,3 µm (see Annex B).

Experience gained in testing filters for respiratory protective devices has shown that by using a test aerosol of the most penetrating size range, the greatest penetration through the filter will be shown compared to any size aerosol. Therefore it is not necessary to subject the filter to a bio-aerosol as a condition of test.

It is recognized that transmission of micro-organisms across a filter can occur due to "channelling" and "grow through". There are at present no accepted methods to quantify this occurrence. This test method is for comparison purposes only and has no proven clinical relevance. The results are specific to the test method and no risk factor should be derived from it.

1 Scope

This part of this European Standard establishes a short-term airborne sodium chloride particle challenge test method for assessing the filtration performance of breathing system filters (BSFs) intended for the filtration of respired gases in humans. The test method is intended for BSFs used with a clinical breathing system.

It is not intended for other types of filter e.g. those designed to protect vacuum sources or gas sample lines, to filter compressed gases, to protect test equipment or for physiological respiratory measurements.

NOTE Non-filtration aspects of BSFs are addressed in prEN 13328-2.

2 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply:

2.1
breathing system filter
device intended to reduce transmission of particulates including micro-organisms in breathing systems

NOTE Referred to in this European Standard as 'BSF', (plural 'BSFs').

2.2
challenge concentration
C
concentration of sodium chloride particles in the airstream as it enters the BSF

2.3
penetration concentration
P
concentration of sodium chloride particles in the airstream leaving the BSF

2.4
penetration value
PV
concentration of sodium chloride particles passing through the BSF as a percentage of the concentration in the challenge

2.5
filtration efficiency percent
100 minus the penetration value

3 Test method

3.1 Principle

3.1.1. The ability of a BSF to remove particles is measured by nebulizing a sodium chloride solution into an airstream and passing the aerosol produced by the nebulizer through the BSF. Annex B gives a further explanation of the particle size terminology.

3.1.2 The generation of aerosols from a nebulizer produces particles that are charged electrostatically. The magnitude of the charge is reduced by mixing the airstream containing the particles with an ionized flow of air so that, when the two flows are mixed, the particles are neutralized to the Boltzmann equilibrium state.

3.1.3 The flows chosen for testing represent the typical flows likely to be encountered during the intended use of the BSF.

3.1.4 The performance of the BSF is assessed by measuring the penetration concentration of sodium chloride particles in the airstream leaving the BSF and comparing this with the challenge concentration in the airstream entering the BSF. BSFs are tested in the unused state as removed from their packaging and after conditioning to simulate clinical use.

3.2 Test conditions

The ambient conditions during the tests shall be:

- temperature: (23 ± 2) °C;
- relative humidity: (60 ± 15) %;
- pressure: (96 ± 10) kPa.

3.3 Apparatus

3.3.1 Flowmeter, with an error limit of ± 5 % of the actual value to be measured.

3.3.2 Sodium chloride aerosol generator, capable of generating an aerosol at (25 ± 5) °C and relative humidity of (30 ± 10) % with a concentration from 10 $mg \cdot m^{-3}$ to 20 $mg \cdot m^{-3}$ which has been neutralized to the Boltzmann equilibrium state.

NOTE Suitable equipment is Model 8118A sodium chloride aerosol generator, TSI Inc., PO Box 64394, St. Paul, MN 55164, USA.[1)]

3.3.3 Scanning mobility particle sizer, or equivalent instrument.

NOTE Suitable equipment is Model 3936 scanning mobility particle sizer, TSI Inc., PO Box 64394, St. Paul, MN 55164, USA.[1)]

3.3.4 Suitable forward-light-scattering photometer, or equivalent instrument.

NOTE Suitable equipment is Model AFT 8130, TSI Inc., PO Box 64394, St. Paul, MN 55164, USA.[1)]

[1)] This information is given for the convenience of users of this standard and does not constitute an endorsement by CEN of the product named.

3.4 Conditioning of BSFs

Condition the BSF in accordance with annex A.

3.5 Sample size

The BSF manufacturer shall document the rationale for the test BSF sample size chosen in order to demonstrate the filtration efficiency of the BSF.

3.6 Procedure

NOTE Rationales for various aspects of this method are given in annex C.

3.6.1 Set the flow through the test apparatus (see Figure 1) to the appropriate value for the intended use of the BSF given in Table 1, using the flowmeter (3.3.1).

3.6.2 Using the aerosol generator (3.3.2), generate a sodium chloride aerosol at (25 ± 5) °C and relative humidity of (30 ± 10) % with a concentration from 10 $mg \cdot m^{-3}$ to 20 $mg \cdot m^{-3}$ which has been neutralized to the Boltzmann equilibrium state.

3.6.3 Using the scanning mobility particle sizer (3.3.3), confirm that the sodium chloride test aerosol has a particle size distribution with a count median diameter of (0,075 ± 0,020) µm and a geometric standard deviation not exceeding 1,86 at the specified test conditions.

NOTE 1 A particle size distribution with a count median diameter of 0,075 µm and a geometric standard deviation of 1,86 has a mass median aerodynamic diameter (MMAD) of 0,26 µm. See annex B.

NOTE 2 This is a calibration step and only needs to be performed as recommended by the manufacturer of the test equipment.

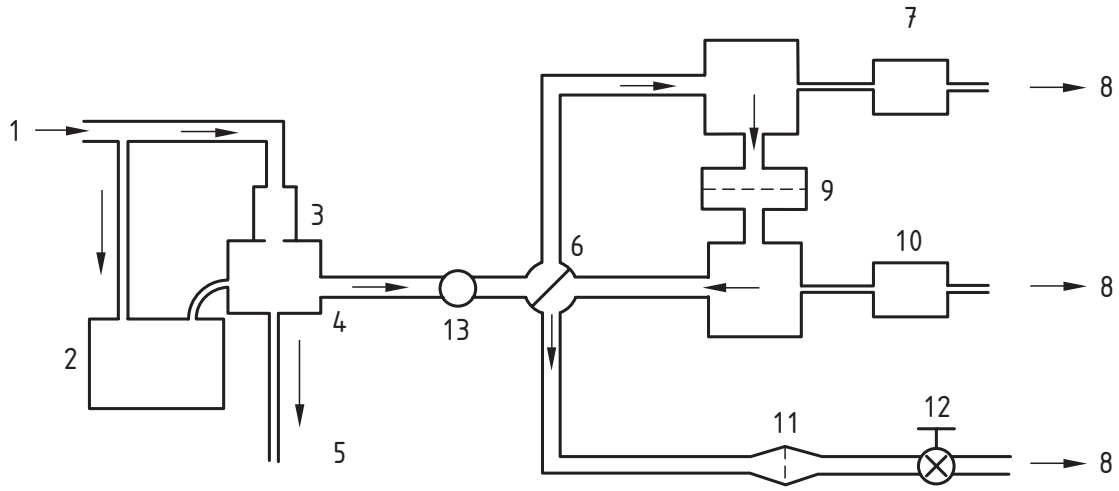
3.6.4 Without a BSF attached, interconnect the two photometers (3.3.4) and measure the challenge concentration at the upstream photometer. Check that the challenge concentration at the downstream photometer is ± 2,5 % of this value each time the apparatus is switched on, when the airflow is changed and after the BSF sample size (3.5) has been tested.

3.6.5 Fit a BSF in the unconditioned state to the test apparatus. Test the BSF using the flow direction stated by the manufacturer. If the flow direction is not stated, perform the test with the airstream entering the BSF at the machine port.

3.6.6 Repeat 3.6.2.

3.6.7 Measure the challenge concentration (*C*) and penetration concentration (*P*) whilst continuing the test until an aerosol mass of (0,2 ± 0,1) mg for adult BSFs or (0,1 ± 0,05) mg for paediatric BSFs has contacted the BSF.

3.6.8 Repeat 3.6.5 to 3.6.7 using a BSF in the conditioned state (see 3.4).



Key

1 Compressed air
2 Aerosol generator
3 Neutralizer
4 Mixing chamber
5 Exhaust
6 Switching valve
7 Upstream photometer
8 To vacuum
9 BSF under test
10 Downstream photometer
11 Flowmeter
12 Flow control valve
13 Position for scanning mobility particle sizer, when used

Figure 1 - Apparatus for testing BSF

4 Calculation and expression of test results

For the BSFs tested, calculate the penetration value (*PV*) from the following expression:

$$PV = P/C \times 100$$

where

P is the penetration concentration, determined in accordance with 3.6;

C is the challenge concentration, determined in accordance with 3.6.

Table 1 – Flow rates for testing BSFs

BSF intended use	Flow rate $l \cdot min^{-1}$
paediatric	15
adult	30