

Hingamissüsteemi filtrid tuimastuseks ja respiratoorseks kasutuseks. Osa 1: Soolakatsemeetod filtreerimisjõudluse hindamiseks

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 13328-1:2002 sisaldab Euroopa standardi EN 13328-1:2001 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 16.01.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 13328-1:2002 consists of the English text of the European standard EN 13328-1:2001.</p> <p>This document is endorsed on 16.01.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: This Standard establishes a short-term airborne sodium particle challenge test method for assessing the filtration performance of breathing systems filters (BSFs) intended for the filtration of respired gases in humans.</p>	<p>Scope: This Standard establishes a short-term airborne sodium particle challenge test method for assessing the filtration performance of breathing systems filters (BSFs) intended for the filtration of respired gases in humans.</p>
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Võtmesõnad: anaesthetic equipment, asf, breathing equipment, definition, definitions, filters, gas filters, medical technology, medicine, particle filters, rating tests, specification (approval), specifications, testing

ICS 11.040.10

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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