SLOVENSKI STANDARD
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Sistem dihalnih filtrov za anestezijsko in dihalno uporabo - 2. del: Nefiltracijski vidiki

Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects

Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung - Teil 2: Aspekte, die nicht die Filtration betreffen

Filtres pour systemes respiratoires utilisés en anesthésie et soins respiratoires - Partie 2: Propriétés autres que la filtration

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Filter für Atemsysteme zur Anwendung bei Anästhesie und Beatmung - Teil 2: Aspekte, die nicht die Filtration betreffen

This European Standard was approved by CEN on 8 August 2002.

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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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Contents

Foreword

This document (EN 13328-2:2002) 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of an identical text or by endorsement, at the latest by May 2003, and conflicting national standards shall be withdrawn at the latest by May 2003.

This document 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 document.

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*

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This Part of this European Standard specifies requirements for non-filtration aspects of breathing system filters (BSFs) intended for the filtration of respired gases in humans when used with a breathing system. It addresses connection ports, leakage, resistance to flow, packaging, marking and information supplied.

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 used for physiological respiratory measurements.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 556-1, Sterilization of medical devices – Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices

EN 868-1, Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods

EN 980, Graphical symbols for use in the labelling of medical devices

EN 1281-1, Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

EN 1281-2, Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:1987 modified)

EN 13328-1:2001, Breathing system filters for anaesthetic and respiratory use – Part 1: Salt test method to assess filtration performance

EN 60601-1, Medical electrical equipment — Part 1: General requirements for safety

EN ISO 9360-1, Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)

3 Terms and definitions

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

3.1
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').

3.2
BSF breathing system port
port of the BSF that connects to the breathing system

3.3
BSF patient connection port
port of the BSF intended for connection to devices such as a tracheal or tracheostomy tube connector or a face mask

3.4
BSF accessory port
port of the BSF intended for connection to an accessory device for purposes such as gas sampling, monitoring and pressure measurement

3.5
BSF internal volume
volume contained within the BSF when unpressurized, minus the volume of all solid elements within the BSF and the volume inside all female connectors.

4 BSF port connectors

4.1 Breathing system and patient connection ports

The connectors at the breathing system port and the patient connection port shall comply with EN 1281-1.

4.2 Accessory ports

If the BSF incorporates any accessory ports, those ports shall not accept 15 mm or 22 mm conical connectors that comply with EN 1281-1 or EN 1281-2 and shall be provided with a means of closure of the ports.

NOTE See clause 8 j).

5 Test methods

5.1 Ambient conditions of test

Refer to EN 13328-1:2001, 3.2.

5.2 Measurement of pressure drop

The measurement of pressure drop shall be determined in accordance with EN ISO 9360-1, using the flow(s) given in table 1. The conditioning procedure in Annex A of EN 13328-1:2001 shall be used.

Table 1 — Flow for measurement of pressure drop

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

5.3 Test method for gas leakage

The BSF shall be tested for gas leakage as specified in EN ISO 9360-1. The conditioning procedure in Annex A of EN 13328-1:2001 shall be used.

6 Requirements for BSFs supplied sterile

6.1 Sterility assurance

BSFs supplied and marked as ‘STERILE’ shall satisfy the requirements of EN 556-1

6.2 Packaging of BSFs supplied sterile

The pack shall serve as an effective barrier to the penetration of micro-organisms and particulate material, in accordance with the relevant sections of EN 868-1.

7 Marking

7.1 Use of symbols

Some of the requirements of 7.3 and 7.4 can be met by use of appropriate symbols as given in EN 980.

7.2 Marking of BSF

BSF shall be marked with the following:

a) the direction of orientation towards the patient in the case of orientation-sensitive BSF;

b) the letters ‘APG’ (in accordance with EN 60601-1) if the manufacturer states that the BSF is safe for use with flammable anaesthetics.

7.3 Marking of package

The package shall be marked with the following:

a) the name and/or trademark of the manufacturer and/or supplier;

b) the intended use of the BSF;

c) the word ‘STERILE’ , if appropriate;

d) storage instructions;

e) Lot number or batch code;

f) use-by date, if the BSF is sensitive to storage or has a limited shelf-life.

7.4 BSF intended for single use

For BSF intended for single use, either the BSF or the package shall be marked with the words ‘single use’ or the equivalent.

8 Information to be provided by the manufacturer

The following information shall be provided by the manufacturer:

a) instructions for use;

b) the recommended range of tidal volumes and/or flow rates;

c) the pressure drops as measured in accordance with 5.1 and 5.2;

d) the internal volume of the BSF in millilitres;

e) the gas leakage, in millilitres per minute, measured as specified in 5.3;

f) if applicable, a warning of the hazards associated with the use of the BSF with any types of inhalants during inhalation therapy, anaesthetic gases and vapours, and humidifiers and nebulizers;

g) if the BSF or parts thereof are reusable, instructions for maintenance and details of cleaning, disinfection and sterilization;

h) recommended maximum time of use before either disposal or cleaning;

i) instructions for safe disposal after use ;

j) if the BSF is fitted with one or more Luer connectors, a warning highlighting the potential for inappropriate connection to other devices that can result in a patient hazard.