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Breathing system filters for anaesthetic and respiratory use —

Part 2: Non-filtration aspects

Filtres pour matériel d'anesthésie et de réanimation respiratoire —

Partie 2: Aspects autres que filtration

Reference number
ISO 23328-2:2002(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 23328 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 23328-2 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

ISO 23328 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*

Introduction

This part of ISO 23328 gives requirements for non-filtration aspects of breathing system filters (BSF).

BSF are used to reduce particulates, including microorganisms, in gases delivered to and exhaled from patients.

BSF are exposed to various levels of humidity during clinical use. Exposure of the BSF to humidified air to simulate clinical use forms part of the test method, as it is possible that such exposure can influence the filtration performance of the BSF. A test method to assess filtration performance is found in ISO 23328-1.

Breathing system filters for anaesthetic and respiratory use —

Part 2:
Non-filtration aspects

1 Scope

This part of ISO 23328 specifies requirements for non-filtration aspects of breathing system filters (BSF) intended for anaesthetic and respiratory use, and addresses connection ports, leakage, resistance to flow, packaging, marking and information supplied. The test method is intended for BSF used with a clinical breathing system.

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

NOTE A method for assessing filtration performance of BSF is given in ISO 23328-1.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 23328. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 23328 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 9360-1:2000, *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 11607, *Packaging for terminally sterilized medical devices*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*; Amendment 1:1991 and Amendment 2:1995

3 Terms and definitions

For the purposes of this part of ISO 23328, the following terms and definitions apply:

3.1
breathing system filter
BSF
device intended to reduce transmission of particulates, including microorganisms, in breathing systems

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 a device such as a tracheal or tracheostomy tube connector or a face mask

3.4
BSF accessory port
port of the BSF that can be connected to an accessory device for purposes such as gas sampling, monitoring and pressure measurement

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

3.8
pressure drop
difference between the pressure measured in a gas stream flowing into a BSF and the pressure measured in the gas stream flowing out of the BSF at a constant gas flowrate through the BSF

4 BSF port connectors

4.1 BSF breathing system and patient connection ports

The connectors at the breathing system port and the patient connection port shall comply with ISO 5356-1.

4.2 Accessory ports

If the BSF incorporates an accessory port, that port shall not accept 15 mm or 22 mm conical connectors that comply with ISO 5356-1 and ISO 5356-2 and shall be provided with means of closure of the port.

5 Test methods

5.1 Ambient conditions of test

The ambient conditions during the tests shall be:

— temperature: (23 ± 2) °C;

— relative humidity: (60 ± 15) % RH;

— pressure: (96 ± 10) kPa.

5.2 Measurement of pressure drop

The measurement of pressure drop shall be determined in accordance with 6.3 of ISO 9360-1:2000, using the flowrates given in Table 1.

Table 1 — Gas flowrates for measurement of pressure drop

BSF intended use	Flowrate $l \cdot min^{-1}$
Pediatric	15
Adult	30

5.3 Test for gas leakage

The BSF shall comply with 6.4 of ISO 9360-1:2000.

6 Packaging of sterile BSF

The packaging of BSF supplied sterile shall comply with the requirements of ISO 11607.

7 Marking

7.1 Use of symbols

Some of the requirements of 7.3 and 7.4 may be met by use of appropriate symbols as given in ISO 15223 or ISO 7000.

7.2 Marking of BSF

BSF shall be marked with the following:

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

b) the letters “APG” (see IEC 60601-1:1988) if the manufacturer states that the BSF is safe for use with flammable anesthetics.

7.3 Marking of package

The package shall be marked with the following:

a) the name or trademark and address of the manufacturer or supplier, or their authorized representative;

b) the intended use of the BSF;

c) the word “STERILE” (or the equivalent), if applicable;

d) storage instructions, if appropriate;

e) date of manufacture or lot number or batch number;

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.