

Breathing system filters for anaesthetic and respiratory use —

Part 1: Salt test method to assess filtration performance

ICS 11.040.10

National foreword

This British Standard is the UK implementation of EN ISO 23328-1:2008. It is identical with ISO 23328-1:2003. It supersedes BS EN 13328-1:2001 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/121, Anaesthetic and respiratory equipment, to Subcommittee CH/121/5, Lung ventilators, tracheal tubes and related equipment.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

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English Version

Breathing system filters for anaesthetic and respiratory use -
Part 1: Salt test method to assess filtration performance (ISO
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Filtres pour matériel d'anesthésie et de réanimation
respiratoire - Partie 1: Méthode d'essai à l'aide d'une
solution saline pour l'évaluation de l'efficacité de filtration
(ISO 23328-1:2003)

Filter für Atemsysteme zur Anwendung bei Anästhesie und
Beatmung - Teil 1: Prüfverfahren mit Salzpartikeln zur
Bewertung der Filterleistung (ISO 23328-1:2003)

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

Foreword

The text of ISO 23328-1:2003 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 23328-1:2008 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of an identical text or by endorsement, at the latest by September 2008, and conflicting national standards shall be withdrawn at the latest by September 2008.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13328-1:2001.

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 EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 23328-1:2003 has been approved by CEN as a EN ISO 23328-1:2008 without any modification.

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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 2.

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.

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ISO 23328-1 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 a method of test for assessing the filtration performance of breathing system filters (BSF).

BSF are used to reduce the number of 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 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 most penetrating size range, i.e. 0,1 μm to 0,3 μm (see Annex C).

It is recognized that transmission of microorganisms across a filter can occur due to “channeling” and “grow-through”. There are at present no accepted methods to quantify these occurrences. 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.