First edition 2002-10-15

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)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2002

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office Case postale 56 • CH-1211 Geneva 20 Tel. + 41 22 749 01 11 Fax + 41 22 749 09 47 E-mail copyright@iso.ch Web www.iso.ch

Printed in Switzerland

Contents

Forew	ordi	v
Introd	uction	v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4 4.1 4.2	BSF port connectors BSF breathing system and patient connection ports Accessory ports	2
5 5.1 5.2 5.3	Test methods Ambient conditions of test Measurement of pressure drop Test for gas leakage	2 2
6	Packaging of sterile BSF	3
7 7.1 7.2 7.3 7.4	Marking Use of symbols Marking of BSF Marking of package BSF intended for single use	3 3 3
8	Information to be provided by the manufacturer	4
Biblio	graphy	5

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.