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Breathing system filters for anaesthetic and respiratory use —

Part 1:
Salt test method to assess filtration performance

Filtres pour matériel d'anesthésie et de réanimation respiratoire —

Partie 1: Méthode d'essai saline pour l'évaluation de l'efficacité de filtration

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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.

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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.