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Gas mixers for medical use — Stand-alone gas mixers

Mélangeurs de gaz à usage médical — Mélangeurs de gaz indépendants

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This second edition cancels and replaces the first edition (ISO 11195:1995), which has been technically revised.

The main changes compared to the previous edition are as follows:

— scope has been amended by stating that this document applies to STAND-ALONE GAS MIXERS intended for mixing oxygen with another gas for medical use and that it excludes STAND-ALONE GAS MIXERS connected to an oxygen concentrator;

— definitions have been updated;

— requirements on ESSENTIAL PERFORMANCE have been identified;

— gas outlet connector has been specified for STAND-ALONE GAS MIXERS with an integral flow control;

— requirements for gas supply inlet pressure have been added;

— requirements on ALARM CONDITIONS have been amended;

— requirements on reverse gas flow have been amended;

— requirements on gas supply failure have been restructured and amended;

— requirements on marking and ACCOMPANYING DOCUMENTS have been amended.

Introduction

This document specifies basic requirements for STAND-ALONE GAS MIXERS intended for medical use. A known hazard associated with the use of STAND-ALONE GAS MIXERS is the reverse flow of gas from one gas inlet to another, resulting in the contamination of one gas supply system with another gas and the delivery of an incorrect gas mixture that can cause PATIENT injury. As a consequence of this hazard, particular attention has been paid in this document to minimizing reverse flow. It is recognized that innovations in design which offer performance advantages and yet may conflict with specific design aspects of this document may appear. Such innovations are not to be discouraged. If techniques and technologies advance beyond those in current usage, they should nevertheless meet the safety and performance requirements given in this document. If these techniques and technologies differ significantly from those specified, this document may be amended or revised to encompass them.

Rationales for some of the requirements of this document are given in Annex A. Such requirements are indicated by the asterisk (*) after the clause number in the main text.

In this document, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— *test methods: italic type*;

— TERMS DEFINED IN THIS DOCUMENT: SMALL CAPS.

The attention of member bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Gas mixers for medical use — Stand-alone gas mixers

1 Scope

This document specifies requirements for the performance and safety of STAND-ALONE GAS MIXERS intended for mixing oxygen with another gas for medical use.

This document does not apply to:

a) blocks of flowmeters with separate controls for the flow of each gas;

b) STAND-ALONE GAS MIXERS which mix oxygen with ambient air;

c) STAND-ALONE GAS MIXERS with more than two different gas inlets;

d) STAND-ALONE GAS MIXERS connected to an oxygen concentrator.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 11114-3, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test for non-metallic materials in oxygen atmosphere*

ISO 14971:2012[1)], *Medical devices — Application of risk management to medical devices*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

IEC 60601-1:2012[2)]+Amd 1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-8:2006[3)]+Amd 1:2012, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

EN 13544-2:2002, *Respiratory therapy equipment — Part 2: Tubing and connectors*

1) Under revision.

2) A consolidated edition, IEC 60601-1:2012, which includes IEC 60601-1:2005 and its amendment (IEC 60601-1:2005/Amd 1:2012) is available.

3) A consolidated edition, IEC 60601-1-8:2006, which includes IEC 60601-1-8:2006 and its amendment (IEC 60601-1-8:2006/Amd 1:2012) is available.