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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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Contents

Page

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.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

Note 1 to entry: An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.

Note 2 to entry: An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.

[SOURCE: IEC 60601-1-8:2006+Amd 1:2012, 3.1]

3.2
ALARM LIMIT
threshold used by the ALARM SYSTEM to determine an ALARM CONDITION

[SOURCE: IEC 60601-1-8:2006, 3.3]

3.3
ALARM SIGNAL
type of signal generated by an ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[SOURCE: IEC 60601-1-8:2006, 3.9]

3.4
ALARM SYSTEM
parts of ME equipment or ME system that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

Note 1 to entry: The abbreviated terms ME equipment and ME system stand for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEM, respectively.

[SOURCE: IEC 60601-1-8:2006, 3.11, modified — Note 1 to entry has been added.]

3.5
ESSENTIAL PERFORMANCE
performance necessary to achieve freedom from unacceptable RISK

Note 1 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

[SOURCE: IEC 60601-1:2005+Amd 1:2012, 3.27]

3.6
GAS-SPECIFIC
having characteristics which prevent connections between different gas services

[SOURCE: ISO 7396-1:2016, 3.17, modified — "or vacuum services" has been deleted.]

3.7
MEDICAL GAS PIPELINE SYSTEM
complete system which comprises a supply system, a monitoring and ALARM SYSTEM and a distribution system with terminal units at the points where medical gases or vacuum are required

[SOURCE: ISO 7396-1:2016, 3.36]

3.8
STAND-ALONE GAS MIXER
non-integrated device that can deliver an adjustable or fixed concentration of medical gas derived from two separate medical gas supplies

4 *Requirements for ESSENTIAL PERFORMANCE

ESSENTIAL PERFORMANCE requirements are found in the clauses listed in Table 1.

Table 1 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Clause
Maintaining the set concentration of oxygen, or generation of a TECHNICAL ALARM CONDITION	11, 12, 13
Maintaining the set flow, if applicable, or generation of a TECHNICAL ALARM CONDITION	11,13
Prevention of a hypoxic mixture or generation of a TECHNICAL ALARM CONDITION	11, 12, 13
Prevention of reverse gas flow from one inlet to the other	9

5 General requirements

5.1 RISK MANAGEMENT

This document specifies requirements that are generally applicable to RISKS associated with STAND-ALONE GAS MIXERS. An established RISK MANAGEMENT process complying with ISO 14971 shall be performed for the STAND-ALONE GAS MIXER and related accessories.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

5.2 Usability

The MANUFACTURER shall apply a usability engineering process to assess and mitigate any RISKS in NORMAL USE and use errors (see IEC 60601-1-6 and IEC 62366-1).

Check compliance by inspection of the USABILITY ENGINEERING FILE.

6 Materials

6.1 Biocompatibility

STAND-ALONE GAS MIXERS, in their ready-to-use state after any preparation recommended by the MANUFACTURER, shall satisfy the appropriate biocompatibility requirements (see ISO 18562 series).

Check compliance by inspection of the technical file.

6.2 Phthalates

MANUFACTURERS of STAND-ALONE GAS MIXERS intended for the treatment of children or pregnant or nursing women that include components made of materials that incorporate phthalates, which are classified as carcinogenic, mutagenic or toxic to reproduction, shall provide a specific justification for the use of these substances in their technical file. See also 19.6 d) and 20.1 for additional marking and instructions for use requirements.

Check compliance by inspection of the marking, the instructions for use and the technical file.

6.3 Natural rubber (latex)

MANUFACTURERS of STAND-ALONE GAS MIXERS that include components made of materials that incorporate natural latex shall provide a specific justification for using these substances in their technical file. See also 19.6 e) and 20.1 for additional marking and instruction for use requirements.

Check compliance by inspection of the marking, the instructions for use and the technical file.

6.4 Effects of cleaning, disinfecting or sterilizing agents

The recommended cleaning, disinfecting or sterilizing agents shall not alter the specified performance of the device throughout the expected service life. See also 20.1 m).

Check compliance by inspection of the instructions for use and the technical file.

6.5 Gas compatibility

6.5.1 *The materials in contact with the gases, during NORMAL USE, shall be resistant to corrosion and compatible with oxygen and the other gases and their mixtures in the temperature range of −20 °C to +60 °C.

NOTE 1 Corrosion resistance includes resistance against moisture and surrounding materials.

NOTE 2 Compatibility with oxygen involves both combustibility and ease of ignition. Materials that burn in air burn violently in pure oxygen. Many materials that do not burn in air will do so in pure oxygen, particularly under pressure.

Similarly, materials that can be ignited in air require lower ignition energies in oxygen. Many such materials can be ignited by friction at a valve seat or by adiabatic compression produced when oxygen at high pressure is rapidly introduced into a system initially at low pressure.

NOTE 3 ISO 15001 contains information on selection of metallic and non-metallic materials and other aspects of compatibility of equipment with oxygen.

6.5.2 The auto-ignition temperature of the non-metallic components in contact with the gas, including the sealing materials and lubricants (if used), as determined in accordance with ISO 11114-3, shall be not lower than 160 °C.

Check compliance by inspection of the technical file.

NOTE 1 Regional or national regulations might require the provision of evidence to a competent authority or conformity assessment body (e.g. notified body in the European Economic Area) upon request.

NOTE 2 The maximum permitted operating temperature of tested material is 100 °C lower than the auto-ignition temperature at the corresponding oxygen pressure. This safety margin is necessary because it covers both an unforeseen increase in the operating temperature and the fact that the auto-ignition temperature is not a constant. Values of the auto-ignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

6.5.3 Springs, highly strained components and parts liable to wear which come in contact with the gas shall not be plated.

NOTE Plating could come off.

Check compliance by inspection of the technical file.

6.6 Cleanliness

Components of STAND-ALONE GAS MIXERS in contact with medical gases during NORMAL USE shall meet the cleanliness requirements of ISO 15001.

Check compliance by inspection of the technical file.

6.7 Lubricants

If lubricants are used, they shall be compatible with oxygen, the other medical gases and their mixtures in the temperature range specified in 6.5.1 up to the test pressure of 1 000 kPa.

Check compliance by inspection of the technical file.

7 Normal operating conditions

Normal operating conditions shall be with the STAND-ALONE GAS MIXER connected to the inlet gas supplies at all pressures and pressure differentials in the range stated by the MANUFACTURER [see 20.2 p)] and at any setting of the STAND-ALONE GAS MIXER control with either flow or no-flow conditions.

8 Requirements for gas supply inlet pressure

The STAND-ALONE GAS MIXER shall operate and meet the requirements of this document throughout the RATED range of gas supply inlet pressures and shall not cause an unacceptable RISK under the SINGLE FAULT CONDITION to a maximum pressure of 1 000 kPa (10 bar).

If the STAND-ALONE GAS MIXER is intended to be connected to either

— a MEDICAL GAS PIPELINE SYSTEM complying with ISO 7396-1 via terminal units complying with ISO 9170-1 and flexible hose connections complying with ISO 5359, or

— a pressure regulator complying with ISO 10524-1, then

the RATED range of gas supply inlet pressures shall cover the range specified in those standards.

NOTE Internal pressure regulators can be required to accommodate the RATED range of gas supply inlet pressure and the SINGLE FAULT CONDITION of maximum gas supply inlet pressure.

The gas shall continue to flow to the PATIENT under a SINGLE FAULT CONDITION of overpressure. Under this condition the flowrate may be out of specification.

Check compliance by functional testing in normal operating condition with the most adverse operating settings and inspection of the technical file.

9 Reverse gas flow

The reverse flow of gas from one gas inlet to the other shall not exceed 10 ml/h under normal operating conditions and SINGLE FAULT CONDITION.

*The MANUFACTURER shall maintain documentation of methods by which compliance with this requirement has been verified, together with data supporting the validity of the methods.