INTERNATIONAL STANDARD

ISO 11195

Second edition
2018-01

Gas mixers for medical use — Stand-alone gas mixers

Mélangeurs de gaz à usage médical — Mélangeurs de gaz indépendants

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Reference number
ISO 11195:2018(E)

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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.

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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.

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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.

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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.]

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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.

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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.

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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.

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Check compliance by functional testing, inspection of the technical file and the instructions for use [see 20.1 b)].

10 *Leakage to atmosphere

STAND-ALONE GAS MIXERS shall not leak to atmosphere by more than 50 ml/min.

NOTE This does not include gas vented to atmosphere by design

Gas vented to atmosphere by design (bleed flow) shall be restricted to oxygen and/or air.

Check compliance by the test given in B.2.

11 ALARM SYSTEMS

11.1 Electrically powered ALARM SYSTEM

If an ALARM SYSTEM is electrically powered it shall:

a) comply with IEC 60601-1-8;

b) indicate if the SUPPLY MAINS has failed;

c) if equipped with a reserve electrical power source, provide an indication that it is operating from the reserve electrical power source.

Check compliance by inspection and functional testing.

11.2 Non-electrically powered ALARM SYSTEM

A non-electrically powered ALARM SYSTEM shall generate auditory ALARM SIGNALS with an A-weighted sound pressure level at least 2 dB above a background white noise level of 55 dB as measured by the method of ISO 3744.

Check compliance by inspection and functional testing with the method of ISO 3744.

11.3 High pressure ALARM CONDITION

The STAND-ALONE GAS MIXER shall generate an ALARM SIGNAL to indicate when the gas supply inlet pressure from either gas has exceeded the maximum pressure specified in the technical description [see 20.2 p)].

The STAND-ALONE GAS MIXER need not be equipped with a high-pressure ALARM SIGNAL if the STAND-ALONE GAS MIXER is capable of working with at least twice the RATED MAXIMUM DISTRIBUTION PRESSURE provided by a MEDICAL GAS PIPELINE SYSTEM.

NOTE The MAXIMUM DISTRIBUTION PRESSURE specified in ISO 7396-1 is 500 kPa.

The ALARM SIGNAL shall be auditory and either electrically powered or non-electrically powered. If electrically powered it shall be of at least MEDIUM PRIORITY.

Check compliance by inspection and functional testing.

11.4 Differential pressure ALARM CONDITION

If the differential pressure can affect the performance of the STAND-ALONE GAS MIXER, an ALARM SIGNAL shall be generated when the gas supply inlet pressure differential has exceeded the range specified in the technical description [see 20.2 p)].

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The ALARM SIGNAL shall be auditory and either electrically powered or non-electrically powered. If electrically powered it shall be of at least MEDIUM PRIORITY.

Check compliance by functional testing and inspection of the technical file.

11.5 Gas supply failure ALARM CONDITION

11.5.1 The STAND-ALONE GAS MIXER shall be equipped with an ALARM SYSTEM that detects when a failure of any one gas supply occurs, whether the supply is derived from cylinders or from a MEDICAL GAS PIPELINE SYSTEM, and generates an ALARM SIGNAL. The ALARM SIGNAL shall be activated when the gas supply pressure reaches the ALARM LIMIT stated by the MANUFACTURER [see 20.1 d)].

Check compliance by functional testing.

The ALARM SIGNAL shall be auditory and either electrically powered or non-electrically powered. If electrically powered, it shall be of HIGH PRIORITY.

Check compliance by inspection of the technical file.

If the ALARM SIGNAL is gas-powered, it shall be powered by either

a) the oxygen or air supply of an oxygen and air STAND-ALONE GAS MIXER, or

b) the oxygen supply alone for a STAND-ALONE GAS MIXER of oxygen and any other medical gas.

Check compliance by functional testing.

The auditory ALARM SIGNAL shall be automatically de-activated when the gas supply pressure is restored.

Check compliance by functional testing.

11.5.2 *The auditory ALARM SIGNAL, for STAND-ALONE GAS MIXERS designed for attended use shall be of at least 7 s duration and for unattended use of at least 60 s.

Check compliance by the tests given in B.3.

11.5.3 For a STAND-ALONE GAS MIXER intended for mixing oxygen and air the OPERATOR may initiate AUDIO OFF, for gas supply failure, after activation of the alarm.

Check compliance by inspection and functional testing.

11.5.4 For a STAND-ALONE GAS MIXER intended for mixing oxygen and any other gas, it shall not be possible to initiate AUDIO OFF for gas supply failure, after activation of the alarm without restoring the gas supply pressure to above the ALARM LIMIT.

Check compliance by inspection and functional testing.

12 *Accuracy of indicated oxygen concentration

12.1 The oxygen concentration of the delivered gas shall:

a) be within ±5 % (*V*/*V*) of the indicated value over the RATED range, as specified in the instructions for use, of:

   1) gas supply inlet pressure [see 20.1 o)];

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2) operating temperature, ambient pressure and humidity [see 20.1 p)];

b) not result in a delivered oxygen concentration of less than 20 % (*V/V*).

The accuracy requirement shall apply only to marked concentration values and need not apply between markings, unless otherwise indicated in the instructions for use.

Check compliance by the test given in B.1.

12.2 The STAND-ALONE GAS MIXER shall continue to function within the specified tolerances of oxygen concentration throughout the RATED range of gas supply inlet pressures and gas flowrates, as specified in the instructions for use. See 20.1 n) to o).

13 Gas supply failure

13.1 Oxygen

13.1.1 If the oxygen supply pressure falls below the ALARM LIMIT stated in the instructions for use [see 20.1 d)] an ALARM SIGNAL shall be activated and the supply of the other gas (except air) shall be cut off.

Check compliance by functional testing using the test method given in the instructions for use [see 20.1 e)].

13.1.2 Gases shall not be cut off before the gas supply failure alarm is activated.

Check compliance by functional testing using the test method given in the instructions for use [see 20.1 e)].

The sole means of resetting the gas cut-off device shall be the restoration of the oxygen supply pressure to a level above that at which the gas cut-off device is activated.

Check compliance by functional testing using the test method given in the instructions for use [see 20.1 e)].

13.2 Other medical gas (except air)

If the other medical gas supply pressure falls below the ALARM LIMIT stated in the instructions for use [see 20.1 d)], the flow of oxygen shall be maintained.

Check compliance by functional testing using the test method given in the instructions for use [see 20.1 e)].

13.3 Air/Oxygen

If the oxygen or air supply pressure for air/oxygen STAND-ALONE GAS MIXERS falls below the ALARM LIMIT stated in the instructions for use [see 20.1 d)], the flow of the remaining gas shall be maintained.

Check compliance by functional testing using the test method given in the instructions for use [see 20.1 e)].

14 Gas connectors

14.1 Inlet connectors

The inlet connectors shall be GAS-SPECIFIC and compatible with the outlet connectors specified in ISO 5359:2014, 4.6.8.3.

Check compliance by inspection of the technical file.

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14.2 *Outlet connectors

If the STAND-ALONE GAS MIXER has an integral flow control the outlet connector shall be a weight-bearing screw- threaded connector for oxygen complying with EN 13544-2:2002, Figure B.1.

NOTE In view of the many combinations of gases, the oxygen connector was chosen.

Check compliance by inspection of the technical file.

15 Inlet filter

Each gas inlet shall be provided with a filter having a pore size not exceeding 100 µm.

Check compliance by inspection and inspection of the technical file.

16 Flow controls

For a rotary flow adjustment control, a counter-clockwise rotation shall cause an increase in flow and, conversely, a clockwise rotation shall cause a decrease in flow.

The stem of a rotary flow control valve shall be captive, so that it cannot be disengaged from its housing without the use of a tool.

Check compliance by functional testing.

17 Low-pressure hose assemblies

Low-pressure hose assemblies to connect the STAND-ALONE GAS MIXER to a MEDICAL GAS PIPELINE SYSTEM or a pressure regulator on a medical gas cylinder shall comply with ISO 5359.

Check compliance by the tests given in ISO 5359.

18 Electrical safety

STAND-ALONE GAS MIXERS with electrically powered components (e.g. the gas supply failure alarm), shall comply with IEC 60601-1:2005+Amd 1:2012.

Check compliance by the tests in IEC 60601-1:2005+Amd 1:2012.

19 Marking

19.1 Each gas inlet shall be clearly marked with the name or the chemical symbol of the gas in accordance with ISO 5359. If colour coding is used in addition, the colour shall be in accordance with ISO 5359.

Check compliance by inspection and the tests given in ISO 5359.

19.2 The gas outlet(s) shall be clearly marked.

Check compliance by inspection.

19.3 If the STAND-ALONE GAS MIXER has more than one outlet capable of delivering gas of different compositions, the gas outlets shall be clearly marked with the names or chemical symbols of the gases that may be delivered.

Check compliance by inspection.

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19.4 The concentration adjustment control shall indicate the concentration of oxygen in units of percent (*V/V*) in the delivered gas with a mark at least every 10 % between 20 % (*V/V*) and 100 % (*V/V*).

Check compliance by inspection and testing in accordance with B.1.

19.5 The concentration adjustment control or its surroundings shall be legibly marked with the name or chemical symbol of the gases being mixed in accordance with ISO 5359. If colour coding is used in addition to identify the gases, the colour shall be in accordance with ISO 5359.

Check compliance by inspection and the tests described in ISO 5359.

19.6 The STAND-ALONE GAS MIXER shall be marked with the following:

a) a warning to consult the instructions for use (e.g. ISO 15223-1:2016, symbol 5.4.3);

b) the name or trade name and address of the MANUFACTURER or supplier; in addition, where applicable, the name and address of the authorized representative;

c) the batch code, preceded by the word "LOT", or the serial number (e.g. ISO 15223-1:2016, symbol 5.1.5, 5.1.6 or 5.1.7);

d) if appropriate, an indication that phthalates are present in the device;

EXAMPLE Symbol given in EN 15986.

e) if appropriate, an indication that natural rubber (latex) is present;

EXAMPLE ISO 15223-1:2016, symbol 5.4.5.

Check compliance by inspection.

19.7 Durability of marking

The marking on STAND-ALONE GAS MIXERS shall be durable.

Check compliance by the requirements and tests described in IEC 60601-1:2005+Amd 1:2012, 7.1.3.

20 ACCOMPANYING DOCUMENTS

20.1 Instructions for use

In addition to the information given in 19.6, the instructions for use shall include the following:

a) a warning to the effect that for a STAND-ALONE GAS MIXER with a gas supply failure ALARM SIGNAL shorter than 60 s, the STAND-ALONE GAS MIXER shall be constantly attended during use;

b) instructions for assembly of the STAND-ALONE GAS MIXER, connection of gas supplies and functional testing, including checking the reverse gas flow requirements of Clause 9, together with the intervals between such testing;

c) a recommended test procedure and interval for checking the oxygen concentration of the delivered gas, using an oxygen monitor complying with ISO 80601-2-55 (see Figure 1 for an example of a test arrangement);

d) a statement of the operating pressures of the gas supply failure alarm and the associated cut-off device(s) including, as applicable:

1) the ALARM LIMIT for the pressure of the oxygen supply at which the supply of other medical gases apart from air will be cut off;

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2) the ALARM LIMIT for the supply pressure of other medical gases apart from air at which the STAND-ALONE GAS MIXER shall maintain the flow of oxygen (see 13.2);

3) the ALARM LIMIT for the oxygen or air supply pressure at which the flow of the remaining gas shall be maintained;

e) the methods of testing the function of the ALARM SYSTEM and cut-off device(s);

f) a statement that the STAND-ALONE GAS MIXER should be checked by a qualified technician at the intervals recommended by the MANUFACTURER;

g) a warning that the STAND-ALONE GAS MIXER is not suitable for use with Oxygen 93;

h) instructions for any maintenance that is required to be performed by the OPERATOR;

i) any special storage and/or handling conditions;

j) any special operating instructions;

k) any warnings and/or precautions to take;

l) year of manufacture; this indication may be included in the batch or serial number;

m) instructions for cleaning, disinfecting and, if applicable, sterilization;

n) the maximum input flow required by the STAND-ALONE GAS MIXER for each gas;

o) the maximum and minimum gas supply inlet pressure;

p) the operating temperature, ambient pressure and humidity;

q) the minimum and maximum output flow;

r) the characteristics of a bleed flow if used;

s) a warning to the effect that bleed oxygen flow can cause ignitions;

t) if there is an integrated flowmeter, the accuracy for the range of concentrations of the different gases.

It is recommended that the instructions for use include any relevant information on physical performance of the liquids/gases in different environmental circumstances as well as the impact of these situations on agent performance and/or potency.

Check compliance by inspection.

20.2 Technical description

The technical description shall include at least the following:

a) the pressure and flow characteristics of the delivered gas at the maximum and minimum gas supply inlet pressures ;

b) the test method used to confirm compliance with the reverse gas flow requirement given in Clause 9;

c) the range of usable output flows from the STAND-ALONE GAS MIXER;

d) the effects on the delivered gas characteristics of gas supply inlet pressures of between 0 and 1,5 times the design inlet pressures [see 20.2 a)];

e) a statement of the dryness specification required for all gases supplied to the STAND-ALONE GAS MIXER expressed in units of milligrams of water per cubic metre of gas and, in addition, for compressed air and nitrous oxide, as the dew point in degrees Celsius at the maximum gas supply inlet pressure;

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f) a statement of the composition and cleanliness specification required for all gases supplied to the STAND-ALONE GAS MIXER;

g) a list of all replaceable parts with their part numbers and their recommended replacement intervals;

h) a schematic flow diagram;

i) if applicable, a statement that all OPERATOR-detachable inlet pressure hoses supplied with the STAND-ALONE GAS MIXER comply with ISO 5359;

j) a statement of the opening pressure characteristics of all pressure-relief valves fitted to the STAND-ALONE GAS MIXER (if applicable);

k) the RATED RANGE of the oxygen concentration of the delivered gas;

l) the characteristics of a bleed flow if used;

m) the recommended test methods of measurement of flow, pressure and oxygen concentration of the delivered gas;

n) a statement that the STAND-ALONE GAS MIXER has been degreased for oxygen service prior to delivery;

o) a statement of the spatial orientation for use of the STAND-ALONE GAS MIXER if the orientation can affect the performance or safety of the STAND-ALONE GAS MIXER;

p) the range of gas supply inlet pressures including pressure differentials necessary for normal operation;

q) a list of recommended lubricants;

r) a statement of the range and accuracy of the flow controller (if fitted).

Check compliance by inspection.

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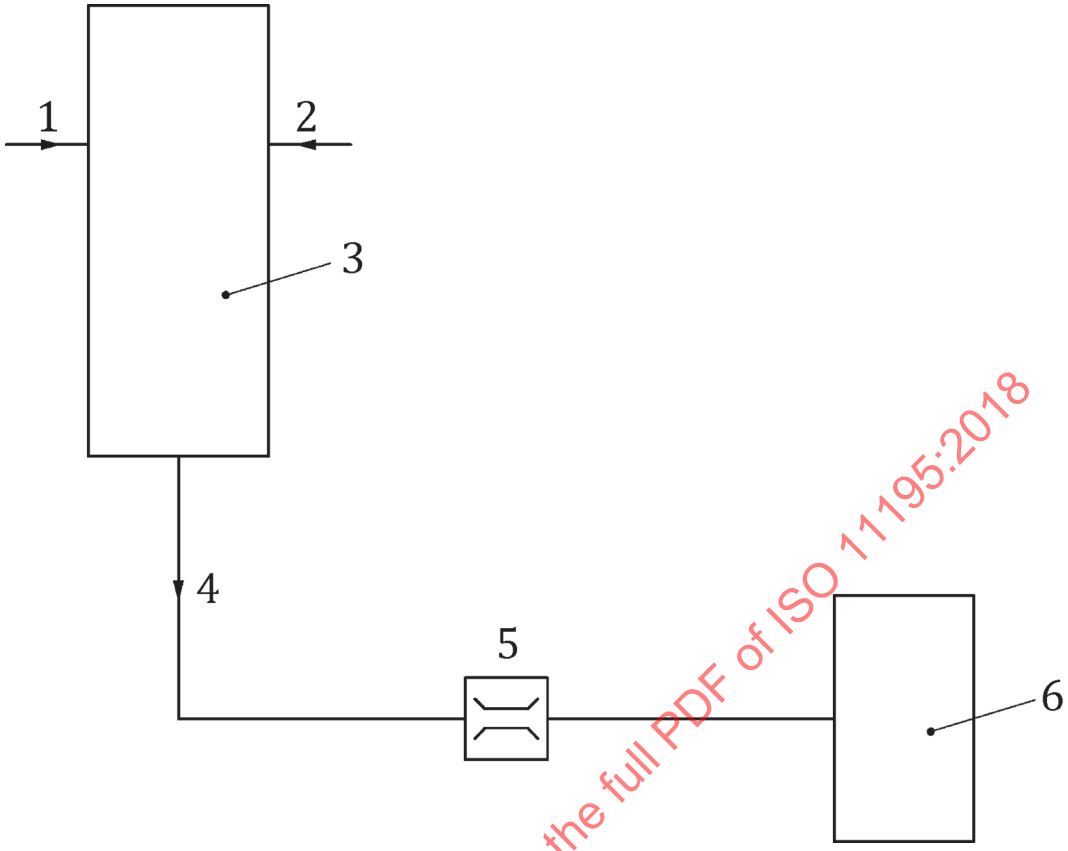

Key

1 gas input 1
2 gas input 2
3 STAND-ALONE GAS MIXER under test
4 gas output
5 flowmeter
6 oxygen monitor complying with ISO 80601-2-55

Figure 1 — Example of test arrangement for checking the oxygen concentration of the delivered gas

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Annex A
(informative)

Rationale

A.1 General

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.2 Requirements for ESSENTIAL PERFORMANCE (Clause 4)

If the set concentration or the set flow is not constant, then there is a RISK to the wellbeing of the PATIENT.

Delivery of a hypoxic mixture, particularly pertinent when mixing oxygen and nitrous oxide, is unacceptable as this would cause extreme harm to the PATIENT and is therefore an ESSENTIAL PERFORMANCE requirement.

A.3 Materials — Gas compatibility (6.5.1)

The ergonomics, technical simplicity, potential portability and clinical utility of STAND-ALONE GAS MIXERS create the potential for these products to be used over a wide environmental range. In some cases, the performance specifications of the device (see Clause 6) have a wider range than that of the delivered drug product or mixture. This is particularly true under different operating conditions (e.g. altitude, back of ambulance left outside overnight, hyperbaric chamber, etc.). Similarly, mixed gases can separate at low temperatures.

A.4 Reverse gas flow (Clause 9)

The reverse gas flow from each gas inlet to every other gas inlet under normal operating conditions has been limited to the very low value of 10 ml/h, which is a value comparable to that given in standards for pressure regulators. The value for reverse gas flow can be achieved by designs which step down the pressure from the gas supply inlet pressure to a lower pressure at which the gas is mixed.

Attention needs to be given to the possibility of reverse gas flow occurring in alarm or bypass circuits under SINGLE FAULT CONDITIONS.

A reverse flow of 10 ml/h over a 72-hour weekend would result in less than 1 l of contaminant gas in a pipeline. This volume is considered to be a minimal hazard.

Because no one single test that would adequately cover all STAND-ALONE GAS MIXERS could be specified, the MANUFACTURER should make available documentation that the methods used and the resulting data are valid to prove compliance with Clause 9 to, for example, notified bodies/test houses for conformity assessment or to competent authorities/regulatory bodies upon request.

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