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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.

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.

International Standard ISO 11195 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

Annex A forms an integral part of this International Standard. Annex B is for information only.

Introduction

This International Standard specifies basic requirements for stand-alone gas mixers intended for medical use. A known hazard associated with the use of 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 International Standard to minimizing reverse flow. It is recognized that innovations in design may appear which offer performance advantages and yet may conflict with specific design aspects of this International Standard. 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 International Standard. If these techniques and technologies differ significantly from those specified, this International Standard may be amended or revised to encompass them.

Gas mixers for medical use — Stand-alone gas mixers

1 Scope

This International Standard gives requirements for the performance and safety of stand-alone gas mixers intended for medical use and intended for connection to a medical gas supply system. Rationales for some of the requirements are given in annex B.

This International Standard does not apply to

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

b) gas mixers which mix oxygen with ambient air;

c) gas mixers which depend on other medical devices for functions required by this standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 3744:1994, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Engineering method in an essentially free field over a reflecting plane.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 7767:1988, *Oxygen analyzers for monitoring patient breathing mixtures — Safety requirements.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 stand-alone gas mixer; gas mixer: Device which receives separate supplies of oxygen and other medical gas(es) and which delivers the mixed gases in concentrations adjustable by the operator and which is not an integral component of any other medical device.

3.2 medical gas supply system

(1) Non-flammable medical gas pipeline system comprising a central supply system, control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases or vacuum may be required.

(2) Any other installation having no permanent pipeline system but employing a medical gas supply source complete with pressure regulators.

3.3 gas-specific: Having characteristics which prevent interchangeability, thereby allowing assignment to one gas or vacuum service only.

3.4 alarm: Indicator of an abnormal state or output of a gas mixer.

4 Gas connectors

Gas inlet connectors shall be gas-specific and shall be either screw-threaded (i.e. NIST or DISS) or quick-connect; they shall comply with ISO 5359.

NOTE 1 The outlet connector is not specified because of the diversity of application of gas mixers.

5 Normal operating conditions

5.1 Normal operating conditions shall be with the gas mixer connected to inlet gas supplies at all pressures and pressure differentials in the range stated by the manufacturer and at any setting of the mixer control with either flow or no-flow conditions.

5.2 The gas mixer shall have an auditory alarm to indicate that the inlet pressure conditions are outside the range of normal operating conditions specified by the manufacturer [see 15.2 p)]. If electrically powered, the alarm signal shall be a medium priority alarm complying with ISO 9703-2.

NOTE 2 The gas mixer need not be provided with a high-pressure alarm if the upper limit of the input pressure specified by the manufacturer is higher than the normal maximum pressure provided by a medical gas pipeline. The maximum gas pressure which a medical gas pipeline conforming with ISO 7396:1987, *Non-flammable medical gas pipeline systems*, will deliver in normal use is proposed, in the forthcoming new edition, to be 600 kPa.

6 Reverse gas flow

6.1 Means shall be provided so that the reverse flow of gas from each gas inlet to every other shall not exceed 10 ml/h (0,0169 kPa l/min) under normal operating conditions or under any single fault condition which is not alarmed. Test according to A.3.

6.2 Means shall be provided so that the reverse gas flow from each gas inlet to every other shall not exceed 100 ml/min (0,13 kPa l/min) during any single fault condition which is indicated by an alarm. Test according to A.3.

6.3 The manufacturer shall maintain documentation of methods by which compliance with 6.1 and 6.2 has been verified, together with data supporting the validity of the methods.

7 Inlet filter

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

8 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 each rotary flow control valve shall be captive, so that it cannot be disengaged from its housing without the use of tools.

9 Leakage to atmosphere

Except for gas which is vented (bled) from the mixer by design, gas mixers shall not leak to atmosphere by more than 50 ml/min (5,065 kPa l/min) when tested according to A.4.

10 Low-pressure flexible connecting hose assemblies

All external, operator-detachable inlet low-pressure hose assemblies supplied with the gas mixer shall comply with ISO 5359.

11 Accuracy of operating data

11.1 When tested according to A.2, the oxygen concentration of the delivered gas shall be within ± 5 % (*V/V*) of the indicated value. The tolerance shall not result in an oxygen concentration of less than 20 % (*V/V*). The accuracy requirement shall apply only to marked concentration values and not between markings, unless otherwise stated by the manufacturer.

11.2 When tested according to A.2, the gas mixer shall continue to function within the specified tolerances throughout the range of input pressure variation stated by the manufacturer [see 15.2 a)].

12 Gas supply failure

12.1 Gas supply failure alarm

NOTE 3 See also 15.1 e).

12.1.1 General

12.1.1.1 The gas mixer shall have an alarm to indicate failure of any one gas supply, whether the supply is derived from cylinders or from a pipeline system. This alarm shall be either gas-powered or electrically-powered. If electrically-powered, it shall comply with the requirements for a high priority alarm given in ISO 9703-1 and ISO 9703-2. The auditory alarm shall be automatically de-activated when the gas supply is restored.

12.1.1.2 Electrically-powered alarms shall be operative in the case of electrical power failure, except when an electrical power failure alarm is fitted. Means shall be provided for testing the alarm systems.

12.1.1.3 When tested in accordance with A.1, the alarm shall be activated at the gas supply pressure stated by the manufacturer [see 15.1 e)].

12.1.2 Gas mixers intended for mixing oxygen and nitrous oxide

12.1.2.1 When tested in accordance with A.5, the auditory alarm shall be of at least 7 s duration and, when tested as described in ISO 3744, its A-weighted sound pressure level shall be at least 2 dB above a background white noise of 55 dB.

12.1.2.2 If the alarm is gas-powered, the energy required to operate it shall be derived from the oxygen supply pressure.

12.1.2.3 It shall not be possible to shut off or re-set the alarm without first restoring the gas supply pressure to above the alarm point.

12.1.3 Gas mixers intended for mixing oxygen and any gas other than nitrous oxide

When tested in accordance with A.5, the auditory alarm shall be of at least 60 s duration and, when tested as described in ISO 3744, its A-weighted sound pressure level shall be at least 2 dB above a background white noise of 55 dB.

NOTE 4 The alarm may be silenced after activation.

12.2 Cut-off devices for gases other than air and oxygen in the event of oxygen supply failure

12.2.1 The gas mixer shall be fitted with a gas cut-off, which shall be activated when the oxygen supply pressure falls below the value stated in the instructions for use, and shall operate in one of the following ways:

a) cut off the supply of all gases other than air and oxygen; or

b) progressively reduce the flow of all other gases while maintaining the preset oxygen flow until the supply of oxygen finally fails, at which point the supply of all other gases shall be cut off; or

c) progressively reduce the flow of all other gases while maintaining the preset oxygen concentration until the oxygen finally fails, at which point the supply of all other gases shall be cut off.

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

12.2.3 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.

12.2.4 When tested in accordance with A.1, the gas cut-off device shall operate at the gas supply pressure stated by the manufacturer [see 15.1 e)].

12.3 Failure of air or oxygen supply

For an air/oxygen gas mixer, when one gas fails the flow of the remaining gas shall be maintained.

12.4 Failure of supply of gases other than air with oxygen

For a gas mixer capable of mixing a gas other than air with oxygen, when the supply of that gas fails the gas mixer shall deliver 100 % oxygen.

12.5 Restoration of gas mixer output

The sole means of restoring the gas mixer output following failure of the gas supply shall be the restoration of the gas supply pressure.

13 Electrical safety

If the gas mixer has electrically-powered components (e.g. the gas supply failure alarm), the gas mixer shall comply with IEC 601-1.

14 Marking

14.1 Each gas inlet shall be clearly and durably 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 32.

14.2 The gas outlet(s) shall be clearly and durably marked "outlet".

14.3 If the gas mixer has more than one outlet capable of delivering gas of different composition, the gas outlets shall be clearly and durably marked with the names or chemical symbols of the gases that may be delivered.

14.4 The concentration adjustment control(s) shall indicate the concentration of oxygen in units of percent (*V*/*V*) in the delivered gas and shall comply with 11.1.

14.5 The concentration adjustment control(s) or its surroundings shall be clearly and permanently marked in accordance with ISO 5359 with the name or chemical symbol of the gases being mixed. If colour coding is used in addition to identify the gases, the colours shall be in accordance with ISO 32.

14.6 The gas mixer shall be marked with

a) symbol 14 of appendix D of IEC 601-1:1988;

b) the name or trademark of the manufacturer or supplier;

c) the serial number or other means of traceability.

15 Accompanying documents

15.1 Instructions for use

The instructions for use shall include the following:

a) instructions for assembly of the gas mixer, connection of gas supplies and functional testing, including checking the reverse gas flow requirements of 6.1 and 6.2, together with the intervals between such testing;

b) a recommended test procedure for checking the oxygen concentration of the delivered gas, using an oxygen monitor complying with ISO 7767 (see figure 1 for an example of a test arrangement);

c) a statement recommending the use of an oxygen monitor whenever the gas mixer is in use;

d) the statement "Before use on a patient, the oxygen concentration of the delivered gas should be checked at the setting intended for use.";

e) a statement of the operating pressures of the gas supply failure alarm and the associated cut-off device(s);

f) the methods of testing the function of the alarm system and cut-off device(s);

g) a statement that the gas mixer should be checked by a qualified technician at the intervals recommended by the manufacturer;

h) instructions for any maintenance that is required to be performed by the user.

15.2 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 inlet pressures recommended by the manufacturer;

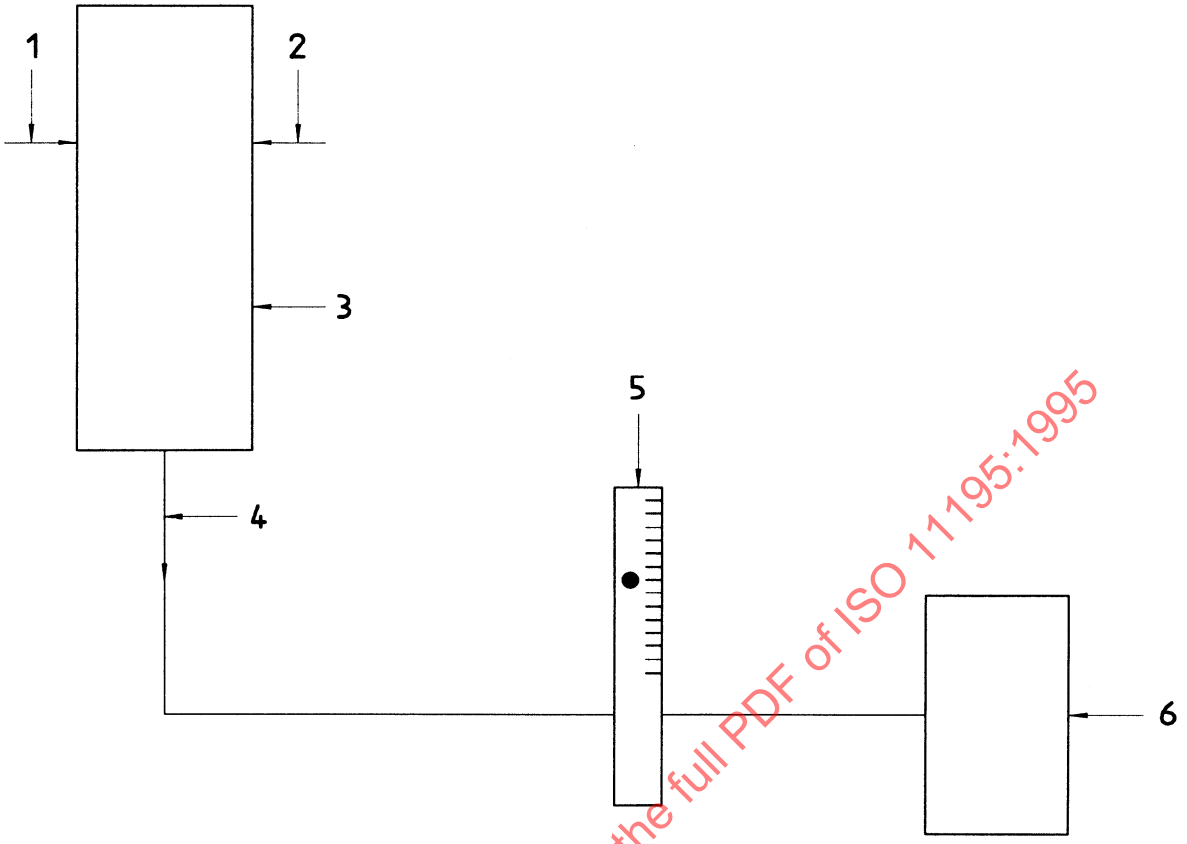
b) a statement that the reverse gas flow complies with the requirements of clause 6;

c) the range of usable output flows from the gas mixer;

d) the effects on the delivered gas characteristics of input pressures of between 0 and 1,5 times the design input pressures [see 15.2 a)];

e) a statement of the dryness specification required for all gases supplied to the 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 dewpoint in degrees Celsius at the maximum input pressure;

f) a statement of the composition and cleanliness specification required for all gases supplied to the gas mixer;



Key

1 Gas input 1
2 Gas input 2
3 Gas mixer under test
4 Gas output
5 Flowmeter
6 Oxygen monitor complying with ISO 7767

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

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

h) a schematic flow diagram;

i) a statement that all operator-detachable inlet pressure hoses supplied with the gas mixer comply with ISO 5359;

j) a statement of the opening pressure characteristics of all pressure relief valves fitted to the gas mixer;

k) a statement of the accuracy of the oxygen concentration of the delivered gas;

l) a statement of the amount of any vented gas flow (bleed gas flow);

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

n) a statement that the gas mixer has been degreased for oxygen service prior to delivery;

o) a statement of the spatial orientation for use of the gas mixer if the orientation may affect the performance or safety of the gas mixer;

p) the range of gas supply pressures necessary for normal operation;

q) use of appropriate lubricants.

Annex A
(normative)

Test methods for alarm system, delivered gas and leakage to atmosphere

A.1 Test of alarm system

Test the function of the alarm system and cut-off device(s) in accordance with the procedures given by the manufacturer [see 15.1 f)].

A.2 Test of delivered gas

Measure the flow, pressure and oxygen concentration of the delivered gas at the maximum and minimum input pressures specified by the manufacturer, using the test methods stated by the manufacturer [see 15.2 m)].

A.3 Reverse gas flow test

Verify that the requirements of 6.1 and 6.2 are met using the procedures given by the manufacturer [see 6.3 and 15.1 a)].

A.4 Leakage to atmosphere

A.4.1 Set up the gas mixer with the low-pressure flexible connecting assemblies (hose assemblies) supplied by the manufacturer. Occlude the gas outlet.

A.4.2 Connect all the hose assemblies to gas sources at the maximum inlet pressure(s) specified by the manufacturer.

A.4.3 Immerse the gas mixer and the hose assemblies in water and examine for leaks. Collect (e.g. in a bell jar) for a suitable time any gas that leaks continuously, and measure the volume to an accuracy of ± 10 %.

A.4.4 Correct the total leakage from the gas mixer and the hose assemblies to 20 °C and 101,3 kPa. Do not apply any correction for solubility in water.

A.4.5 Repeat the test at maximum, minimum and mean concentration settings on the gas mixer.

A.5 Duration of gas supply failure alarms

A.5.1 Set up the gas mixer with the low-pressure flexible connecting assemblies (hose assemblies) supplied by the manufacturer.

A.5.2 Connect the oxygen hose assembly to a source of oxygen at the minimum input pressure recommended by the manufacturer.

A.5.3 Disconnect the oxygen hose assembly at the source (not at the gas mixer) and at the same time start a stopwatch.

A.5.4 Measure the time taken for the A-weighted sound pressure level to fall below 57 dB.

Annex B
(informative)

Rationales

B.1 General

This annex provides concise rationales for the important requirements of this International Standard and is intended for those who are familiar with the subject of the Standard but have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for the proper application of this Standard. The clause numbers in this annex refer to the clauses of the Standard.

B.2 Scope (clause 1)

This International Standard does not apply to gas mixers which are incorporated into other medical equipment such as anaesthetic machines or lung ventilators. The clauses in this Standard have been reviewed to assess their relevance to non-stand-alone gas mixers. Clauses and subclauses 5, 6, 8, 9, 11, 12.2, 12.3, 12.4, 13, 14.4 and 15.1 b) to 15.1 h) are always applicable to non-stand-alone gas mixers. Clause 7 and subclause 12.1 are applicable but the location is not specified. Subclause 15.2 is not always applicable. Clauses 4, 10, 14 (except 14.4) and 15.1 a) do not apply.

B.3 Gas connectors (clause 4)

Gas mixers are used for many different applications which require different outlet connectors on the gas mixer. The user should be free to choose outlet connectors which are appropriate for the intended use.

B.4 Normal operating conditions (clause 5)

Subclause 5.1 The condition of no gas outflow frequently occurs during normal use and is therefore a normal operating condition. In this condition the gas mixer should meet the requirements for minimum reverse gas flow.

Subclause 5.2 The normal range of input pressures should match the range of input pressures provided by medical gas supply systems. The design characteristics of gas mixers may require that the range of input pressures is restricted. In order to avoid possible malfunction of the gas mixer at pressures outside the manufacturer's specified ranges, alarms should be provided to indicate that the restricted range of input pressures has been exceeded.

B.5 Reverse gas flow (clause 6)

Subclause 6.1 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 (0,0169 kPa l/min) 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 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-h weekend would result in less than 1 l of contaminant gas in a pipeline. This volume is considered to be a minimal hazard.

Subclause 6.2 When operating conditions fall outside the normal range, alarms should be generated by the gas mixer. Alarms may also be generated by the gas mixer during single fault conditions. In the presence of such alarms a higher value of reverse gas flow may be accepted on the assumption that intervention by the user will occur in a short time.

Subclause 6.3 Because no one single test could be specified that would adequately cover all gas mixers, the manufacturer should make available documentation that the methods used and the resulting data are valid to prove compliance with 6.1 and 6.2 to, for example, notified bodies/test houses for conformity assessment or to competent authorities/regulatory bodies upon request.

B.6 Leakage to atmosphere (clause 9)

The intention of this clause is to limit the total leakage of nitrous oxide to the atmosphere. Pollution levels

from nitrous oxide are a matter of concern in the hospital environment.

B.7 Accuracy of operating data (clause 11)

The accuracy specification for the oxygen concentration delivered by the gas mixer of ± 5 % (*V/V*) of the indicated value has been endorsed by clinicians from several countries. The lower limit of 20 % oxygen (*V/V*) is also clinically approved.

B.8 Gas supply failure alarms (12.1.2 and 12.1.3)

Subclauses 12.1.2 and 12.1.3 specify the duration of auditory alarms for gas supply failure. In the case of gas mixers for oxygen/nitrous oxide the duration is at least 7 s (12.1.2.1) while for all other gas mixers the duration is at least 60 s.

These differences reflect the operational requirements of gas mixers which are used in anaesthesia (oxygen/nitrous oxide) and in general use (oxygen/air).

For anaesthesia use it is considered that there will always be personnel in continuous close attendance to the gas mixer so that a long duration of alarm is not required. The minimum of 7 s which is specified can be powered by the residual gas in the oxygen supply in the case of oxygen failure. To avoid atmospheric pollution by nitrous oxide it is considered undesirable to power the alarm from the nitrous oxide supply.

The diverse uses of gas mixers for oxygen/air cannot be expected to necessitate personnel in close attendance. The duration of the alarm is therefore specified as a minimum of 60 s. In this case the alarm may be powered by any source, which will typically be the gas supply which has not failed.

B.9 Marking (14.2)

Subclause 14.2 The composition of the gas output is self-evident if there are only two gases being mixed. For those gas mixers which can be switched from nitrous oxide/oxygen to air/oxygen it is desirable that there be separate outlets, each clearly marked to avoid misconnection by the user.