American National Standard

ANSI/AAMI/ ISO 11195: 1995

Gas mixers for medical use—Stand-alone gas mixers

AAMI
Advancing Safety in Medical Technology

This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.

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Gas mixers for medical use – Stand-alone gas mixers

Approved as an American National Standard with deviations by:

ASTM International

ASTM Deviations to ISO 11195: 1995

Clause 2 - Normative references

Delete the following:

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

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.

Add the following:

CGA C-9: 1993 *Standard color marking of compressed gas containers intended for medical use.*

ASTM/ISO 5359:2003, Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.

ASTM/ISO 7767:2002, Oxygen analyzers for monitoring patient breathing mixtures - Safety requirements.

Rationale for ASTM International Deviations:
CGA C-9 contains the medical gas color code used in the United States, which is different from the medical gas color code established by ISO 32.

ASTM/ISO 5359:2003 is the recent adoption by ASTM International of the most current edition of ISO 5359. The ASTM International adoption of ISO 5359 includes deviations to reflect the requirements of low-pressure hose assemblies for use with medical gases in the United States.

ASTM/ISO 7767:2002 is the recent adoption by ASTM International of the most current edition of ISO 7767. The ASTM International adoption of ISO 7767 includes deviations to reflect the requirements of oxygen analyzers for monitoring patient breathing mixtures-safety requirements in the United States.

Clause 4 – Gas Connectors

Delete the following:
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.

Add the following:
Gas inlet connectors shall be gas-specific and comply with the applicable requirements of ASTM/ISO 5359:2003. If screw-threaded, the gas inlet connectors shall be DISS.

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

Rationale for ASTM International Deviation:
NIST connectors are not used in the United States.

Clause 10 – Low-pressure flexible connecting hose assemblies

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

Add the following:
All external, operator-detachable low-pressure hose assemblies supplied with the gas mixer shall comply with ASTM/ISO 5359:2003.

Rationale for ASTM International Deviation:
ASTM/ISO 5359:2003 is the recent adoption by ASTM International of the most current edition of ISO 5359. The ASTM International adoption of ISO 5359 includes deviations to reflect the requirements of low-pressure hose assemblies for use with medical gases in the United States.

Clause 14.1 - Marking

Delete the following:
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.

Add the following:
Each gas inlet shall be clearly and durably marked with the name or the chemical symbol of the gas in accordance with ASTM/ISO 5359:2003. If color coding is used in addition, the color shall be in accordance with CGA C-9:1993.

Rationale for ASTM International Deviation:
CGA C-9 contains the medical gas color code used in the United States, which is different from the medical gas color code established by ISO 32.

ASTM/ISO 5359:2003 is the recent adoption by ASTM International of the most current edition of ISO 5359. The ASTM International adoption of ISO 5359 includes deviations to reflect the requirements of low-pressure hose assemblies for use with medical gases in the United States.

Clause 14.5 - Markings

Delete the following:
The concentration adjustment control(s) or its surroundings shall be clearly and permanently marked in accordance with ISO 5359 with the names or chemical symbols 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.

Add the following:
The concentration adjustment control(s) or its surroundings shall be clearly and permanently marked in accordance with ASTM/ISO 5359:2003 with the name or chemical symbol of the gases being mixed. If color coding is used in addition to identify the gases, the colors shall be in accordance with CGA C-9:1993.

Rationale for ASTM International Deviation:
CGA C-9 establishes the medical gas color code used in the United States, which is different than the medical gas color code established by ISO 32.

ASTM/ISO 5359:2003 is the recent adoption by ASTM International of the most current edition of ISO 5359. The ASTM International adoption of ISO 5359 includes deviations to reflect the requirements of low-pressure hose assemblies for use with medical gases in the United States.

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

In the "Key" - Delete the following:
6 Oxygen monitor complying with ISO 7767

Add the following:
6 Oxygen monitor complying with ASTM/ISO 7767:2002

Rationale for ASTM International Deviation:
ASTM/ISO 7767:2002 is the recent adoption by ASTM International of the most current edition of ISO 7767. The ASTM International adoption of ISO 7767 includes deviations to reflect the requirements of oxygen analyzers for monitoring patient breathing mixtures-safety requirements in the United States.

Clause 15.2 Item i) – Technical documentation

Delete the following:
a statement that all operator-detachable inlet pressure hoses supplied with the gas mixer comply with ISO 5359;

Add the following:
a statement that all operator-detachable inlet pressure hoses supplied with the gas mixer comply with ASTM/ISO 5359:2003;

Rationale for ASTM International Deviation:
ASTM/ISO 5359:2003 is the recent adoption by ASTM International of the most current edition of ISO 5359. The ASTM International adoption of ISO 5359 includes deviations to reflect the requirements of low-pressure hose assemblies for use with medical gases in the United States.

INTERNATIONAL STANDARD

ISO 11195

First edition
1995-10-01

Gas mixers for medical use — Stand-alone gas mixers

Mélangeurs de gaz à usage médical — Mélangeurs de gaz indépendants

Reference number
ISO 11195:1995(E)

Contents

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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.