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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.