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Anaesthetic machines for use with humans

Appareils d'anesthésie pour utilisation chez l'homme



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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 5358 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

This second edition cancels and replaces the first edition (ISO 5358:1980), of which it constitutes a technical revision.

Annexes A, B, C and D form an integral part of this International Standard. Annex E is for information only.

Introduction

This International Standard specifies basic requirements for anaesthetic machines, particularly requirements for performance and safety. 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.

Attention is drawn to the International Standard for anaesthetic workstations in preparation by ISO/TC 121. When that International Standard is published, the status of ISO 5358 will be reviewed.

Anaesthetic machines for use with humans

1 Scope

This International Standard specifies basic requirements for anaesthetic machines and associated components thereof for use with humans. It includes requirements for anaesthetic vaporizers intended for incorporation into anaesthetic machines covered by this International Standard.

The following are outside the scope of this International Standard:

- a) anaesthetic machines which primarily depend on electric or electronic means for control or proper functioning;
- b) intermittent-flow anaesthetic machines which only deliver gas to the breathing system at varying rates in response to the patient's inspiratory efforts;
- c) dental nitrous oxide-oxygen analgesia machines.

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 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections*.

ISO 3744:1981, *Acoustics — Determination of sound power levels of noise sources — Engineering methods for free-field conditions over a reflecting plane*.

ISO 4135:1979, *Anaesthesiology — Vocabulary*.

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5356-2:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*.

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

ISO 7396:1987, *Non-flammable medical gas pipeline systems*.

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

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

3 Definitions

For the purposes of this International Standard, the definitions given in ISO 4135 and the following definitions apply.

3.1 anaesthetic machine: Equipment for dispensing and delivering medical and anaesthetic gases and vapours into a breathing system.

3.2 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.

3.3 machine gas piping: All pipework, including unions, from unidirectional valves in the pipeline inlets and from the outlets of the pressure regulators to the flow control system, as well as the piping connecting the flow control system and the piping connecting the vaporizers to the common gas outlet. It includes piping leading to and from pneumatic

alarm systems, gauges, oxygen flush and gas power outlets.

3.4 common gas outlet: That port through which the dispensed mixture from the anaesthetic apparatus is delivered to the breathing system.

3.5 flow control system: Device or assembly which controls and indicates the flow of gas.

3.6 flowmeter: Any device which indicates the volume of a specific gas passing through it in a unit of time.

3.7 pressure regulator: Gas pressure reducing and controlling device designed to provide a constant delivery (downstream) pressure over a range of variable inlet pressures and/or flows.

3.8 anaesthetic vaporizer: Device designed to facilitate the change of an anaesthetic agent from a liquid to a vapour.

3.9 vaporizer chamber: That part of a vaporizer where fresh gas becomes enriched or saturated with the vapour of the anaesthetic agent.

4 General

4.1 Anaesthetic machines should be designed to facilitate cleaning. All exposed surfaces should be able to withstand commonly used cleaning and disinfecting agents.

The suitability of materials should be assessed in respect of their compatibility with compressed oxygen and anaesthetic gases and vapours.

4.2 Anaesthetic machines shall comply with the following clauses of IEC 601-1:1988:

- a) clause 22 — Moving parts;
- b) clause 23 — Surfaces, corners and edges;
- c) clause 24 — Stability in normal use;
- d) clause 25 — Expelled parts;
- e) clause 28 — Suspended masses.

4.3 All controls and gauges shall be clearly visible, and all gauges shall be legible, to an operator having visual acuity, corrected if necessary, of at least 1 seated or standing 1 m in front of the anaesthetic machine at an illuminance of 215 lx.

The markings and graduations should be readily identifiable with the controls, gauges, meters or other indicators with which they are associated.

Flowmeters, gauges, controls and other displays that need to be read most frequently should be grouped together and should be placed as close as possible to the operator's field of vision when he/she is in the normal position for operating the anaesthetic machine and observing the patient.

4.4 Components which are intended to release anaesthetic gases or vapours during normal operation shall be provided with a means of collecting those gases for disposal via an anaesthetic gas scavenging system.

4.5 Except for vaporizers (see 13.2.11), if colour coding is used on the anaesthetic machine, it shall be in accordance with ISO 32, unless otherwise required by national regulations.

4.6 If the anaesthetic machine has built-in monitors, the monitors shall be enabled whenever the machine is enabled.

5 Medical gas cylinder connections

5.1 Medical gas cylinder connections shall be non-interchangeable between different gas services. All anaesthetic machines shall be provided with means of connection to a reserve oxygen supply.

5.2 Each cylinder connection or group of interconnected cylinder connections shall be provided with a filter having a pore size not exceeding 100 µm.

5.3 If medical gas cylinders have pin index yoke-type valve connections as specified in ISO 407, whether used as a service or reserve supply, they shall be connected to the anaesthetic machine by a corresponding pin indexed yoke.

If hanger yokes are provided, all yoke details, including the pin index safety system, shall be in accordance with ISO 407.

5.4 If two or more gas supply connections are provided for the same gas, means shall be provided to limit the leakage of gas to a flow not exceeding 100 ml/min, corrected to 20 °C and 101,3 kPa, from an open cylinder at a pressure of 15 MPa to any one of the following:

- a) an empty cylinder;
- b) through a cylinder connection to atmosphere;
- c) a pipeline supply.

5.5 Each cylinder connection shall be permanently and legibly marked with the name or chemical symbol of the corresponding gas.