INTERNATIONAL STANDARD

ISO 5358

Second edition
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Anaesthetic machines for use with humans

Appareils d'anesthésie pour utilisation chez l'homme

Reference number
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Contents

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Annexes

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.

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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.

6 Pipeline inlet connections

6.1 If the anaesthetic machine is intended for use with a medical gas pipeline system, the oxygen and nitrous oxide gas systems shall each include pipeline hose inlets for connection to pipelines specified in ISO 7396. These inlets shall be the body (see figure 1) of the fittings specified either in ISO 5359 or in appropriate national standards. Such inlet connections shall be non-interchangeable and gas-specific.

6.2 Unidirectional valves shall be provided such that the reverse flow of gases from the anaesthetic machine to the pipelines or to atmosphere, if yokes for cylinders are also provided, shall not exceed 50 ml/min, corrected to 20 °C and 101,3 kPa, at the design working pressure(s) in the machine gas piping.

6.3 If pipeline inlet connections for gases other than nitrous oxide and oxygen (outlet connections for vacuum) are provided, they shall be gas-specific.

7 Pressure gauges, and pressure and contents indicators

7.1 General

NOTE 1 Pressure gauges cannot indicate the contents of cylinders containing liquefied gas.

7.1.1 Except for cyclopropane, each gas supplied at cylinder pressure to the anaesthetic machine shall be monitored by a cylinder pressure gauge or contents indicator. The scale of the gauge or indicator shall extend to a pressure at least 33 % greater than either the filling pressure of the cylinder or the full indication position at a temperature of 20 °C ± 3 °C.

7.1.2 If only one gauge is provided for a group of connections, it shall be possible to open the cylinder valves in any sequence so that the pressure in separate cylinders can be determined.

If more than one gas cylinder connection is supplied for any gas, one gauge or contents indicator should be provided for each connection.

7.1.3 Gases supplied by pipeline from central supplies shall be monitored by pressure gauges or indicators. These gauges or indicators shall monitor the pressure of gas in the pipeline supply hoses upstream of the unidirectional valve (see 6.2). If a gauge is used, it shall be capable of indicating a pressure not less than 33 % greater than the pipeline design working pressure.

7.1.4 All cylinder and pipeline pressure gauges shall be graduated in units of kPa × 100 and the units shall be clearly marked on the dial (see 4.3).

Additional markings and units of graduation may be used.

7.1.5 The maximum error of all gauges and indicators shall not exceed ± 4 % of the full scale reading.

7.1.6 If, in a single-fault condition, the pressure on the pressure-sensing element can be conveyed to the gauge case or enclosure, the gauge shall be designed and constructed in such a manner that when a pressure equal to the maximum pressure indicated on the dial or display is applied to a gauge having the pressure-sensing element removed, no parts shall be expelled free of the gauge enclosure. The cases of such gauges shall have a means of venting, to prevent a build-up of pressure within the case.

Gauges may be furnished with restrictors in the inlet pressure connection.

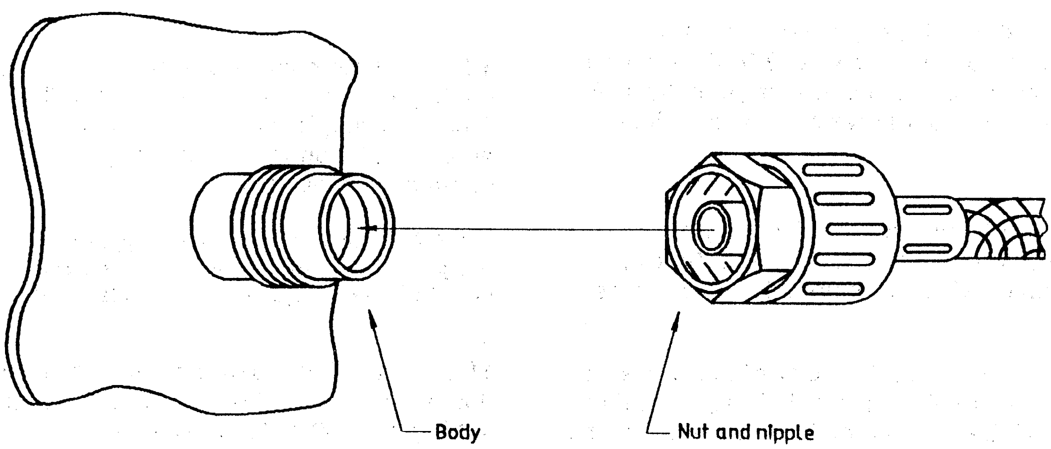

Figure 1 — Gas-specific connectors illustrating body and nut and nipple components

7.2 Gauges with analogue scales

7.2.1 All cylinder pressure gauges of a circular type on any individual anaesthetic machine shall have equal span angles to within ± 10°. The span angle, from the lowest pressure indication to the maximum pressure indication, shall be not less than 180° and not more than 300°, with the lowest pressure graduation mark at the same position between 6 o'clock and 9 o'clock on the dial.

7.2.2 The indicating end of the pointer shall be immediately apparent and shall contrast with the background. The pointer shall overlap but not obscure the scale marking. The tail end of the pointer shall be shorter than the indicating end and shall either blend with the background or be masked from view.

7.2.3 Analogue gauges shall have a scale length of not less than 50 mm and, if circular, shall be at least 38 mm in diameter. They shall be readily identifiable with the gas that they monitor.

8 Pressure regulators

8.1 There shall be an automatic pressure regulating system for each gas supplied to the anaesthetic machine from gas cylinder(s).

Each system may comprise either one automatic pressure regulator, or two or more automatic pressure regulators in series.

If the anaesthetic machine is connected to both the pipeline and a cylinder, the regulators should be set so that the anaesthetic machine uses the gas supply from the pipeline, when the pipeline is delivering at its rated value, in preference to other supplies that are connected to it.

8.2 With an indicated oxygen flow of 2 l/min, the time taken to restore the flow to 2 l/min ± 1 l/min after ten cycles of operating the oxygen flush for 10 s, with a pause of 5 s between flushes, shall not exceed 2 s.

8.3 A single regulator or the first regulator in a series shall be fitted with a relief valve that opens at not more than twice the nominal delivery pressure.

In a single-fault condition, the body of the pressure-regulating system shall maintain its integrity and the relief valve shall be capable of limiting the pressure in the system to not more than three times the nominal delivery pressure when the supply pressure is 50 % greater than the nominal maximum.

9 Machine gas piping

9.1 Machine gas piping shall withstand a pressure of at least twice its design working pressure without rupture.

9.2 Except for venting of air or oxygen from fluidic or pneumatic components, the leakage from that portion of the machine gas piping upstream of the flow control system shall not, at the design working pressure(s), exceed 25 ml/min corrected to 20 °C and 101,3 kPa for each gas service.

9.3 The leakage from that portion of the machine gas piping between the flow control system and the common gas outlet shall not, at a pressure of 3 kPa, exceed 50 ml/min corrected to 20 °C and 101,3 kPa for each gas service. This requirement shall be met under the following conditions:

a) with the vaporizer on;

b) with the vaporizer off;

c) if the anaesthetic machine is fitted with a user-detachable vaporizer, with the vaporizer removed.

9.4 Except where the connectors of gas piping are non-interchangeable, anaesthetic machine pipework shall be labelled at each junction, and where the piping joins a component, with the name, chemical symbol or other coding of the gas.

9.5 Gas system components, either separately or in combination, shall be compatible with the appropriate gas under the conditions of containment and use.

10 Flow control system

10.1 A flow control system shall be provided for each gas. To prevent incorrect adjustment of the flow of a single gas, there shall be only one flow adjustment control for each gas delivered to the common gas outlet.

NOTE 2 Devices to prevent hypoxic mixtures whereby oxygen is made to flow with other gas(es) are not considered to be flow adjustment controls.

10.2 Each flow control system shall maintain any flow within its graduated range to within ± 10 % of setting or ± 30 ml/min, whichever is the greater, for 10 min when the supply pressure and the pressure at the common gas outlet are varied within the range of pressures stated by the manufacturer.

10.3 Rotary flow adjustment controls shall continuously increase the gas flow when turned in an anti-clockwise direction and continuously decrease the gas flow when turned in a clockwise direction.

10.4 When the common gas outlet is venting to atmosphere, each rotary flow adjustment control, except those for carbon dioxide and cyclopropane, shall require rotation through at least 180° to adjust its associated flowmeter or flow indicator through the upper 90 % of the scale range.

10.5 The leakage through a rotary flow adjustment control or other device intended to shut off gas shall not exceed 5 ml/min at the design pressure.

NOTES

3 An increasing number of anaesthetic machines are being designed whereby the oxygen and nitrous oxide controls interact to prevent the oxygen concentration falling below 25 % (*V*/*V*) when these two gases only are in use.

4 Some anaesthetic machines may incorporate a minimum pre-set flow of oxygen.

10.6 Each flow adjustment control shall be adjacent to or readily identifiable with the flowmeter or flow indicator that it controls.

10.7 The flow adjustment control or its surroundings shall be permanently and legibly marked with the name or chemical symbol of the gas which it controls.

10.8 The stem of each rotary flow adjustment control shall be captive such that it cannot be disengaged from its housing without the use of tools.

10.9 For rotary flow adjustment controls, the oxygen control knob shall have a physically distinguishable profile in accordance with figure 2. All other flow adjustment control knobs shall be round.

NOTE 5 The oxygen control knob may be arranged to project beyond the knobs controlling other gases when they are grouped.

The diameter of the oxygen control knob shall be not less than the diameter of the knobs controlling other gases. The surface finish serrations of these other knobs shall have a depth not exceeding 1 mm.

10.10 If the flow control system uses threaded needle valves, when axial push and pull forces of 10 N ± 2 N are applied to the spindle of each valve, without rotation, with the flow at 25 % of maximum indicated flow, any change in flow shall not exceed 10 % or 10 ml/min, whichever is the greater.

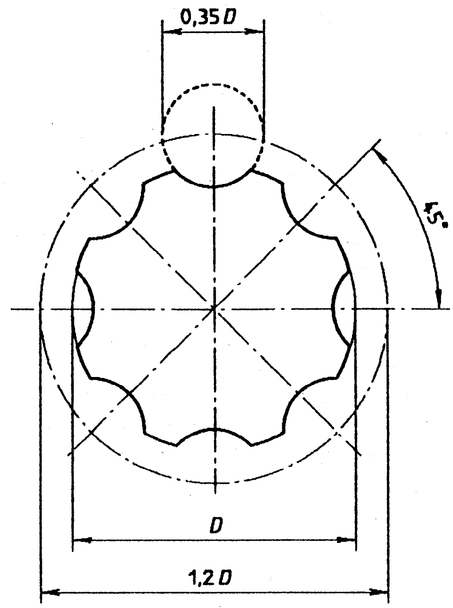

Figure 2 — Profile of oxygen flow control knob for applications other than vaporizer flow control

11 Flowmeters

11.1 The requirements given in this clause apply to flowmeters for single or pre-mixed gases.

Measures should be taken to minimize the build-up of electrostatic charges both inside and outside the tubes and housings of tube-type flowmeters.

NOTE 6 An anaesthetic machine may be equipped with one or more flowmeters for each gas supplied. (See also 10.1 and NOTE 2.)

11.2 Each flowmeter shall be calibrated for discharge into an ambient atmosphere of 101,3 kPa at an operating temperature of 20 °C.

All flowmeters shall be graduated in units of litres per minute. For flows of less than 1 l/min, the flow shall be expressed either in millilitres per minute or in decimal fractions of a litre per minute, with a zero before the decimal point. For flows of 1 l/min and above, sub-divisions of a litre shall be expressed in decimal parts. The method of graduation of all flowmeters on the anaesthetic machine shall be the same.

If tube-type flowmeters are used, the flowmeter scale shall be either marked on the flowmeter tube, or, if separate, shall be on the right-hand side of the tube as viewed from the front. In all cases, the name(s) or chemical symbol(s) of the gas or gas mixture shall be marked on the flowmeter. The scale markings shall be visible when viewed through an