International Standard 5358

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Continuous flow inhalational anaesthetic apparatus (anaesthetic machines) for use with humans

Appareils d'anesthésie par inhalation à débit continu pour utilisation chez l'homme

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards institutes (ISO member bodies). The work of developing International Standards is carried out through ISO technical committees. Every member body interested in a subject for which a technical committee has been set up 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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 5358 was developed by Technical Committee ISO/TC 121, *Anaesthetic equipment and medical breathing machines*, and was circulated to the member bodies in February 1979.

It has been approved by the member bodies of the following countries :

Australia	Germany, F. R.	South Africa, Rep. of
Austria	Ireland	Sweden
Canada	Japan	Switzerland
Chile	Netherlands	United Kingdom
Czechoslovakia	New Zealand	USA
France	Romania	USSR

No member body expressed disapproval of the document.

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0 Introduction

This International Standard specifies basic requirements for continuous flow anaesthetic machines, particularly for the performance and safety considerations. It is recognized that innovations in design 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 must meet the safety and performance criteria described in this International Standard. If these technologies and techniques differ significantly from those described, this International Standard may be amended or a new International Standard written to encompass new distinctive aspects.

The following words are used in this International Standard in the senses given below :

shall : Denotes a mandatory requirement.

should : Denotes a recommendation, i.e. a desirable but not mandatory requirement.

may : Denotes an optional requirement.

1 Scope and field of application

This International Standard specifies basic requirements for continuous flow inhalational anaesthetic apparatus (anaesthetic machines) and associated components thereof for use with humans.

Requirements for on-demand or intermittant flow anaesthetic machines are excluded from the scope of this International Standard.

2 References

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

ISO 407, *Yoke-type valve connections for small medical gas cylinders.*[1)]

ISO 4135, *Anaesthesiology — Vocabulary.*

ISO 5356, *Breathing attachments for anaesthetic apparatus —*

Part 1 : Conical fittings and adaptors.[2)]

Part 2 : Screw threaded weight bearing fittings.[2)]

ISO 5362, *Anaesthetic reservoir bags.*[2)]

ISO 7281, *Anaesthetic gas scavenging systems.*[2)]

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

3 Definitions

The definitions of terms contained in ISO 4135 shall apply.

4 General

4.1 The anaesthetic machine should be as light as possible and easily movable except where the machine is designed to be permanently attached to a wall or ceiling structure. The design of castors and weight distribution of components should be such as to minimize the possibility of the machine tipping over.

4.2 The anaesthetic machine shall be designed to provide for patient safety and simplicity in use.

4.3 All controls and gauges shall be clearly visible to an operator with 6/6 vision (corrected) seated or standing 1 m in front of the machine illuminated at a light level of 215 lx (20 foot candles). The markings and calibrations shall be simple and clearly identified with the controls and gauges, meters or indicators with which they are associated.

1) At present at the stage of draft. (Revision of ISO/R 407-1964.)

2) At present at the stage of draft.

4.4 Wherever components require periodic service, cleaning or calibration, the design shall facilitate these operations, and the manufacturer shall recommend the intervals at which this service shall be performed.

NOTE — Anaesthetic machines should be serviced at regular intervals in accordance with the recommendations of the manufacturer.

4.5 Fragile components of the anaesthetic apparatus, such as flowmeters, shall be well protected and secured to minimize accidental damage.

4.6 The apparatus should be designed to facilitate cleaning by hand and by mechanical devices. Finishes should withstand anaesthetic agents and commonly used cleaning and disinfecting agents (see clause A.2 of the annex). The apparatus shall be free from sharp edges and all accessible corners shall be well-rounded.

4.7 The breathing system and anaesthetic ventilator, if fitted, should be provided with means to convey the surplus or waste gas to a system for its disposal (see ISO 7281).

4.8 All components of the entire breathing system (i.e., breathing tubes, directional valves, absorber and absorbent containers, etc.), except for disposable components, shall be designed to withstand accepted methods of steam sterilization, or the manufacturer shall describe in the operating manual the sterilization or disinfection methods which may be used and state any special precautions which may be required. The design of breathing system components shall provide easy disassembly where required for satisfactory sterilization.

4.9 Electrically operated components, if provided, shall comply with the relevant requirements of IEC Publication 601-1.

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 for the entrapment of particulate matter prior to delivery of the gas at a needle valve or pressure regulator.

5.3 Each medical gas cylinder having a pin index yoke-type valve connection as specified in ISO 407, whether used as a service or reserve supply, shall be connected to the anaesthetic machine by a corresponding pin-indexed yoke. The yoke may also (but need not) provide for the support and orientation of the cylinder (i.e. be a hanger yoke). Where hanger yokes are provided, all yoke details, including the pin index safety system, shall be in accordance with ISO 407.

If two more interconnected yokes are provided for the accommodation of cylinders of the same gas on the anaesthetic machine, means shall be provided to limit the leakage of gas to a flow not exceeding 200 ml/min measured at room temperature and pressure, from an open cylinder in one yoke at a pressure up to 15 000 kPa through another yoke to atmosphere or to an empty cylinder.

5.4 Each cylinder connection shall be clearly and permanently marked with the name or chemical symbol of the corresponding gas. Where colour coding is additionally used, it shall be in accordance with ISO 32, unless otherwise required by national regulations.

6 Pipeline inlet connections

6.1 The oxygen and nitrous oxide gas systems should each include pipeline hose inlets for connection to pipelines commonly installed in hospitals and other buildings for distribution of these gases from central supplies. These inlets shall be the "body" (see figure 1) of the fittings as covered in the appropriate national standard until an International Standard is agreed. Such inlet connections shall be non-interchangeable and gas specific.

NOTE — Further consideration is to be given to the preparation of an International Standard for non-interchangeable and gas specific connectors.

6.2 Uni-directional valves shall be provided which prevent reverse flow of gases from the apparatus to the pipelines or to atmosphere if connections for gas cylinders are also provided.

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 cylinder contents indicators

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

7.1 Each gas supplied at cylinder pressure to the anaesthetic machine shall be monitored by a cylinder pressure gauge or contents indicator. An exception may be made for cyclopropane. The gauge shall be capable of indicating a pressure of at least 33 % greater than the normal maximum working pressure of the cylinder at 20 ± 3 °C.

7.2 If more than one cylinder yoke is supplied for any gas, one gauge should be provided for each yoke. If only one gauge is provided for a group of yokes, it shall be possible to open the cylinder valves in any sequence so that the pressures in separate cylinders can be determined.

7.3 Gases supplied by pipeline from central supplies at reduced pressures may be monitored by pressure gauges. These gauges shall indicate the pressure of gas in the pipeline hoses when attached to the machine. The gauge scale shall be capable of indicating a pressure of at least 33 % greater than the nominal pipeline pressure.

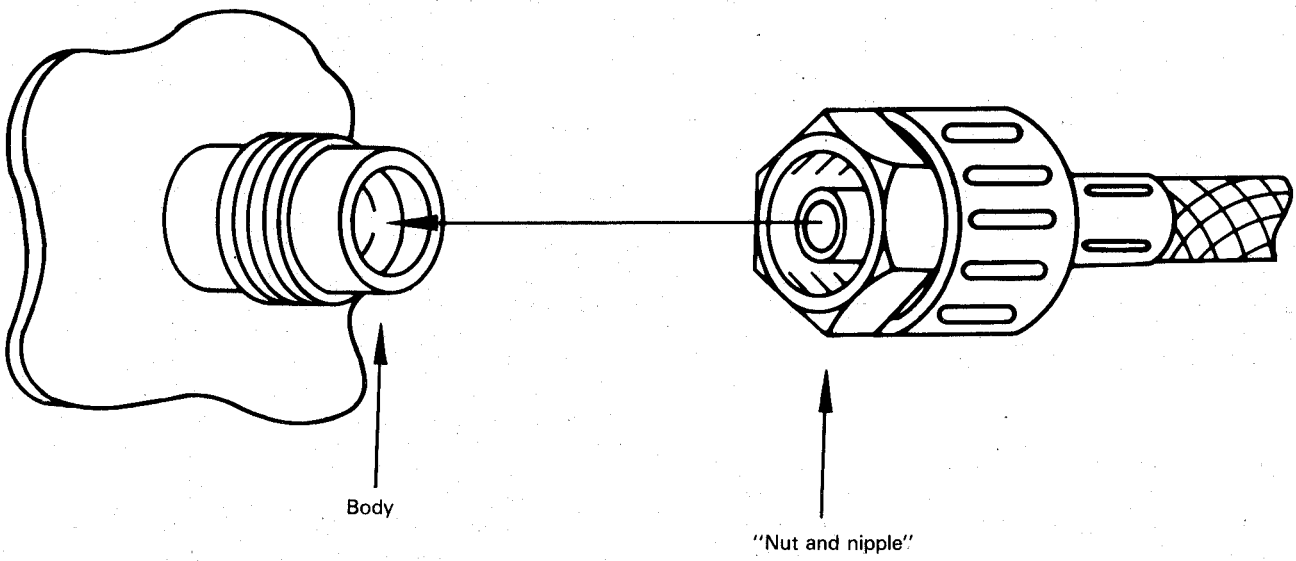

Figure 1 — Gas specific connectors illustrating "body" and "nut and nipple" components (see 6.1))

7.4 The maximum error of all gauges described above shall not exceed ± 4 % of the full scale reading.

7.5 All cylinder pressure gauges of a circular type on any individual anaesthetic machine shall have a substantially equal span angle 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 and 9 o'clock on the dial.

7.6 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 as short as practicable and significantly shorter than the indicating end and should either blend with the background or be masked from view.

7.7 The gauge shall have a scale length of not less than 50 mm and, if circular, should be at least 38 mm in diameter. The gauge shall be clearly identifiable with the name or chemical symbol for the gas it monitors. Where colour coding is additionally used, it shall be in accordance with ISO 32, unless otherwise required by national regulations.

7.8 Cylinder and pipeline pressure gauges shall be graduated in kPa × 100*; the units shall be clearly marked on the dial.

7.9 The gauge shall be designed and constructed in such a manner that when a pressure equal to the maximum pressure indicated on the dial is applied to a gauge having the pressure sensing element removed, no parts shall be expelled free of the gauge enclosure. The gauge may be furnished with restrictors in the inlet pressure connection and the gauge case shall have means of venting to prevent case internal pressure build-up. If employed, vent covers not secured to the gauge case shall be designed to open at a suitably low pressure and shall be of a resilient material that will reduce the risk of injury to personnel.

NOTE — Reference should be made to the annex concerning the choice of materials.

7.10 Pressure gauges for breathing systems shall be graduated in either Pa × 100**, or cmH_2O.

* 100 kPa ≈ 1 013 mbar

** 100 Pa ≈ 1 cmH_2O

8 Pressure regulators

8.1 There shall be an automatic pressure reducing regulator system for each gas supplied to the machine at a pressure in excess of 1 000 kPa. Each system may consist of one automatic pressure reducing regulator, or of two or more automatic pressure reducing regulators in series.

8.2 The regulators should be designed 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.

8.3 To ensure that the flow through one flow control valve is not seriously affected by any change in the adjustment of another such valve controlling gas from the same source, the delivery pressure of the regulator system to such valves shall increase by not more than 10 % of its initial value when the flow of gas is reduced from 10 l/min to the lowest flow for which a flowmeter for that gas is calibrated.

8.4 To ensure that the flow through a flow control valve is not seriously affected by abrupt changes in supply pressure, the delivery pressure of the regulator system to such a valve shall change by not more than 0,7 kPa per 100 kPa change in supply pressure.

8.5 To ensure that the flow of oxygen is restored substantially to its previous value after each operation of the oxygen flush valve the following type test shall be performed : using an indicated oxygen flow of 2 l/min, the flow shall be restored to 2 ± 0,1 litres within 2 s of the end of each of ten cycles of flush valve operation of 10 s duration each with a pause of 5 s between flushes.

8.6 To ensure the safety of anaesthetic machines and adjacent structures and personnel, 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 the event of failure or malfunction of the regulator, the relief valve shall be capable of limiting the pressure in the regulator to not more than three times the nominal delivery pressure when the supply pressure is 50 % greater than the nominal maximum.

NOTE — This relief valve can only be effective in a situation in which the delivery pressure slowly increases as the result of leakage at the regulator valve seat and cannot safeguard against its catastrophic failure.

In a regulator with a diaphragm designed to rupture under overpressure conditions, the diaphragm shall rupture at between three and six times the nominal delivery pressure. The body of the regulator shall be sufficiently robust to maintain its integrity in the event of diaphragm rupture.

9 Machine gas piping

9.1 Any gas piping system shall be capable of withstanding four times its normal working pressure without rupture. Joints and unions in the system shall not loosen in normal use.

9.2 The maximum permissible leakage on each gas service, except oxygen, between the high pressure and/or pipeline inlets and the flow control valves shall be 25 ml/min at normal operating pressure. Venting of air or oxygen from fluidic or pneumatic components shall be excluded from this requirement. The maximum leakage rate on all gas services between the flow control valves and the common gas outlet shall be 50 ml/min at a pressure of 3 kPa (30 cmH_2O). Vaporizers fitted to the machine by the manufacturer shall be turned on for this test.

9.3 The manufacturer's maintenance manual shall include instructions for testing for correct assembly and connection of each gas supply system and any vaporizers fitted to the machine and such tests shall be carried out before the apparatus is released for use or when repairs or changes have been carried out on a machine which involve the gas piping or vaporizers.

9.4 Except where the connectors of gas piping are non-interchangeable, anaesthetic machine pipework shall be readily identifiable by appropriate labelling at each junction and where the piping joins a component, for example a valve. Either the name, chemical symbol or other coding of the gas shall be used at each junction.

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

10 Flow control valves

10.1 The device which controls the rate of flow of any gas through its associated flowmeter by manual adjustment shall be referred to as a flow control valve.

10.2 Each rotary flow control valve shall continuously increase flow (within the limits of its associated flowmeter) by being turned in a counter-clockwise direction and vice versa.

10.3 Each flow control valve shall be capable of adjusting the rate of flow to any value within the range of its associated flowmeter whenever the supply and delivery pressure are within normal limits for the intended application.

10.4 Under conditions of constant inlet and outlet pressure and constant ambient temperature the flow control valve shall maintain within ± 10 % or ± 10 ml/min whichever is greater, the established rate of flow for a period of 10 min.

10.5 At an inlet pressure of at least 300 kPa and the minimum normal delivery pressure, each rotary flow control valve shall require rotation of its control knob through at least 90° in order to achieve adjustment of its associated flowmeter through the upper 90 % of its scale range.

10.6 Each flow control valve, when in the closed position, shall be capable of limiting the flow under the pressure limits given in 10.5 to not more than 1 ml/min measured at 20 ± 3 °C and at a pressure of one standard atmosphere (1 013 mbar).

10.7 Type test : Rotary flow control valves shall permit the operation of the stem through 5 000 cycles of at least one full rotation in each direction to open and close the valve before the seal leakage rate exceeds 5 ml/min when measured at 20 ± 3°C at a pressure of one standard atmosphere (1 013 mbar).

10.8 Each flow control valve shall be adjacent to or readily identifiable with the flowmeter it controls.

10.9 The knob for each flow control valve shall be clearly and permanently marked with the name or chemical symbol of the gas which it controls. Where colour coding is additionally used, it shall be in accordance with ISO 32, unless otherwise required by national regulations.

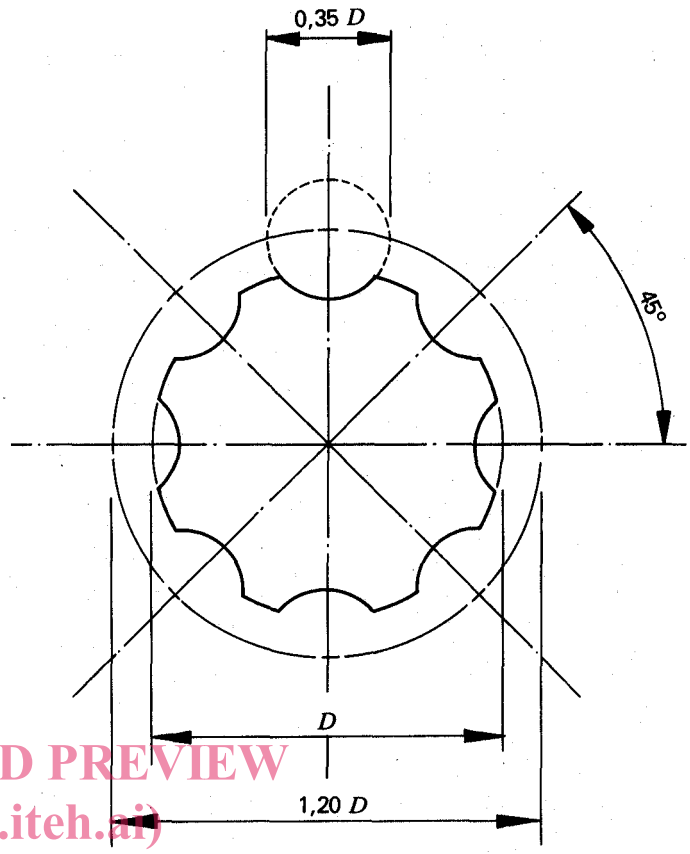

Figure 2 — Profile of oxygen flow control knob for applications other than vaporizer flow control

10.10 Flow control knobs for vaporizer flowmeters shall be labelled "VAPORIZER", or, in the case of an agent-specific vaporizer, with the name of the agent for which the vaporizer is intended to be used.

10.11 The stem of a rotary flow control valve shall be designed so that either it cannot be disengaged from the balance of the valve by continuation of the adjusting motion, or the motion required shall be at least five full turns or double the number required to effect adjustment over the upper 90 % of the flowmeter scale length, whichever is the greater.

10.12 To make the oxygen flow control knob physically distinguishable it shall have a characteristic profile in accordance with figure 2. It may be arranged to project beyond the knobs controlling other gases in a bank of flow meters and it shall not be recessed. Its diameter shall be not less than the diameter of the knobs controlling all other gases. This configuration shall be used only for the oxygen control knob. All other flow control knobs, including those for vaporizers, shall be round. The surface finish serrations of these other knobs shall have a depth not exceeding 1 mm.

10.13 The flow control knobs should be so designed as to minimize inadvertent change from a preset position, preferably by providing a recess, shield or other barrier which protects the control knobs.

11 Flowmeters

11.1 The anaesthetic machine may be equipped with one or more flowmeters for each gas supplied to the patient but only one flow control valve shall be provided for each gas.

11.2 Each flowmeter shall be graduated for discharge into a standard atmosphere at an operating temperature of 20 °C. All flowmeters shall be graduated in units of litres per minute. For flows of 1 l/min or less, the flow may be expressed either in millilitres per minute or in decimal fractions of a litre per minute (with a zero before the decimal sign) subject to the method of graduation being consistent on any one anaesthetic machine. Flowmeter scales for heated flowmeter-controlled vaporizers which are maintained at a constant temperature shall be graduated in units of flow of vapour. Unheated flowmeter-controlled vaporizers shall be graduated in units of flow of carrier gas.

11.3 The manufacturer shall state in the machine specification and instruction manual the limit of error for each of the flowmeters, this to be expressed as a maximum percentage deviation from the indicated flow when measured at ambient conditions of 20 °C and a standard atmosphere (1 013 mbar).