International Standard ISO 5358

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION•МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ•ORGANISATION INTERNATIONALE DE NORMALISATION

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

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

First edition — 1980-12-15

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UDC 615.471 : 616-089.5-032 : 611.2 **Ref. No. ISO 5358-1980 (E)**

Descriptors : medical equipment, anaesthesia, artificial breathing apparatus, specifications, gas pipes, pipe fittings, manometers, pressure regulators, flowmeters, vaporizing, safety devices, warning systems.

Price based on 11 pages

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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Printed in Switzerland

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

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.

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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.

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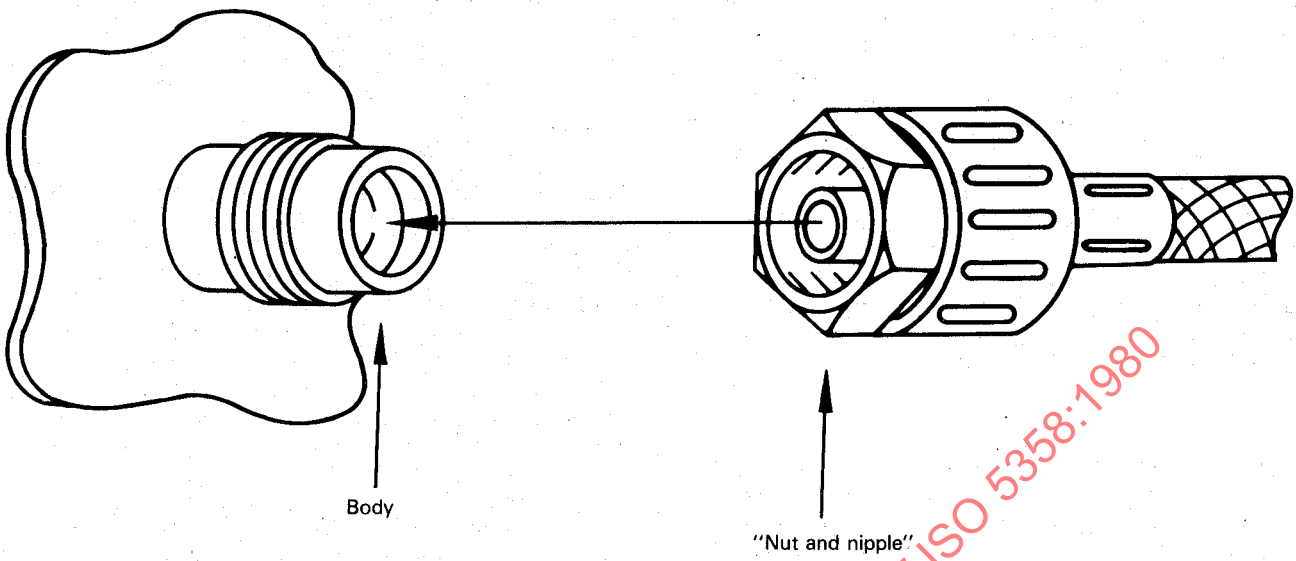

Figure 1 — Gas specific connectors illustrating "body" and "nut and nipple" components (see 6.1))

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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.

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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.

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.

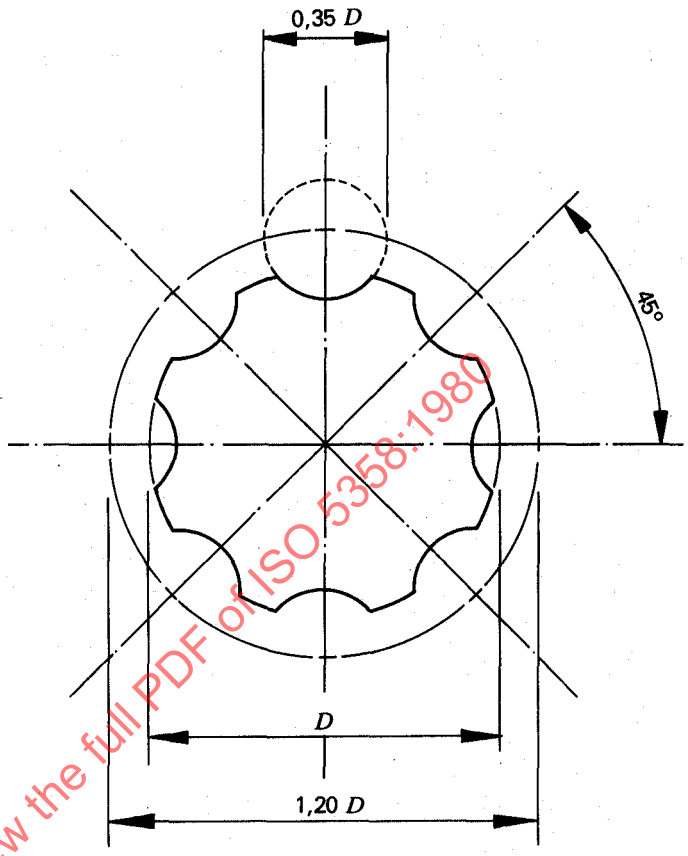

Figure 2 — Profile of oxygen flow control knob for applications other than vaporizer flow control

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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).

11.4 Appropriate measures should be taken to minimize the build up of electrostatic charges both inside and outside the flowmeter tubes and their housings.

11.5 Where oxygen and other gases are delivered by their respective flowmeters into a common manifold, the oxygen shall be delivered downstream of all other gases.

11.6 The oxygen flowmeter shall be situated at one extremity of a bank of flowmeters. The carrier gas flowmeter for a flowmeter-controlled vaporizer which is an integral part of the anaesthetic machine shall be situated at the opposite end of the flowmeter bank to the oxygen flowmeter. If there is a separate vaporizer with an attached flowmeter, then this flowmeter shall be separated by at least 100 mm from the oxygen flowmeter.

11.7 Flowmeters of the tube type shall be clearly separated to avoid confusion. The flowmeter scale shall be marked on the flowmeter tube or if separate shall be located on the right-hand side of the tube as viewed from the front and shall be so designed that the scale, tube and float are linked. In all cases the name or symbol for the gas shall be marked on the flowmeter tube, for example low flow oxygen or high flow oxygen. Means should be employed to identify the float with its scale and tube.

11.8 The manufacturer shall, as far as practicable, ensure that the flowmeters and their tubes are not interchangeable between the correct flowmeter locations or between high and low flow locations of the same gas.

11.9 At present it is difficult to prevent incorrect re-assembly between float and tube. A service check is therefore essential after re-assembly. Each flowmeter assembly shall be clearly and permanently marked with its calibrations, the unit of measure, and the name or chemical symbol of the gas or gas mixture it measures, except that if it measures a gas acting as a vehicle for a vaporizer whose effluent is a substantially constant ratio of the vehicle gas and the vapour of a single agent, the flowmeter may be calibrated for the flow of vapour and identified by the name of the vaporized agent. Where colour coding is additionally used, it shall be in accordance with ISO 32, unless otherwise required by national regulations. Devices may be provided to assist visibility.

11.10 The indicator of the flowmeter shall be visible to the user at all settings. The point of reference for reading the float or indicator shall be indicated on the flowmeter assembly.

12 Connections for vaporizers

All connections for vaporizers shall be in accordance with ISO 5356, namely :

a) Vaporizers unsuitable for use in the breathing system shall not be fitted with breathing system connectors. The direction of gas flow shall be marked with arrows.

Where such a vaporizer not intended for use in a breathing system is provided with conical connectors at its inlet and outlet ports these shall be of nominal 23 mm size in accordance with ISO 5356 and with the inlet port male and the outlet port female.

Any other system of connecting ports on vaporizers of this type shall be designed so that the vaporizer cannot be attached to the machine incorrectly.

b) Vaporizers suitable for use in the breathing system shall — except where c) applies — have standard male/female 22 mm fittings or standard threaded weight bearing fittings. The inlet and outlet ports should be so marked and the direction of gas flow shall be indicated by arrows.

c) *Where a vaporizer otherwise suitable for use in a* breathing system is nevertheless part of an assembly which is not a part of the breathing system (for example on the "back bar") its ports shall be fitted with connections in accordance with a).

13 Mixing devices

13.1 Where a mixing device is used in addition to or instead of independent flow of different gases, it shall be clearly marked to indicate the gases controlled, and the percentage of oxygen delivered. *Means should be provided to verify the* delivered oxygen concentration output of the mixing device. Mixing devices shall comply with the requirements of 10.4 and 11.3. The total rate of flow of the gas mixture delivered shall also be indicated.

13.2 The function of all controls of mixing devices shall be clearly indicated. Flow control valves, if fitted, shall be adjacent to or readily identifiable with their respective flowmeters.

14 Flowmeter-controlled vaporizer systems

14.1 The anaesthetic machine may be equipped with one or more vaporizer systems in which the concentration of vapour in the mixture delivered to the common gas outlet shall be predictable if the absolute pressure in the vaporizer, the vapour pressure of the volatile agent, and the rate of flow of vehicle *and diluent gases are known, provided that the gas passing* through the vaporizer chamber is saturated with the agent.

This system shall include a flow control valve and associated flowmeter for metering gas through the vaporizer, a vaporizer, a shut-off valve and/or check valve. The performance of the flow control valve and flowmeter shall be in accordance with clauses 10 and 11 respectively.

Flowmeter scales for heated flowmeter-controlled vaporizers which are controlled at 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. All vaporizers on one machine shall be similarly graduated.

14.2 The shut-off valve, or similar device shall operate to stop the flow of vapour from the vaporizer to the common gas outlet of the anaesthetic machine. All carrier gas flowing through the vaporizer flowmeter shall be delivered to the common gas outlet. The check valve shall operate to prevent the reflux of any gas into the vaporizer from its outlet.

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The shut-off valve control shall be visible to the operator from his normal operating position. The valve shall be designed so that it will normally remain in either the "on" or "off" position.

14.3 The vaporizer shall be equipped with a thermometer, to indicate the vapour or liquid temperature within the vaporizer when it is filled to the minimum level recommended by the manufacturer. The manufacturer shall state in the operating manual the performance specifications and limits of error of the vaporizer and whether the temperature measured is that of the vapour or liquid phase. This shall include the conditions which affect vaporizer performance (for example temperature, barometric pressure, flowmeter accuracy and degree of filling of vaporizer).

14.4 The vaporizer shall be equipped with a liquid level indicator. The vaporizer shall be designed so that it cannot be overfilled and can be readily emptied in accordance with manufacturer's instructions.

14.5 If the vaporizer is designed for use with a single agent the filling and emptying mechanism may be fitted with a permanently attached standard agent-specific filling device.[1)]

14.6 A removable keyed liquid anaesthetic agent filling and emptying device may be provided for universal flow controlled vaporizers. Such a device shall automatically empty the vaporizer when it is detached and prevent refilling until the filling/draining mechanism is re-attached.

14.7 To prevent cross-contamination of the contents of one vaporizer with another agent, a system should be provided which isolates the vaporizer(s) not in use from each other and prevents gas passing through the vaporizer chamber of one vaporizer and then through that of another. The method of attachment of vaporizers to the machine should permit their ready interchange by the user.

14.8 The vaporizer system shall incorporate means which effectively prevent the displacement of liquid or foam from the vaporizer to the common gas outlet either with the use of flows 50 % greater than the sum of the ranges of its vaporizer carrier gas flowmeters or by changes in pressure caused by occluding and then opening the common gas outlet at any flow through the vaporizer flowmeters within the sum of their calibration ranges and at any filling up to the maximum indicated level (see also remarks on foaming of anaesthetic agents in the annex). The vaporizer system shall incorporate means which effectively prevent the displacement of liquid from the vaporizer to its flowmeter(s) in the event of occlusion of the common gas outlet if the system is otherwise free of defects.

14.9 Type test : The average delivered concentration (volume percentage or partial pressure) from the vaporizer shall not change by more than 20 % under the following test conditions at an ambient temperature of 20 ± 1 °C at one standard atmosphere (1 013 mbar) :

a) The vaporizer is filled to the minimum level recommended by the manufacturer.

b) The pressure fluctuation produced at the common gas outlet at 15 cycles per minute is 4 kPa (40 cmH_2O).

c) This pressure falls from its maximum to its minimum value in 1 ± 0,2 s.

d) The total gas flow is 1 l/min.

e) The vaporizer flowmeter is set to deliver 3 % of its maximum graduated flow or the minimum graduated flow if this is greater than 3 % of the maximum graduation value.

f) The concentration shall be measured after the intermittent back pressure condition has been maintained for between 2 and 5 min.

g) The test shall be repeated with the same conditions except that the flow shall be 10 l/min and the pressure fluctuation produced shall be 10 kPa (100 cmH_2O).

14.10 If an anaesthetic machine is fitted with flowmeter-controlled vaporizers calibrated in units of flow of vapour produced by the carrier gas, then all flowmeter-controlled vaporizers on that machine shall be similarly graduated, each vaporizer being labelled for the exclusive use of, and graduated for, the vapour of the intended agent (see also 14.1).

14.11 Electrically heated vaporizers

14.11.1 If the vaporizer system includes means for electrically heating the vaporizer and its contents, a thermostatic control shall be provided to initiate the operation of the heater when the vaporizer temperature falls below a selected temperature in the range of 20 to 25 °C and terminate the operation of the heater before the vaporizer temperature has risen by 2°C above the selected temperature.

14.11.2 Each electrically heated vaporizer shall be equipped with an indicator lamp which is illuminated whenever the heater is operated. The indicator lamp shall be visible to an operator standing or sitting 1 m in front of the machine.

14.11.3 Electrically heated vaporizers shall comply with the relevant requirements of IEC Publication 601-1 and the particular publication[2)] dealing with electrical requirements for anaesthetic machines.

14.12 Manufacturers' manuals shall state the intervals at which vaporizers should be serviced and the accuracy of calibration checked.

1) This will form the subject of a future publication.

2) IEC publication 601-10 is at present under consideration.

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15 Concentration-calibrated vaporizers

15.1 The anaesthetic machine may be equipped with one or more concentration calibrated vaporizers which are capable of accepting a gas flow of 15 l/min from the anaesthetic machine flowmeters and in turn, delivering the gas flow with a predictable concentration of vapour. Control of the vapour concentration shall be provided by means of calibrated knobs or dials. The conditions of use may include extreme variations in ambient temperature, ambient pressure, back pressure and input flow. Their effects on performance shall be stated in catalogues and instruction manuals.

15.2 The extent to which temperature and input flow influence the vapour concentration shall be stated by the manufacturer on the vaporizer or the anaesthetic machine itself, or in a manual. If this information is provided in the manual only, then a label shall be placed on the vaporizer listing the variables which affect its performance and directing the users attention to the manual.

15.3 Concentration-calibrated vaporizers should be located between the flowmeter manifold outlet and the common gas outlet. To prevent cross contamination of the contents of one vaporizer with another agent, a system should be provided which isolates the vaporizer(s) not in use from each other and prevents gas passing through the vaporizing chamber of one vaporizer and then through that of another. The method of attachment of vaporizers to the machine should permit their ready interchange by the user.

15.4 As presently available controls are unable to prevent trace concentrations of anaesthetic vapour escaping into the breathing system, it is desirable that means be provided to isolate the vaporizer and its vapour from the breathing system when the control is in the "off" position.

15.5 The calibrated knob, or dial, should be marked in such a way that it can be easily read standing at a distance of 1 m in front of the machine by a person having 6/6 corrected vision under normal operating room conditions. The marking shall indicate volume per cent and the "off" position.

15.6 The vaporizer shall be equipped with a liquid level indicator. The vaporizer shall be designed so that it cannot be overfilled when in the normal operating position and can be drained in accordance with the manufacturer's instructions of substantially all liquid but that contained in the wick.

15.7 If the vaporizer is designed for use with a single agent the filling and emptying mechanism may be fitted with a permanently attached standard agent-specific filling device.

15.8 All vaporizer control knobs shall open counter-clockwise (i.e. in the same direction as for gas flow control valves) and the units of calibration shall be marked on the control knobs or on a scale.

15.9 The vaporizer system shall permit flows up to 75 l/min from the flowmeter assembly with the vaporizer either in the "on" or "off" position with the vaporizer filled to the maximum indicated level without the discharge of any liquid through the vaporizer outlet when used in accordance with the manufacturer's recommendations.

15.10 Type test : The average delivered concentration from the vaporizer shall not change by more than 20 % under the following test conditions at an ambient temperature of 20 ± 1 °C at one standard atmosphere (1 013 mbar) :

a) The vaporizer is filled to the minimum level recommended by the manufacturer.

b) The pressure fluctuation produced at the common gas outlet at 15 cycles per minute is 4 kPa (40 cmH_2O).

c) This pressure falls from its maximum to its minimum value in 1 ± 0,2 s.

d) The total gas flow is 1 l/min.

e) The vaporizer graduated scale is set to deliver 20 % of its maximum numerical graduated value or the minimum operating graduation value if this is greater than 20 % of the maximum graduation value.

f) The concentration shall be measured after the intermittent back pressure condition has been maintained for between 2 and 5 min.

g) The test shall be repeated with the same conditions except that the flow shall be 10 l/min and the pressure fluctuation produced shall be 10 kPa (100 cmH_2O).

15.11 Any vaporizer equipped with an electrical heater shall comply with the relevant requirements of IEC Publication 601-1 and the particular publication dealing with electrical requirements for anaesthetic machines.

15.12 Each electrically heated vaporizer shall be equipped with an indicator lamp which is illuminated whenever the heater is operated. The indicator lamp shall be visible to an operator standing, or sitting 1 m in front of the machine. Such vaporizers shall be fitted with a thermometer visible from the front of the machine marked to indicate the correct operating temperature range.

15.13 Manufacturers' manuals shall state the intervals at which such vaporizers should be serviced and the accuracy of calibration checked.

16 Non-calibrated vaporizers

NOTE — Performance requirements for non-calibrated vaporizers cannot be specified.

16.1 The anaesthetic machine may be equipped with one or more non-compensated vaporizers of a simple "flow-over" or "bubble-through" type, designed to accept total gas flow. If the flow is uni-directional, the flow direction shall be marked on the vaporizer body and in bubble-through types a mechanism shall be incorporated to prevent the discharge of liquid agent and/or foam even in the event of reverse gas flow.

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