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Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment

Systèmes d'anesthésie par inhalation — Alimentation en vapeur et équipements annexes

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

In other circumstances, particularly when there is an urgent market requirement for such documents, a technical committee may decide to publish other types of normative document:

— an ISO Publicly Available Specification (ISO/PAS) represents an agreement between technical experts in an ISO working group and is accepted for publication if it is approved by more than 50 % of the members of the parent committee casting a vote;

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An ISO/PAS or ISO/TS is reviewed after three years in order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn. If the ISO/PAS or ISO/TS is confirmed, it is reviewed again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TS 18835 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

Introduction

The continuous-flow anaesthetic system described in ISO 8835-2 to ISO 8835-5 relies upon supplies of compressed medical gases and an uninterrupted electricity supply. These in turn depend upon a highly developed infrastructure of transport facilities, power generation and technical service.

The World Federation of Anaesthesiologists (WFSA) has requested ISO to ensure that the needs for safe anaesthesia for people in the populous and developing countries of the world are also addressed in ISO standards for anaesthetic equipment. This should include a practical standard for draw-over vaporizers and associated equipment.

In accordance with this request, this Technical Specification deals with such a system that is not dependent on compressed gas and electrical power.

It is based on the use of ambient air, preferably with the addition of supplementary oxygen, as the carrier gas to convey anaesthetic vapour to a patient from a draw-over vaporizer.

Attention is drawn to IEC 60601-2-13 and the ISO 8835 series of standards relating to other devices used for inhalational anaesthesia.

Throughout this Technical Specification, text for which a rationale is provided in Annex C is indicated by an asterisk (*).

Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment

1 Scope

This Technical Specification specifies safety and performance requirements for draw-over vaporizers and associated equipment to provide draw-over anaesthetic systems for patients weighing greater than 15 kg using both non-flammable and, in places where regulations permit their use, flammable anaesthetic agents.

No requirements for monitoring the equipment are given in this Technical Specification.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

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

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

ISO 5360, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 8835-2:1999, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems for adults*

ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

IEC 60601-1:1988 + A1:1991 + A2:1995 and corrigendum 1995 mod, *Medical electrical equipment — Part 1: General requirements for safety*

IEC/SC62A/389/CDV; 2002, *Medical electrical equipment — Part 1: General requirements for safety and performance (revision of IEC 60601-1:1988)*

EN 13544-2, *Respiratory therapy equipment — Part 2: Tubing and connectors*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

3.1
air/oxygen reservoir
tubular container, open to ambient air at one end, with an inlet for connection to an oxygen supply and an outlet port through which the air/oxygen mixture passes to the draw-over vaporizer

3.2
inflating bellows device
device with unidirectional valve(s) and a connection to a concertina-type bellows

NOTE Manual operation of the bellows will cause unidirectional flow towards the patient.

3.3
inflating valve
valve that closes the expiratory pathway during the inspiratory phase of intermittent positive-pressure ventilation

3.4
anaesthetic patient valve
APV
valve at the patient end of a draw-over anaesthetic system that has three operating functions: as a unidirectional valve to prevent flow towards the vaporizer during exhalation, as an inflating valve to permit intermittent positive-pressure ventilation, and as a unidirectional exhaust valve to prevent inhalation of air through the exhaust port during spontaneous ventilation

NOTE This type of valve is similar to “non-rebreathing exhaust valve” defined in ISO 8835-2 and to “patient valve” defined in ISO 10651-4. However, it has a combination of functions not mandated in either of the earlier definitions.

4 * Air/oxygen reservoir

4.1 Connections

4.1.1 Ambient air inlet

The ambient air inlet shall not be a conical connection complying with ISO 5356-1 or ISO 5356-2.

The ambient air inlet should be designed to reduce the risk of accidental obstruction.

Consideration should be given to provision for attaching particulate filters to reduce the risk of inhaling particulate matter.

4.1.2 Oxygen inlet port

The oxygen inlet port shall comprise a nipple in accordance with EN 13544-2.

4.1.3 Outlet port

If operator-detachable, the outlet port shall be a 22 mm male conical connection in accordance with ISO 5356-1 or ISO 5356-2.

4.2 Draw-over vaporizer

4.2.1 Inlet port

If operator-detachable, the inlet port shall be a 22 mm female conical connector complying with ISO 5356-1 or ISO 5356-2.

4.2.2 Outlet port

If operator-detachable, the outlet port shall be a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2.

4.3 Inflating bellows device

4.3.1 Inlet port

If operator-detachable, the inlet port shall be a 22 mm female conical connector complying with ISO 5356-1 or ISO 5356-2.

4.3.2 Outlet port

The outlet port shall be a 22 mm male conical connector complying with ISO 5356-1 or ISO 5356-2.

4.3.3 Connection for attachment of the bellows unit to the inflating bellows device

The connection for the bellows unit shall not be a conical connector complying with ISO 5356-1 or ISO 5356-2 (see Figure B.1 for an example).

4.3.4 Connection for breathing system pressure monitor

If provided, the connection for a pressure monitor shall not be compatible with connectors specified in EN 13544-2. It should be self-sealing or may be provided with an audible warning of disconnection, e.g. a whistle.

4.4 Anaesthetic patient valve

4.4.1 Inlet port

The inlet port shall be a 22 mm female conical connector complying with ISO 5356-1.

4.4.2 Patient connection port

The patient connection port shall be a 22 mm male conical connector with coaxial 15 mm female conical connector, both complying with ISO 5356-1.

4.4.3 * Exhaust port

The exhaust port shall be a 30 mm male conical connector complying with ISO 5356-1.

4.5 Connecting tubes

If provided, connecting tubes shall be anaesthetic breathing tubes complying with ISO 5367 and, if operator-detachable, fitted at one end with a tube adaptor to provide a 22 mm male conical connector complying with ISO 5356-1.

5 Construction

5.1 General

5.1.1 * Components for use with flammable anaesthetic agents

All components intended to be used with flammable anaesthetic agents shall comply with Annex G of IEC/SC62A/389/CDV:2002.

5.1.2 Materials

The materials from which all components are made shall be selected to take into account the chemical and physical properties of any substances with which the manufacturer declares that they may come into contact during use.

The selection procedures used for materials shall be documented and retained by the manufacturer.

NOTE Draw-over vaporizers and associated equipment have been used in areas where “normal” cleaning materials are not available and many corrosive and abrasive materials have been substituted as cleaners. Water has also been used to flush out draw-over vaporizers after use.

5.2 Draw-over vaporizer

5.2.1 Mechanical hazards

The requirements given in IEC 60601-1:1988, Clauses 21 to 24, apply.

5.2.2 Contents indicator

The draw-over vaporizer shall be provided with a visual indication of the level of liquid anaesthetic agent contained within.

5.2.3 Output control

5.2.3.1 Vapour output control

A calibrated control shall be provided to adjust the vapour concentration (volume fraction). Under normal operating conditions it shall not be possible to set the control above the calibrated range. The calibrated control may have a separate “OFF” position in addition to a “0” or “zero” position.

5.2.3.2 Unintentional adjustment of control

Means shall be provided to prevent unintended change of the calibrated control from its set position.

Compliance is checked by visual inspection and functional testing.

5.2.4 Filler port

If the vaporizer is fitted with an agent-specific filler, the filler shall comply with the requirements of ISO 5360.

5.2.5 Prevention of overfilling

When operated in accordance with the manufacturer's instructions, it shall not be possible to overfill the draw-over vaporizer such that

a) its performance is affected, or

b) the fluid level is no longer visible or indicated.

Compliance is checked by visual inspection and functional testing.

5.2.6 Stability in use

The draw-over vaporizer either shall be provided with mounting fittings suitable to enable it to be rigidly supported or shall have a base designed to provide stability when free-standing.

Compliance is checked by visual inspection and functional testing.

5.3 Air/oxygen reservoir

The oxygen inlet should be as close as possible to the inlet of the draw-over vaporizer.

A length of breathing hose complying with ISO 5367 may be used as the air/oxygen reservoir.

5.4 * Inflating bellows device

5.4.1 Bellows form

The bellows shall be designed to give a visual indication of spontaneous respiration.

5.4.2 * Unidirectional valves

A unidirectional valve shall be provided at the inlet port. If a unidirectional valve is provided at the outlet port, means shall be provided to retain the valve in the fully open position.

Each valve shall be designed and located such that their function is visible to the operator

5.4.3 Stability in use

If free-standing, the inflating bellows device shall be provided with a base to provide stability during use. The device shall not fall over when a force of 30 N is applied in a downward direction to the top of the bellows at any angle up to 30° from the vertical.

5.4.4 Pressure-limiting device

A pressure-limiting device shall be provided within the gas path of the inflating bellows device (see 6.3.3).

5.5 Anaesthetic patient valve dismantling and reassembly

The valve shall be designed so that it can be dismantled without the use of a tool for cleaning, disinfection and sterilization.

The design should aim to reduce the risk of incorrect assembly after dismantling. The valve body should preferably be transparent to permit the internal components to be visible for checking.

6 Performance

6.1 Draw-over vaporizer

6.1.1 Output when off

When tested in compliance with A.3, the output of the vaporizer in the “0”, “off” or “zero” position shall be less than 0,1 %.

6.1.2 Output in use

When tested in compliance with A.3, the accuracy of output shall be within ± 20 % of set value for concentrations (volume fraction) greater than 1 %, and ± 50 % of set value for concentrations of 1 % or below.

6.1.3 Output when fitted

If the draw-over vaporizer is designed to operate without being rigidly attached to a mounting rail, the draw-over vaporizer output shall remain within the manufacturer's stated performance if the draw-over vaporizer is tilted within an angle of ± 30° from the vertical.

Compliance is checked by functional testing.

6.2 Air/oxygen reservoir

When tested as described in A.4, the oxygen concentration (volume fraction) measured at the air inlet port shall not exceed 21 %.

6.3 Inflating bellows device

6.3.1 Delivered volume

The maximum delivered volume shall be not less than 1 l.

Test by discharging into a spirometer.

6.3.2 Reverse flowrate through unidirectional valves

When tested as described in A.5, the reverse flowrate through each individual valve in the inflating bellows device shall not exceed 60 ml/min.

6.3.3 Pressure-limiting device

The pressure-limiting device shall ensure that, under both normal conditions and single-fault condition, the pressure at the patient connection port shall not exceed 12,5 kPa (125 cmH_2O).

6.4 Anaesthetic patient valve

6.4.1 Unidirectional function from patient to inflating bellows device

When tested as described in A.5, the reverse flowrate from the patient through the unidirectional inlet valve component of the anaesthetic patient valve into the inflating bellows during exhalation shall not exceed 60 ml/min.

6.4.2 Unidirectional function to patient from exhaust port

When tested as described in A.5, the reverse flowrate from the exhaust port to the patient during inhalation shall not exceed 60 ml/min.

6.4.3 * Efficiency of ventilation

The manufacturer shall disclose the range of tidal volumes over which at least 80 % of the displaced volume from an adjustable sine-wave generator is delivered to an appropriate test lung.

6.5 Complete system — Resistance to spontaneous inspiration and expiration

When tested as described in A.6, the resistance to inspiration shall not exceed 0,6 kPa, and the resistance to expiration shall not exceed 0,2 kPa.

7 Arrangement of components in draw-over anaesthetic system

7.1 * Oxygen inlet

If an oxygen inlet is provided, it shall be into a reservoir open to atmosphere.

7.2 * Vaporizer

Unless otherwise stated by the manufacturer, the inflating device shall be on the patient side of the vaporizer.

NOTE Annex B provides diagrams of common arrangements of components.

8 Marking of components

8.1 General

The breathing system, as defined in ISO 4135, starts at the air inlet port and continues through the draw-over system, terminating at the exhaust port. All components of the draw-over system, including the vaporizer, are therefore classified as breathing-system attachments.

8.2 Marking of breathing-system attachments

All components shall be durably and legibly marked with the following:

a) the name and/or trade mark of the manufacturer and/or supplier;

b) an identification reference to the lot or date of manufacture;

c) the maximum limiting pressure, if the component has a designed limiting pressure;

d) for exhaust ports complying with 4.1.3 of ISO 8835-2:1999, the word “EXHAUST” and/or “AGSS” or the equivalent in the national language or an appropriate symbol;

e) the word “ANTISTATIC” for breathing attachments and integrally attached non-metallic components made of antistatic materials;

NOTE They may also bear an indelible yellow-coloured mark.

f) flow-direction-sensitive components shall be marked with at least one arrow to indicate the direction of gas flow.

NOTE 1 The words “INLET” and “OUTLET” or the equivalent in the national language may be marked in addition.

NOTE 2 The safe and correct functioning of certain breathing attachments is dependent upon the direction of gas flow through them.

8.3 Marking of draw-over vaporizer

8.3.1 The graduated scale of vapour output shall be marked with the generic name of the specific anaesthetic agent, or at least with an abbreviated form from the following list:

a) “ENF” — (Enflurane)

b) “HAL” — (Halothane)

c) “ISO” — (Isoflurane)

d) “SEV” — (Sevoflurane)

If colour coding is used, it shall be in accordance with Annex BB of ISO 8835-4:2004.

If a vaporizer is provided with interchangeable scales for more than one agent, no agent identification or colour coding should be provided except on these scales.

8.3.2 Graduated controls shall be marked with the units in which the graduation is made.

8.3.3 Graduated controls shall be marked with “0” or “OFF” at the zero position.

8.3.4 Either the maximum and minimum filling levels shall be marked or the actual useable volume shall be displayed.

8.3.5 The direction of operation of the control to increase the concentration (mass fraction) shall be clearly marked.

8.4 Marking of air/oxygen reservoir

8.4.1 The air inlet shall be marked “AIR INLET — DO NOT OBSTRUCT” and/or the equivalent in the national language.

8.4.2 The oxygen inlet shall be marked “OXYGEN” or “O_2” and/or the equivalent in the national language.

8.5 Marking of inflating bellows device

8.5.1 If a pressure monitor connection is provided, it shall be marked “PRESSURE MONITOR” and/or the equivalent in the national language.

8.5.2 Inflating bellows devices without an outlet unidirectional valve shall be marked “FOR USE ONLY WITH AN ANAESTHETIC PATIENT VALVE” and/or the equivalent in the national language.

8.6 Marking of packages

Packages containing breathing attachments or complete breathing systems shall be legibly marked with the following:

a) a description of the contents;

b) where applicable the words “FOR SINGLE USE”, and/or the equivalent in the national language or symbol No. 1051 (indicating “do not re-use”) given in ISO 7000;

c) if appropriate, the word “STERILE” and/or the equivalent in the national language or a symbol;

d) the name and/or trademark of the manufacturer and/or supplier;

e) an identification reference to the lot or date of manufacture;

f) if applicable, recommended methods of cleaning and sterilization or disinfection, including the maximum number of cycles recommended;

g) if the packages contain breathing attachments or complete breathing systems made of antistatic material, the word “ANTISTATIC” and/or the equivalent in the national language shall be marked legibly on the package.

9 Information to be provided with equipment

9.1 General

The following information shall be provided by the manufacturer/supplier of the complete draw-over vaporizer system:

a) instructions for assembling the complete draw-over anaesthetic system, including specifications for the associated components and their relative positions. and diagrams of the complete system(s);

b) a pre-use checklist.

9.2 Draw-over vaporizer

The following information shall be provided by the manufacturer/supplier of the draw-over vaporizer:

a) instructions for securely mounting the vaporizer prior to use;

b) instructions for filling the draw-over vaporizer, including the volume of agent for filling from minimum to maximum filling levels;

c) effect on the performance of the vaporizer of ambient temperature, tilting, filling volume, minute volume, breathing pattern and duration of use;

d) instructions for maintenance of the vaporizer by the user, including inspection, cleaning and disinfection;

More detailed instructions for servicing by trained technicians should be available on request.

e) if applicable, instructions for the procedure to be followed when changing from one agent to another;

f) details of the test conditions to be followed when checking the output of the vaporizer;

g) a statement to draw the user's attention to the potential hazards of using flammable anaesthetic agents;

h) if applicable, a statement that the calibration of draw-over vaporizers can be inaccurate if intermittent positive-pressure ventilation is applied to the vaporizer;

i) if applicable, details of the performance of the vaporizer when used as a continuous-flow anaesthesia system;

j) the maximum and minimum flow capabilities of the vaporizer;

k) information on precautions to be taken before transporting the vaporizer;

l) performance of the draw-over vaporizer and the conditions under which the performance was determined.

9.3 Inflating bellows

The following information shall be provided by the manufacturer/supplier of the inflating bellows device:

a) the maximum volume displaced from the bellows;

b) the positions of the unidirectional valves, and the method of de-activating the outlet unidirectional valve when it is not required;

c) the pressure/flow characteristics of the pressure-relief valve;

d) instructions for inspection, cleaning, disinfection and general maintenance of the device;

e) a list of component parts which are replaceable;

f) a procedure for checking the correct functioning of the device after servicing.

9.4 Anaesthetic patient valve

The following information shall be provided by the manufacturer/supplier of the anaesthetic patient valve:

a) instructions for inspection, cleaning, disinfection, sterilization and general maintenance of the valve;

b) a list of component parts which are replaceable;

c) a procedure for checking the correct functioning of the valve after servicing;

d) * a warning that the anaesthetic patient valve is not suitable for use in a continuous-flow anaesthetic system.

Annex A
(normative)

Test methods

A.1 General

The ambient temperature during all tests shall be between 20 °C and 25 °C, except where otherwise stated.

The accuracy of all measuring devices used during tests shall be ± 5 % of the variable to be measured, unless otherwise stated.

A.2 Environmental testing

All components shall be subjected to environmental testing in transport, storage and normal-use conditions in accordance with IEC 60601-1:1988, 10.1 and 10.2.

A.3 Test for output performance of draw-over vaporizer

A.3.1 Apparatus

A.3.1.1 **Anaesthetic-agent monitor**.

A.3.1.2 **Adjustable sine-wave generator**.

A.3.2.2 **Non-rebreathing valve**.

A.3.2.3 **Breathing bag**, of not less than 10 l capacity.

A.3.2 Procedure

Fill the vaporizer to half-full with the correct anaesthetic agent and allow the temperature to stabilize for at least 2 h before beginning the test.

Connect the adjustable sine-wave generator to the outlet port of the vaporizer, and arrange it to draw air and agent from the vaporizer and then discharge it through the non-rebreathing valve to the breathing bag.

Connect the anaesthetic-agent monitor to the breathing bag, ensuring that the agent concentration (mass fraction) is measured from completely mixed fresh gas.

Empty the breathing bag between each test to prevent contamination of the gas sample under test.

Start the adjustable sine-wave generator and with the agent concentration (mass fraction) set to the concentration in Table A.1, run the pump for 1 min, collect the fresh gas for the next 1 min and measure the agent concentration in the collected gas sample.

Table A.1 — Settings to be used for output performance of draw-over vaporizer

Order of test	Setting (% volume fraction of anaesthetic vapour)
1	off, standby, and zero, if separately marked
2 [a]	lowest graduation above zero
3	10 % full scale (FS)
4	20 % FS
5	50 % FS
6	75 % FS
7	maximum graduation (full scale)

[a] If 10 % of FS is the lowest graduation, step 2 is omitted.

A.4 Test for capacity of air/oxygen reservoir

A.4.1 Apparatus

A.4.1.1 **Oxygen supply**.

A.4.1.2 **Flowmeter**, to measure up to 6 l/min.

A.4.1.3 **Oxygen analyser**.

A.4.1.4 **Adjustable sine-wave generator**.

A.4.2 Procedure

Connect the adjustable sine-wave generator to the outlet port of the air/oxygen reservoir, arranged in such a way that it draws air out of the reservoir and discharges it to the atmosphere.

Connect the metered oxygen supply to the oxygen inlet and position the sensor of the oxygen analyser adjacent to the air inlet port.

Start the adjustable sine-wave generator and adjust it to deliver a volume of 600 ml ± 10 % at a frequency of 12 cycles per min. After 1 min turn on the oxygen supply at a flowrate of 6 l/min and record the oxygen reading after a further 2 min.

A.5 Test for reverse flow through unidirectional valves

A.5.1 Apparatus

A.5.1.1 **Flow-measuring device**, of accuracy within ± 5 % of the variable to be measured.

A.5.1.2 **Pressure-measuring device**, of accuracies ± 0,01 kPa (± 0,1 cmH_2O) at a pressure of 0,5 kPa (5 cmH_2O) and ± 0,03 kPa (± 0,3 cmH_2O) at a pressure of 5 kPa (50 cmH_2O).

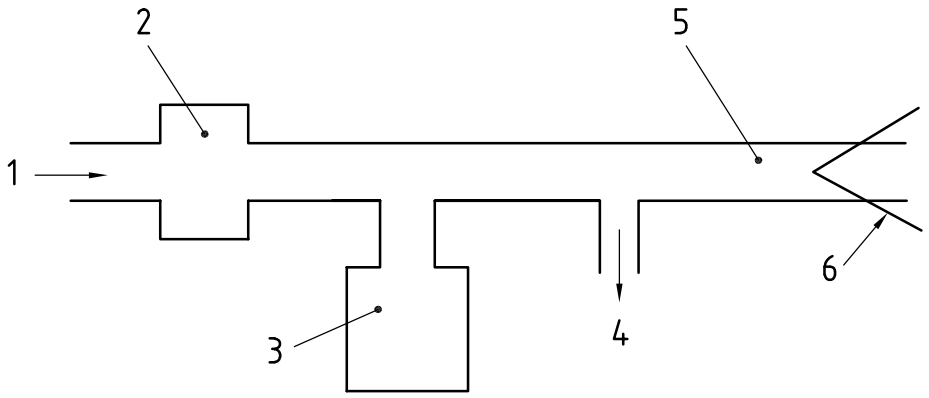
A.5.1.3 **Rigid container**, having a capacity of (5 ± 0,25) l.

A.5.2 Procedure

A.5.2.1 Connect the downstream side of the inspiratory or expiratory valve to a pressure source, the flow-measuring device, the rigid container and the pressure-measuring device as shown in Figure A.1. Adjust the flowrate to a constant 65 ml/min and record the time taken for the pressure to reach 0,5 kPa (5 cmH_2O).

NOTE Within the tolerances of the test apparatus, using a flowrate of 65 ml/min will mean that valves having a reverse flowrate of less than 60 ml/min will meet the requirements (see 6.3.2) and those having a reverse flowrate of more than 70 ml/min will fail.

A.5.2.2 Adjust the flowrate to give a pressure of 5 kPa (50 cmH_2O) and hold this pressure for 1 min. Release the pressure and check that the valve disc or flap has not become dislocated by repeating the procedure described in A.5.2.1 and verifying that the pressure rises to 0,5 kPa (5 cmH_2O) within 5 min.



Key

1 from pressure source
2 flowmeter
3 rigid container
4 to pressure-measuring device
5 thermometer location
6 inspiratory or expiratory valve

Figure A.1 — Arrangement of apparatus to test for reverse flow through inspiratory and expiratory valves supplied as separate components

A.6 Resistance to spontaneous inspiration and expiration

A.6.1 Apparatus

A.6.1.1 **Adjustable sine wave generator**, without unidirectional valves.

A.6.1.2 **Pressure-measuring device**, capable of measuring pressures of − 0,6 kPa and + 0,2 kPa.

A.6.1.3 **Recorder**, for recording the pressure readings and the adjustable sine-wave generator displacement.

A.6.2 Procedure

Assemble the complete draw-over anaesthetic system with an empty (dry) vaporizer and with the bellows in its normal free resting position.

Attach the adjustable sine-wave generator to the patient connection port, and provide a tapping for the pressure-measuring device at this connection.

Adjust the sine-wave generator to provide a delivered volume of 600 ml ± 10 % at a frequency of 12 cycles per min and record the pressure variations at the patient connection for a number of cycles. Note the maximum and minimum pressures recorded.

Perform the test with the vaporizer control both in the OFF position and at full scale.

Annex B
(informative)

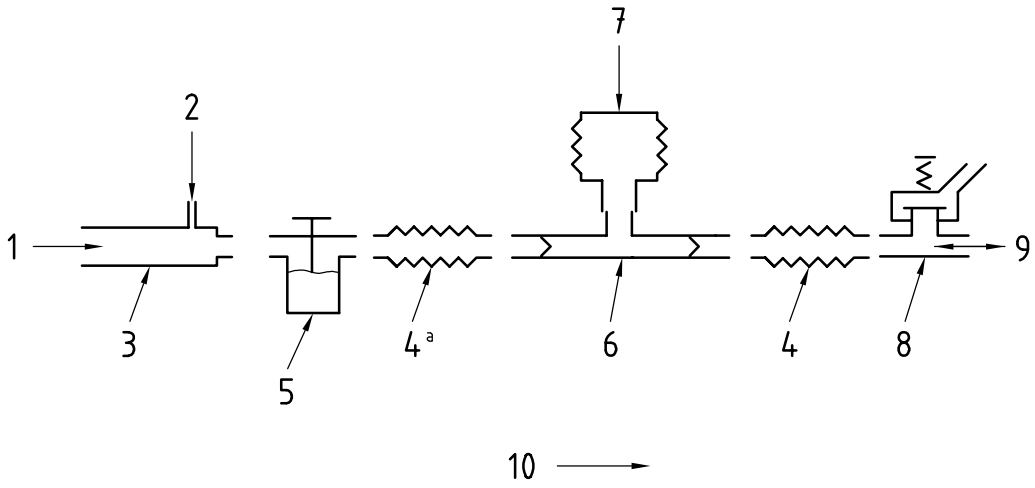
Diagrams of assemblies of components used in draw-over anaesthetic systems

B.1 General

The diagrams presented in this annex are intended to indicate the relative positions of the components in a system based on a draw-over vaporizer and to some extent their functions. They do not represent the construction of individual components, many of which are of proprietary design and therefore not detailed in this Technical Specification.

B.2 Draw-over anaesthetic system

This system includes an inflating bellows device with two unidirectional valves, and an adjustable expiratory valve at the patient connection port. It is very suitable for spontaneously breathing patients, but controlled ventilation presents some problems, as the expiratory valve requires continuous attention and adjustment.



Key

1	air inlet	6	inflating bellows device with two unidirectional valves
2	oxygen inlet	7	bellows free to move or manually controlled
3	air/oxygen reservoir	8	adjustable expiratory valve
4	connecting tube	9	to and from patient
5	draw-over vaporizer	10	direction of flow

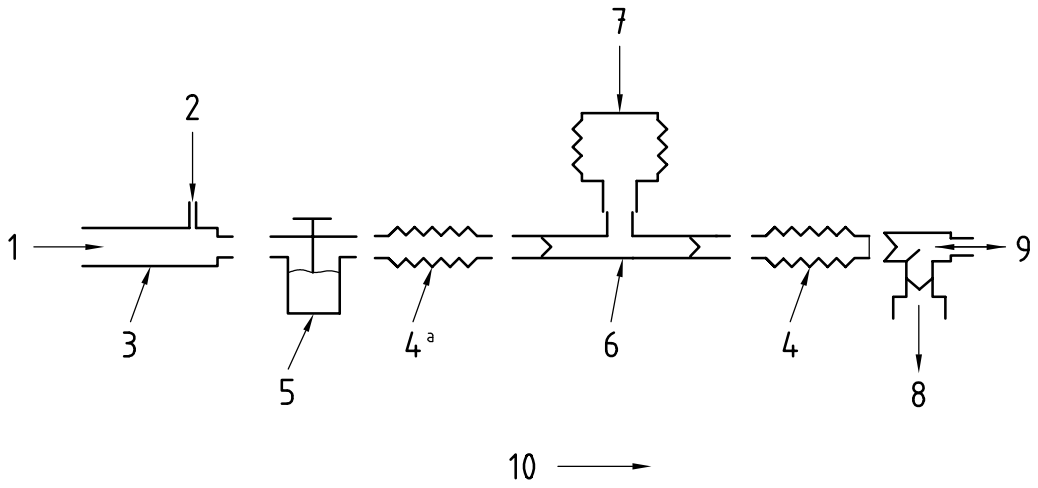
[a] Optional.

Figure B.1 — Draw-over anaesthetic system for spontaneous breathing

B.3 Draw-over anaesthetic system with anaesthetic patient valve

This is the most commonly used system, which includes an inflating bellows device with a unidirectional valve at its inlet only. The outlet unidirectional valve is either put out of action or removed, and its function is transferred to the anaesthetic patient valve.

The system is suitable for both spontaneous breathing and controlled ventilation without alteration to connections or controls.

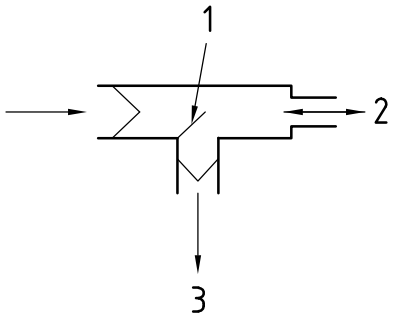


Key

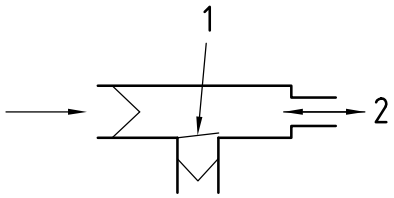
1	air inlet	6	inflating bellows device with inlet unidirectional valve only
2	oxygen inlet	7	bellows free to move, manually operated or mechanically driven
3	air/oxygen reservoir	8	anaesthetic patient valve (APV; see Figure B.3)
4	connecting tube	9	to and from patient
5	draw-over vaporizer	10	direction of flow

[a] Optional.

Figure B.2 — Draw-over anaesthetic system with anaesthetic patient valve for spontaneous breathing or controlled ventilation



a) Normal state of APV during spontaneous breathing and expiratory phase of IPPV



b) State of APV during inspiratory phase of IPPV

Key

1 pressure-operated valve (permits flow to exhaust during normal state but closes during inspiratory phase of IPPV)
2 flow to and from patient
3 flow to exhaust during normal state

Figure B.3 — Anaesthetic patient valve

Annex C
(informative)

Rationale

This annex provides a rationale for some requirements of this Technical Specification, and is intended for those who are familiar with the subject of this Technical Specification but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this Technical Specification necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this Technical Specification. The numbering is, therefore, not consecutive.

C.4

A sequential system of female and male conical connectors has been adopted, as all the major components of this draw-over vaporizer anaesthetic system are flow-direction sensitive. Such a system does not overcome the hazard of omitting a major component or of assembling components in the wrong order, but in view of the small number of components employed, this risk is considered acceptable.

C.4.4.3

A 30 mm conical connector is specified at the exhaust port to facilitate connection to an anaesthetic gas scavenging system (AGSS) complying with ISO 8835-3. It is not anticipated that a sophisticated AGSS will be a high priority, but simple steps such as attaching a hose to lead waste gases to floor level can substantially reduce levels of pollution at the breathing level of theatre staff.

C.5.1.1

An example of a flammable anaesthetic agent in use is diethyl ether. Examples of non-flammable anaesthetic agents are halothane and isoflurane. IEC 60601-2-13:2003 provides in Annexes AA and DD details on the methods of test to determine the flammability of anaesthetic agents.

It is important that the instructions for use draw attention to the potential hazards in using non-APG equipment with flammable agents [see 9.1 g)].

C.5.4

The bellows device has a number of advantages.

a) The concertina bellows, when free to expand and contract axially, provides a very flexible reservoir from which the patient can draw part of the inspired volume when breathing spontaneously, and which refills through the vaporizer during the patient's expiratory phase. This considerably reduces the peak flowrate through the vaporizer.

b) During spontaneous breathing, the bellows move up and down, thereby providing a useful visual indication of respiratory rhythm and changes.

c) When the concertina bellows is compressed manually, it is capable of inflating stiff lungs as it has low compliance when axial expansion is prevented.

d) It is less fatiguing to operate a bellows unit for prolonged ventilation than to squeeze a self-inflating bag.

It is recognized that some systems use a self-inflating bag instead of bellows, but these systems are not covered by this Technical Specification.

C.5.4.2

The operation of the anaesthetic patient valve in changing from inflation to exhalation during IPPV is dependent upon the function of the component that acts as the inflating valve.

If an additional unidirectional valve is provided on the patient side of the inflating bellows device then, under certain circumstances, the pressure that activates the inflating valve component of the anaesthetic patient valve may be maintained above that at the patient connection port thus preventing exhalation and damaging the patient.

C.6.4.3

The inflating valve, or that part of the anaesthetic patient valve that acts as the inflating valve, may not close upon the initiation of inflating flow from the bellows device, thus allowing gas to escape through the expiratory port. This leakage is likely to vary according to the applied waveform and therefore the manufacturer shall specify the conditions under which the valve achieves the required efficiency.

C.7.1

Adding a high flow of oxygen anywhere downstream from the bellows inlet NRV could lead to the build-up of pressure, which would cause the anaesthetic patient valve expiratory port to lock closed. This problem does not arise if the oxygen inlet is upstream of the bellows NRV, as excess gas will simply escape from the air inlet port of the air/oxygen reservoir.

Addition of oxygen or air downstream from the vaporizer will dilute the vapour mixture.

C.7.2

Draw-over vaporizers are designed and calibrated to operate at or slightly below atmospheric pressure. The calibration may not be valid under IPPV.

C.9.4 a)

If that component of the anaesthetic patient valve that acts as the inflating valve is operated pneumatically, then when such a valve is subjected to a flow of gas that is always above ambient pressure, as is the case in a continuous flow anaesthetic system, there will be a risk that it could lock in the inspiratory position and thus harm the patient.

Bibliography

[1] IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

[2] ISO 8835-3, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

[3] ISO 10651-4, *Lung ventilators — Part 4: Particular requirements for operator-powered resuscitators*

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