TECHNICAL SPECIFICATION

**ISO/TS 18835**

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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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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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order to decide whether it will be confirmed for a further three years, revised to become an International Standard, or withdrawn.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again after a further three years, at which time it must either be transformed into an International Standard or be withdrawn.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 %.