INTERNATIONAL STANDARD

ISO 18835

First edition
2015-04-01

Inhalational anaesthesia systems — Draw-over anaesthetic systems

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

Reference number
ISO 18835:2015(E)

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

Published in Switzerland

Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: Foreword — Supplementary information.

This International Standard cancels and replaces ISO/TS 18835:2004, which has been technically revised.

Introduction

The continuous-flow anaesthetic workstations described in ISO 80601-2-13 rely upon an uninterrupted supply of compressed medical gases and electricity. These in turn depend upon a highly developed infrastructure of transport, power generation, and technical services.

The World Health Organization (WHO) and the World Federation of Societies of Anaesthesiologists (WFSA) have requested ISO ensure that the needs for safe anaesthesia for people in populous and low to middle income countries of the world are also addressed in ISO standards for anaesthetic equipment.

In accordance with this request, ISO/TC 121/SC 1 has developed a standard for anaesthetic systems (ISO 8835-7) that can give a safe inhalation anaesthetic without relying on electricity or compressed gas.

To achieve this, it is recognized that the DRAW-OVER ANAESTHETIC SYSTEM is an essential part of this system. A technical specification for DRAW-OVER VAPORIZERS and associated equipment, ISO/TS 18835 has been in publication since 2004 and forms the basis of this International Standard.

Throughout this International Standard, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

In this International Standard, the following print types are used:

— requirements, compliance with which can be verified, and definitions: roman type;

— notes and examples: smaller roman type;

— test methods: *italic type*;

— terms defined in this document: SMALL CAPS.

Inhalational anaesthesia systems — Draw-over anaesthetic systems

1 * Scope

This International Standard specifies basic safety and essential performance requirements for anaesthetic systems utilizing the draw-over method to provide inhalational anaesthesia.

Requirements are included to allow the use of these systems with both non-flammable and flammable anaesthetic agents.

This International Standard also includes requirements for a bellows-type manual ventilator.

NOTE 1 Requirements for automatic anaesthetic ventilators are covered by ISO 80601-2-13.

NOTE 2 Requirements for operator-powered self-inflating bags are covered by ISO 10651-4.

This International Standard does not specify requirements for monitoring of the equipment or the patient.

2 Normative references

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

ISO 4135:2001, *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, *Anaesthetic and respiratory equipment — Breathing sets and connectors*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 23328-1, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

ISO 80369-7[1)], *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

EN 13544-2:2002+A1:2009, *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 4135:2001 and the following apply.

1) This reference will be replaced by ISO 80369-2 once this International Standard has been published.

3.1
CARRIER GAS
respirable gas that carries the anaesthetic agent to the patient

Note 1 to entry: A common example of a CARRIER GAS is entrained ambient air supplemented with oxygen.

3.2
DRAW-OVER ANAESTHETIC SYSTEM
low-resistance system for administering inhalational anaesthesia that can be used in the absence of compressed gas or electricity

3.3
DRAW-OVER VALVE SYSTEM
a valve, or combination of valves, that controls unidirectional flow to the patient during inspiration and unidirectional flow from the patient during exhalation under both spontaneous ventilation and intermittent positive pressure ventilation (IPPV)

3.4
DRAW-OVER VAPORIZER
vaporizer from which a sufficient flow of gas vapour mixture is produced by lowering the pressure at the outlet of the vaporizer below that at its inlet by a patient's inspiratory effort or by a ventilator

[SOURCE: ISO 4135:2001, 4.1.8, modified — the breathing system and the vaporizer are treated as separate devices in this International Standard, and thus, the phrase "either in the breathing system and the vaporizer," as used in ISO 4135, is inappropriate in this International Standard]

3.5
EXHAUST PORT
port through which the patient exhales to the atmosphere or into the inlet port of an anaesthetic gas scavenging transfer system

[SOURCE: ISO 4135:2001, 4.2.1.6, modified — in order to be more specific as the exhaust port is an integral part of the draw-over valve system]

3.6
OPERATOR-DETACHABLE
detachable without the use of a tool

3.7
PATIENT CONNECTION PORT
opening at the patient end of a breathing system intended for connection of an airway device

[SOURCE: ISO 4135:2001, 4.2.1.2, modified — the examples that were not considered necessary for this International Standard have been deleted]

3.8
RESERVOIR
container where the CARRIER GAS mixes with supplementary oxygen

4 General requirements

4.1 Risk management

The manufacturer of a DRAW-OVER ANAESTHETIC SYSTEM or parts intended for use in a DRAW-OVER ANAESTHETIC SYSTEM shall follow a risk management process in accordance with ISO 14971. Any unacceptable risk shall be mitigated by in this order:

a) design features which prevent the hazard;

b) inclusion of a means of protection;

c) inclusion of a monitoring and/or an alarm system;

d) safety and handling advice by marking or labelling.

If the inclusion of such risk mitigation measures is not feasible, the instructions for use shall contain

— a statement recommending that such risk mitigation measures be added prior to the use of the DRAW-OVER ANAESTHETIC SYSTEM,

— sufficient specification of such risk mitigation measures, and

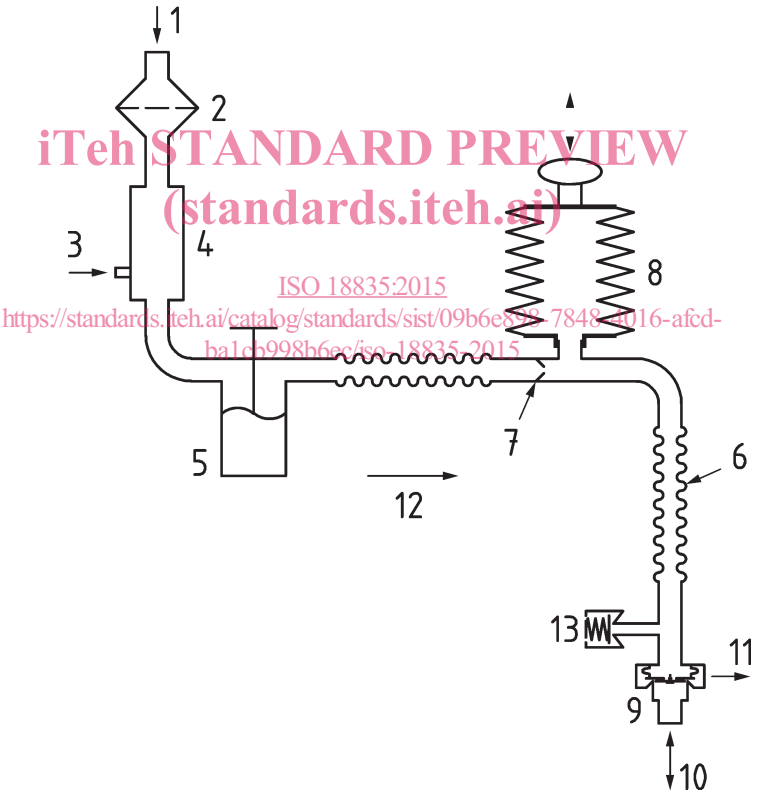
— a description of any residual risk to the patient or user/bystander.

Check compliance by inspection of the risk management file and, if applicable, the instructions for use.

4.2 Construction

A DRAW-OVER ANAESTHETIC SYSTEM shall comprise a DRAW-OVER VAPORIZER and a breathing system. It can also include a ventilator and a RESERVOIR if oxygen is to be added to the CARRIER GAS.

NOTE An example of a DRAW-OVER ANAESTHETIC SYSTEM is shown in Figure 1.



Key

1	ambient air inlet	8	ventilator
2	means of particle protection	9	part of DRAW-OVER VALVE SYSTEM
3	supplementary oxygen inlet	10	flow to and from patient
4	RESERVOIR	11	EXHAUST PORT
5	DRAW-OVER VAPORIZER	12	direction of flow
6	breathing system tubing	13	pressure relief valve
7	part of DRAW-OVER VALVE SYSTEM		

Figure 1 — Schematic representation of the components of a DRAW-OVER ANAESTHETIC SYSTEM

4.3 Performance

The resistance to inspiration for the DRAW-OVER ANAESTHETIC SYSTEM shall not exceed 0,6 kPa and the resistance to expiration shall not exceed 0,2 kPa under the following conditions:

a) a tidal volume of (600 ± 60) ml;

b) a frequency of 12 cycles per minute;

c) using a sinusoidal wave form or at an I:E ratio of 1:1.

Check compliance by the test given in B.3.

4.4 * Components for use with flammable anaesthetic agents

All components intended to be used with flammable anaesthetic agents shall comply with the applicable requirements of IEC 60601-1:2005+A1:2012, 11.4.

Check compliance by inspection of the technical file.

4.5 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 with during use.

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

NOTE DRAW-OVER ANAESTHETIC SYSTEMS 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.

Check compliance by inspection of the technical file.

4.6 Mechanical hazards

DRAW-OVER ANAESTHETIC SYSTEMS shall comply with IEC 60601-1:2005+A1:2012, Clause 9, where applicable.

Check compliance by inspection of the technical file and the tests given in IEC 60601-1:2005+A1:2012.

4.7 Particulate matter

Means shall be provided to reduce the risk of particulate matter from entering the DRAW-OVER ANAESTHETIC SYSTEM and being inhaled by the patient.

NOTE Particulate matter can be taken to mean any foreign bodies including small creatures.

If a breathing system filter is used, it shall comply with ISO 23328-1 and ISO 23328-2.

Check compliance by visual inspection.

4.8 Environmental requirements

DRAW OVER ANAESTHETIC SYSTEMS and components thereof shall not be adversely affected when transported and stored under the following environmental conditions:

a) ambient temperatures between –20 °C and +70°C;

b) relative humidity between 30 % and 100 %;

c) atmospheric pressures between 500 hPa and 1060 hPa.

Check compliance by functional testing.

5 DRAW-OVER VAPORIZER

5.1 Construction

5.1.1 A visual indication of the level of liquid anaesthetic agent contained within the DRAW-OVER VAPORIZER shall be provided [see 9.2.1 f)].

Check compliance by visual inspection.

5.1.2 A control shall be provided to adjust the vapour concentration (volume fraction) calibrated for each intended anaesthetic agent and

a) under normal operating conditions, it shall not be possible to set the control above the calibrated range,

b) the control can have a separate "OFF" position in addition to a "0" or "zero" position, and

c) a means shall be provided to reduce the risk of unintended change of the control from its set position.

Check compliance by visual inspection and functional testing.

5.1.3 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.

Check compliance by visual inspection and functional testing.

5.1.4 The DRAW-OVER VAPORIZER shall either

a) be provided with mounting fittings suitable to enable it to be rigidly supported, or

b) have a base designed to provide stability when freestanding.

Check compliance by visual inspection and functional testing.

5.2 Performance

5.2.1 The output in the "0", "OFF", or "zero" position shall be less than 0,1 %.

Check compliance by the test given in B.2.

5.2.2 * 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 under the following conditions:

a) throughout the temperature range of 20 °C to 30 °C;

b) through the range of minute volumes from 2 l to 8 l;

c) at a frequency of 12 breaths per minute;

d) using a sinusoidal wave form or at an I:E ratio of 1:1.

The manufacturer shall disclose, in his technical file, the test method used to confirm the accuracy requirements of this International Standard.

Check compliance by inspection of the technical file.

5.2.3 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 up to an angle of 30° from the vertical.

Check compliance by functional testing.

5.3 * Ports and connectors

5.3.1 The inlet port, if OPERATOR-DETACHABLE, shall be a 22 mm socket complying with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection and functional testing.

5.3.2 The outlet port, if OPERATOR-DETACHABLE, shall be a 22 mm cone complying with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection and functional testing.

5.3.3 If the DRAW-OVER VAPORIZER is fitted with an agent-specific filler port, it shall comply with the requirements of ISO 5360.

Check compliance by visual inspection and the tests given in ISO 5360.

6 Breathing system

6.1 Construction

6.1.1 The breathing system shall include a DRAW-OVER VALVE SYSTEM. The DRAW-OVER VALVE SYSTEM shall ensure that

a) the patient can inhale and exhale during both spontaneous and positive pressure ventilation,

b) the risk of jamming is minimized,

c) the rebreathing of expired gas is reduced to a minimum (see 6.2.1),

d) the unintentional entrainment of ambient air into the system is reduced to a minimum (see 6.2.2), and

e) the operation of the valve can be seen by the operator.

Check compliance by functional testing.

6.1.2 The breathing system shall be designed so that

a) it is OPERATOR-DETACHABLE, and

b) the risk of incorrect assembly is reduced.

Check compliance by visual inspection, functional testing, and inspection of the risk management file.

6.1.3 Breathing system tubes shall comply with ISO 5367.

Check compliance by inspection of the technical file.

6.1.4 Breathing systems should be designed to reduce the risk of cross contamination.

