BS ISO 18835:2015

BSI Standards Publication

Inhalational anaesthesia systems — Draw-over anaesthetic systems

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National foreword

This British Standard is the UK implementation of ISO 18835:2015. It supersedes DD ISO/TS 18835:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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INTERNATIONAL STANDARD

ISO 18835

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Inhalational anaesthesia systems — Draw-over anaesthetic systems

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

Reference number
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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.

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.

INTERNATIONAL STANDARD ISO 18835:2015(E)

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

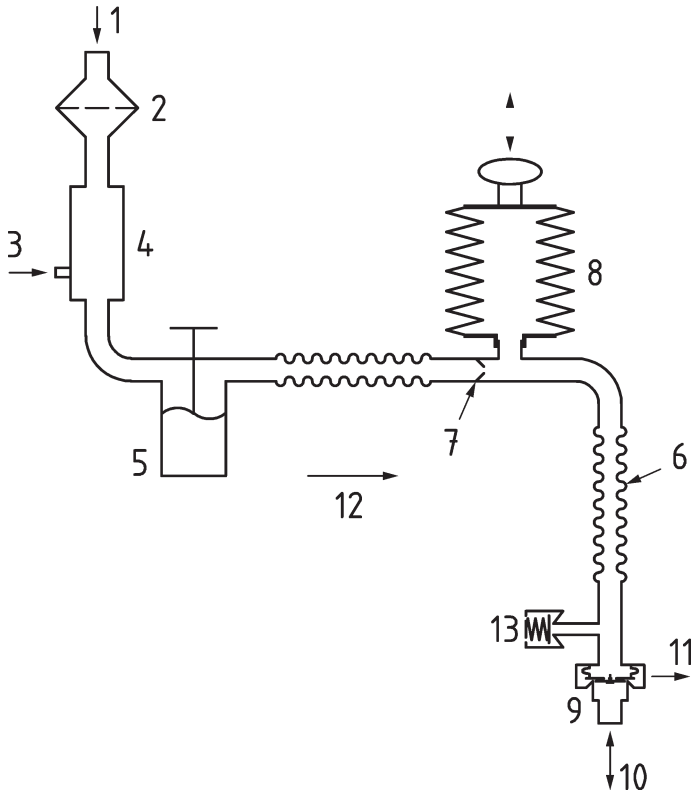
— a description of any residual risk to the patient or user/bystander.

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

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.

6.2 Performance

6.2.1 The reverse flow of gas from the patient shall be less than 1 % of the minute volume over a range of 2 l to 8 l at 12 breaths per minute using a sinusoidal waveform.

Check compliance by functional testing.

6.2.2 The unintentional entrainment of air into the breathing system shall be less than 1 % of the minute volume over a range of 2 l to 8 l at 12 breaths per minute using a sinusoidal waveform.

Check compliance by functional testing.

6.3 Ports and connectors

6.3.1 The inlet port of the breathing system, if OPERATOR-DETACHABLE, shall be a 22 mm socket complying with ISO 5356-1.

Check compliance by visual inspection and functional testing.

6.3.2 The PATIENT CONNECTION PORT shall be a 22/15 mm conical coaxial cone/socket complying with ISO 5356-1.

Check compliance by visual inspection and functional testing.

6.3.3 ***** The EXHAUST PORT of the breathing system shall be a 30 mm cone complying with ISO 5356-1.

Check compliance by visual inspection and functional testing.

6.3.4 Other OPERATOR-DETACHABLE conical cones and sockets used in the breathing system shall comply with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection and functional testing.

7 RESERVOIR

7.1 Construction

7.1.1 The RESERVOIR shall allow entry of ambient air and be fitted with a supplementary oxygen inlet connector.

Check compliance by visual inspection and functional testing.

7.1.2 ***** The supplementary oxygen inlet connector shall be placed as close as possible to the outlet of the RESERVOIR, for example, at the connection to the DRAW-OVER VAPORIZER.

Check compliance by visual inspection.

7.1.3 If a breathing system tube is used as the RESERVOIR, it shall comply with ISO 5367.

Check compliance by visual inspection and functional testing.

7.2 Performance

The pressure in the RESERVOIR shall be limited to a maximum of 0,5 kPa (5 cmH_2O).

Check compliance functional testing.

7.3 Ports and connectors

7.3.1 If OPERATOR-DETACHABLE, the supplementary oxygen inlet connector shall be a nipple complying with EN 13544-2:2002+A1:2009, 3.1.

Check compliance by the tests given in EN 13544-2:2002+A1:2009.

7.3.2 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.

7.3.3 The ambient air inlet port shall

a) be open to the atmosphere (see also 4.7),

b) be designed to reduce the risk of accidental obstruction, and

c) not be compatible with cones and sockets complying with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection.

8 Bellows-type manual ventilator

8.1 * Construction

A means to limit the pressure within the gas pathway of a bellows-type manual ventilator shall be provided (see 8.2.4).

Check compliance by visual inspection.

8.2 Performance

8.2.1 If freestanding, the bellows-type manual ventilator shall not fall over when subjected to a force of 30 N at an angle of 30 ° from the vertical.

Check compliance by seeing whether or not the bellows-type manual ventilator falls over when applying a force of 30 N in a downward direction to the top of the device at an angle of 30° from the vertical.

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

Check compliance by functional testing (e.g. discharging into a spirometer).

8.2.3 The reverse flow of gas during operation of the valve(s) in the bellows-type manual ventilator shall be less than 1 % of the minute volume over a range of 2 l to 8 l at a frequency of 12 breaths per minute using a sinusoidal wave form.

Check compliance by functional testing.

8.2.4 The pressure at the PATIENT CONNECTION PORT shall not exceed 5,5 kPa (55 cmH_2O) under both normal and single-fault conditions.

Check compliance by functional testing.

8.3 Ports and connectors

8.3.1 The inlet port shall be a 22 mm socket complying with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection and functional testing.

8.3.2 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.

8.3.3 The connection for the bellows shall not be a cone or socket complying with ISO 5356-1 or ISO 5356-2.

Check compliance by visual inspection and functional testing.

8.3.4 If provided, the connection for a pressure monitor shall be a luer connector complying with ISO 80369-7 and shall have means of sealing when not connected to the pressure monitoring device.

NOTE It is the intention to replace this luer connector with the new respiratory R1 small-bore connector as soon as the International Standard ISO 80369-2 (in preparation) is published.

Check compliance by visual inspection and functional testing.

9 Marking of operator-assembled components

9.1 General

The requirements of 9.2 to 9.6 can be met by use of the appropriate symbols as given in ISO 15223-1.

9.2 Marking of the DRAW-OVER VAPORIZER

9.2.1 The DRAW-OVER VAPORIZER shall be durably and legibly marked with the following:

a) the name or trade name and address of the manufacturer or supplier;

b) the batch code or serial number;

c) the generic name of the specific anaesthetic agent;

This should be on the vaporizer output graduated scale.

NOTE An abbreviated version can be used, e.g. ENF — Enflurane, HAL — Halothane, ISO — Isoflurane, SEV — Sevoflurane, ETH — Ether.

d) a warning to the effect that the DRAW-OVER VAPORIZER shall not be used with desflurane;

e) if colour coding is used, it shall be in accordance with ISO 5360;

f) graduated controls with the units in which the graduation is made;

g) graduated controls with “0”, “OFF”, or “zero” position;

h) either the maximum and minimum filling levels shall be marked or the actual useable volume shall be displayed;

i) the direction of operation of the control to increase the concentration (mass fraction).

Check compliance by visual inspection and by applying the tests for legibility and durability of markings in accordance with IEC 60601-1:2005+A1:2012, 7.1.2, and 7.1.3 b).

9.2.2 If a DRAW-OVER VAPORIZER is provided with interchangeable scales for more than one agent, no agent identification, as specified in 9.2.1 c), or colour coding, as specified in 9.2.1 e), shall be provided except on these scales.

Check compliance by visual inspection.

9.3 Marking of breathing-system attachments

All components that are OPERATOR-DETACHABLE shall be durably and legibly marked with the following:

a) the name or trade name and address of the manufacturer or supplier;

b) the batch code or serial number;

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

d) for breathing system EXHAUST PORTS, the word "EXHAUST" and/or "AGSS" or the equivalent in the national language;

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

NOTE An indelible yellow-coloured mark can also be used.

f) if flow-direction-sensitive, an arrow to indicate the direction of gas flow unless they cannot be assembled or positioned incorrectly;

NOTE The words "INLET" and "OUTLET" or the equivalent in the national language can be marked in addition.

g) if not for reuse, appropriate wording.

Check compliance by visual inspection and by applying the tests for legibility and durability of markings in accordance with IEC 60601-1+A1:2012, 7.1.2 and 7.1.3 b).

9.4 Marking of RESERVOIR

The RESERVOIR shall be durably and legibly marked with the following:

a) the name or trade name and address of the manufacturer or supplier;

b) the batch code or serial number;

c) at the air inlet, the words "AIR INLET — DO NOT OBSTRUCT" or the equivalent in the national language;

d) at the supplementary oxygen inlet, the words "OXYGEN" or the equivalent in the national language.

NOTE The gas symbol O_2 can be used instead of "OXYGEN".

Check compliance by visual inspection and by applying the tests for legibility and durability of markings in accordance with IEC 60601-1+A1:2012, 7.1.2 and 7.1.3 b).

9.5 Marking of bellows-type manual ventilator

Bellows-type ventilators shall be durably and legibly marked with the following:

a) the name or trade name and address of the manufacturer or supplier;

b) the batch code or serial number;

c) for pressure monitor connections, “PRESSURE MONITOR”, or the equivalent in the national language.

Check compliance by visual inspection and by applying the tests for legibility and durability of markings in accordance with IEC 60601-1+A1:2012, 7.1.2 and 7.1.3 b).

9.6 Marking of packages

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

a) the name or trade name and address of the manufacturer or supplier;

b) the batch code or serial number;

c) a description of the contents;

d) where applicable, the words “FOR SINGLE USE” or the equivalent in the national language;

NOTE Alternatively, symbol 5.4.2 (indicating “do not re-use”) given in ISO 15223-1:2012 can be used.

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

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

g) if the package contains breathing attachments or complete breathing systems made of antistatic material, the word “ANTISTATIC” and/or the equivalent in the national language.

Check compliance by visual inspection.

10 Information supplied by the manufacturer

The manufacturer/supplier of the complete DRAW-OVER ANAESTHETIC SYSTEM, or components thereof, shall provide instructions for use in which the following information shall be included:

a) the name or trade name and address of the manufacturer or supplier;

b) where appropriate, the batch code or the serial number;

c) for the DRAW-OVER ANAESTHETIC SYSTEM:

1) if designed to be assembled by the operator, 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;

2) a pre-use checklist;

3) the range of tidal volumes and respiratory rates over which at least 80 % of the displaced volume from a sine-wave generator is delivered to an appropriate test lung;

4) the optimal method of hand ventilation in order to minimize the volume of gas bypassing the patient.

d) for the DRAW-OVER VAPORIZER:

1) instructions for securely mounting the DRAW-OVER VAPORIZER prior to use;

2) instructions for filling the DRAW-OVER VAPORIZER, including the volume of agent for filling from the minimum to the maximum filling level;

3) effect of ambient temperature, tilting, filling volume, minute volume, breathing pattern, and duration of use on the performance of the DRAW-OVER VAPORIZER and, if appropriate, at continuous flow;

4) instructions for maintenance of the DRAW-OVER VAPORIZER by the user, including inspection, cleaning, and disinfection;

NOTE More detailed instructions for servicing by trained technicians can be available upon request.

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

6) details of the test conditions to be followed when checking the output of the DRAW-OVER VAPORIZER;

7) a warning statement on the potential hazards of using flammable anaesthetic agents;

8) if applicable, details of the performance of the DRAW-OVER VAPORIZER when used as a continuous-flow anaesthetic system;

9) the maximum and minimum flow capabilities of the DRAW-OVER VAPORIZER;

10) information on precautions to be taken before transporting the DRAW-OVER VAPORIZER;

11) performance of the DRAW-OVER VAPORIZER and the conditions under which the performance was determined.

e) for the bellows-type manual ventilator:

1) the maximum volume displaced from the device;

2) the positions of unidirectional valves and the method of deactivating the expiratory unidirectional valve when it is not required;

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

4) instructions for inspection, cleaning, disinfection, and general maintenance of the ventilator;

5) a list of replaceable component parts;

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

f) for the breathing system:

1) methods for cleaning, disinfection, or sterilization;

2) instructions for general maintenance including a list of the replaceable component parts;

3) the procedure for checking correct functioning prior to use;

4) if applicable, a warning to the effect that the breathing system is not suitable for use in a continuous-flow anaesthetic system;

g) the volume of the RESERVOIR.

Check compliance by inspection of the instructions for use.

Annex A
(informative)

Rationale

This annex provides a rationale for some requirements of this International Standard and is intended for those who are familiar with the subject of this International Standard, 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 International Standard necessitated by those developments.

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

A.1 Scope

It is understood, that at the time of writing this International Standard, flammable anaesthetic agents, such as diethyl ether, are still being used in certain countries where DRAW-OVER ANAESTHETIC SYSTEMS are in use.

The use of monitoring is highly recommended and is the subject of the World Health Organization (WHO) guidelines, but was not considered essential with this intrinsically safe system of delivering inhalational anaesthesia. The unreliable supply of electricity and lack of resources for the continuous supply of consumables also render most monitors unsustainable.

ISO 8835-7:2011, 5 c) mandates that a means for the manual ventilation of the patient shall be included and refers to operator-powered resuscitators and inflating bellows. Operator-powered resuscitators are covered by ISO 10651-4. However, as bellows-type manual ventilators do not have a standard, they have been included in this International Standard.

A.4.4 Components for use with flammable anaesthetic agents

An example of a flammable anaesthetic agent in use is diethyl ether. Examples of non-flammable anaesthetic agents are halothane and isoflurane. ISO 80601-2-13:2011, Annex B, provides details on the methods of test to determine the flammability of anaesthetic agents.

A.5.2.2 DRAW-OVER VAPORIZER — Accuracy of output

DRAW-OVER VAPORIZERS are designed and calibrated to operate at or slightly below atmospheric pressure.

The calibration might not be valid when the DRAW-OVER VAPORIZER is pressurized, for example, when used as a “push over” vaporizer.

A.5.3 DRAW-OVER VAPORIZER — Ports and connectors

A sequential system of cones and sockets has been adopted as all the major components of this DRAW-OVER 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.

A.6.3.3 Breathing system — EXHAUST PORT

A 30 mm cone is specified at the EXHAUST PORT to facilitate connection to an anaesthetic gas scavenging system (AGSS) complying with ISO 80601-2-13. 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.

It is important that the instructions for use draw attention to the potential hazards in using non-anaesthetic proof gas (APG) category equipment with flammable agents [see 10 d) 7)].

A.7.1.2 RESERVOIR — Instructions for positioning of the supplementary oxygen inlet

The positioning of the supplementary oxygen inlet connector is crucial. It should be as close as possible to the outlet of the RESERVOIR where the RESERVOIR connects to the inlet of the DRAW-OVER VAPORIZER. If placed elsewhere, there will be an inefficient use of oxygen and the possibility of a build-up of pressure and alteration of vaporizer output.

A.8.1 Bellows-type manual ventilator — Construction

The DRAW-OVER ANAESTHETIC SYSTEM comprises, in its most basic form, a DRAW-OVER VAPORIZER and a breathing system. The breathing system mandates a DRAW-OVER VALVE SYSTEM, which in itself, mandates that the patient must be able to inhale and exhale during both spontaneous and positive pressure ventilation. If a bellows-type manual ventilator is then introduced, these requirements still apply, and as written, will ensure that the patient can inhale and exhale while receiving positive pressure ventilation.

Annex B
(normative)

Test methods

B.1 General

B.1.1 Ambient temperature

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

B.1.2 Accuracy

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

B.2 Test for output performance of the DRAW-OVER VAPORIZER

B.2.1 Apparatus

a) **anaesthetic agent monitor**;

b) **adjustable sine-wave generator**;

c) **non-rebreathing valve**;

d) **breathing bag**, of not less than 10 l capacity.

B.2.2 Procedure

This test is to be carried out with the anaesthetic agent or agents that are intended to be used with the DRAW-OVER VAPORIZER.

Fill the DRAW-OVER VAPORIZER to half-full with the anaesthetic agent and allow the temperature to stabilize for at least 30 min before beginning the test.

Adjust the sine-wave generator to deliver a volume of (600 ± 60) ml at a frequency of 12 cycles per minute. Start the sine-wave generator, and with the agent concentration (mass fraction), set to the concentration in Table B.1, run the pump for 30 min, and measure the agent concentration at 1 min intervals. After the first three minutes, continuously record the output for the remainder of the 30 min.

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

Table B.1 — Settings to be used for output performance of DRAW-OVER VAPORIZERS

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
4	20 % full scale
5	50 % full scale
6	75 % full scale
7	maximum graduation (full scale)
[a] If 10 % of full scale is the lowest graduation, step 2 is omitted.	

B.3 Test for resistance to spontaneous inspiration and expiration

B.3.1 Apparatus

a) **Adjustable sine-wave generator**, without unidirectional valves.

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

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

B.3.2 Procedure

Assemble the complete DRAW-OVER ANAESTHETIC SYSTEM with an empty (dry) DRAW-OVER VAPORIZER and with the bellows-type manual ventilator 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 ± 60) ml at a frequency of 12 cycles per minute and record the pressure variations at the PATIENT CONNECTION PORT 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 C
(informative)

Environmental aspects

The environmental impact generated by a DRAW-OVER ANAESTHETIC SYSTEM is mainly isolated to the following occurrences:

— impact at local environment during operation including routine inspection and adjustments by the user according to the instructions for use or routine procedures;

— use cleaning and disposal of consumables during operation including routine inspection and adjustments by the user according to the instructions for use or routine procedures;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses the requirements or recommendations intended to decrease the environmental impact caused by those aspects during different stages of the DRAW-OVER ANAESTHETIC SYSTEM's life cycle.

See Table C.1 for a mapping of the life cycle of DRAW-OVER ANAESTHETIC SYSTEMS to aspects of the environment.

Table C.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (Inputs and Outputs)		Product life cycle			
		Production and preproduction	Distribution (including packaging)	Use	End of life
		Stage A	Stage B	Stage C	Stage D
		Addressed in clause	Addressed in clause	Addressed in clause	Addressed in clause
1	Resource use	_	9.6	4.5, 9.3 g), 9.6 f)	_
2	Energy consumption	-	-	B.2, B.3	-
3	Emission to air	-	-	4.4, 5.1.3, 5.3.3, 6.3.3, 10 d) 2) 10 5),10 7), A.4.4, A.6.3.3	-
4	Emission to water	-	-	-	-
5	Waste	-	-	-	-
6	Noise	-	-	-	-
7	Migration of hazardous substances	-	-	4.4,5.1.3, 5.3.3, 6.3.3, 10 d) 2), 10 5), 10 7), A.4.4, A.6.3.3	-
8	Impacts on soil	-	-		-
9	Risks to the environment from accidents or misuse	-	-	4.4, 5.1.3, 5.3.3, 6.3.3, 9.2.1 c) to f) 10 d), 10 2), 10 5), 10 7), A.4.4, A.6.3.3	-

Annex D
(informative)

Reference to the essential principles

This International Standard has been prepared to support the essential principles of safety and performance of DRAW-OVER ANAESTHETIC SYSTEMS as medical devices according to ISO 16142-1:— This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles in ISO 16142-1:—. Other means are possible.

Table D.1 — Correspondence between this International Standard and the essential principles

Clause(s)/subclause(s) of this International Standard	Corresponding essential principle of ISO 16142-1:—	Qualifying remarks/Notes
	1	Not covered by this International Standard
	2	Not covered by this International Standard
	3	Not covered by this International Standard
	4	Not covered by this International Standard
	5	Not covered by this International Standard
	6	Not covered by this International Standard
	7	Not covered by this International Standard
4.1, 4.4, 4.5, 9.3 e)	8.1 a)	8.1 b) is not applicable and 8.1 c) and d) have not been addressed
4.1,4.7, 4.8, 6.1.4	8.2	
4.1, 4.4, 4.5, 4.7, 6.1.4, 9.2.1 d)	8.3	
4.1	8.4	Partially covered
4.7	8.5	
4.1, 4.7, 6.1.4, 9.6 f), 10 f) 1)	9.1	
	9.2	Not applicable
	9.3	Not applicable
	9.4	Not applicable
	9.5	Not covered by this International Standard
4.1	9.6	Partially covered
4.1, 9.6 c)	9.7	Partially covered
	10.1	Not applicable

Table D.1 *(continued)*

Clause(s)/subclause(s) of this International Standard	Corresponding essential principle of ISO 16142-1:—	Qualifying remarks/Notes
	10.2	Not applicable
	11.1	Not applicable
	11.2	Not applicable
	11.3	Not applicable
4.1, 5.3, 6.1.2, 6.1.3, 6.3, 7.3, 8.3, 9.3 d), 9.3 f), 9.4 a) and b), 9.5	12.1	
4.1, 4.6	12.2 a)	
4.1, 4.3, 4.4, 5.1, 6.1, 7.1, 8.1, 9, 10	12.2 b)	
4.1, 4.8	12.2 c)	Partially covered
4.1, 4.5, 9.2 b), 9.2.2, 10 d) 7)	12.2 d)	
	12.2 e)	Not covered by this International Standard
	12.2 f)	Not covered by this International Standard
	12.2.g)	Not covered by this International Standard
	12.3	Not applicable
4.1, 4.4, 9.3 e), 9.6 g),10 d) 7)	12.4	
10 d) 4),	12.5	
6.3.3	12.6	Partially covered
5.2	13.1	
9.2.1 i)	13.2	Partially covered
9.2.1 f)	13.3	Partially covered
-	14.1	Not applicable
-	14.2	Not applicable
-	14.3	Not applicable
-	14.4	Not applicable
-	14.5	Not applicable
-	15.1	Not applicable
	15.2	Not applicable
4.1, 4.3, 5.1.3, 6.1.1, 7.2, 8.2.4	16.1	
-	16.2	Not applicable
-	16.3	Not applicable
-	16.4	Not applicable
-	16.5	Not applicable
-	16.6	Not applicable
-	16.7	Not applicable
	17.1	Not applicable
	17.2	Not applicable
	17.3	Not applicable
	17.4	Not applicable

Table D.1 *(continued)*

Clause(s)/subclause(s) of this International Standard	Corresponding essential principle of ISO 16142-1:—	Qualifying remarks/Notes
5.3, 6.1.3, 6.3, 7.2, 8.3, 9.3 f),10 c) 1)	17.5	
	17.6	Not applicable
4.1, 4.3, 5.2, 6.1.1 d), 6.2, 7.2	18.1	
4.1, 5.1.2, 5.1.3,	18.2	
5.1.1, 9.2.1 c), 9.2.1 h), 9.2.1 i)	19.1	
	19.2	Not covered
	20.1	Not applicable
	20.2	Not applicable
	20.3	Not applicable
9, 10	21.1	Partially covered
10 c) 1) and 2)	21.2	
9, 10	21.3	
9	21.4	
9.6	21.5	Partly addressed Labelling requirements of 21.5 a), b), c), d) f), m) are addressed through labelling of the packages containing the breathing attachments or the complete breathing system The requirement that a manufacturer's indication of single use must be consistent is not addressed. The requirement that the address of an authorized representative shall be given on the label if the manufacturer does not have an address within the locale has not been addressed
9.3 a)	21.5 a)	Partly addressed for the breathing attachments
9.3 b)	21.5 c)	Partly addressed for the breathing attachments
9.3 g)	21.5 f)	Partly addressed for the breathing attachments
9.2, 9.3 b), 9.4 b), 9.5 b), 9.6 e), 10 b)	21.6	
9.3 a) 9.4 a), 9.5 a), 9.6 a), 10 a)	21.7 a)	
9.6 c), 10 c)	21.7 b)	
9.6 e)	21.7 c)	
9.6 d)	21.7 d)	Partly covered indication of single use consistency not addressed.
	21.7 g)	Not addressed in this International Standard
10 c) to f)	21.7 h)	

Table D.1 *(continued)*

Clause(s)/subclause(s) of this International Standard	**Corresponding essential principle of** ISO 16142-1:—	**Qualifying remarks/Notes**
10 d) 7), 10 d) 10), 10 f) 4)	21.7 i)	
9.6 f), 10 f) 1)	21.7 j)	
9, 10	21.7 k)	
10 c) 1), 10 d) 1), 10 e) 2), 10, f) 3)	21.7 l)	
10 c) 2), 10 d) 1), 10 d) 4), 10 e) 6), 10 f) 2)	21.7 m)	
9.6 f), 10 f) 1)	21.7 q)	
	21.8	Not addressed
	21.9	Not applicable

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[4] ISO 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

[5] ISO 16142-1:—[2)], *Medical devices — Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

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[7] ISO/TS 18835:2004, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment*

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