INTERNATIONAL STANDARD

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Inhalational anaesthesia systems —

Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases

Systèmes d'anesthésie par inhalation —

Partie 7: Systèmes d'anesthésie pour utilisation dans des zones avec équipement logistique limité en électricité et en gaz anesthésiques

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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.

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 8835-7 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

ISO 8835 consists of the following parts, under the general title *Inhalational anaesthesia systems*:

— *Part 7: Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases*

The following parts are withdrawn and replaced by ISO 80601-2-13:

— *Part 2: Anaesthetic breathing systems*

— *Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

Draw-over vaporizers are described in ISO/TS 18835.

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* Introduction

The World Health Organisation (WHO) and the World Federation of Societies of Anaesthesiologists (WFSA) are concerned about the provision of safe anaesthesia, using appropriately designed anaesthetic equipment, in the large numbers of countries in the world where economics or infrastructure lead to a situation where complex technology is unlikely to function well, if at all, and might introduce hazards of its own.

A total of 152 countries have been identified where the infrastructure or economic restrictions prevent the use of complex equipment, creating a need for an appropriate standard.

Equipment designed for use in these countries should meet the following minimum criteria:

a) ability to function in the absence of a regular supply of compressed medical gases;

b) ability to continue to function safely when the supply of medical gases fails;

c) ability to function if mains electrical supplies are interrupted, or are subject to unpredictable increases or decreases in voltage;

d) ability to function in a challenging environment, including high temperatures, humidity, shocks, vibration, and dust.

This part of ISO 8835 allows for the construction of an anaesthetic system, using the components identified in this part of ISO 8835, to suit the specific economic and environmental issues of each country.

Throughout this part of ISO 8835, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

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Inhalational anaesthesia systems —

Part 7:
Anaesthetic systems for use in areas with limited logistical supplies of electricity and anaesthetic gases

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1 * Scope

This part of ISO 8835 specifies safety and performance requirements for anaesthetic systems and components that:

a) can function in the absence of a supply of compressed medical gases or mains electricity;

b) can withstand a challenging environment, including high temperatures, humidity, shocks and vibration, and dust;

c) allow local servicing and maintenance;

d) may be suitable for use with flammable anaesthetic agents.

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 8359, *Oxygen concentrators for medical use — Safety requirements*

ISO 10083, *Oxygen concentrator supply systems for use with medical gas pipeline systems*

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

ISO 80601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

ISO/TS 18835, *Inhalational anaesthesia systems — Draw-over vaporizers and associated equipment*

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

3 Terms and definitions

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

3.1
anaesthetic system
device for administering anaesthetic gases that may use, but is not reliant on, compressed gas or mains electrical supply for safe use

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4 General requirements

4.1 Electrical safety

Anaesthetic systems or their components that are classed as medical electrical equipment in accordance with IEC 60601-1 shall, in addition to the requirements in this part of ISO 8835, meet the relevant requirements in IEC 60601-1.

Check compliance by testing in accordance with IEC 60601-1.

4.2 Mechanical hazards

Anaesthetic systems or their components shall comply with IEC 60601-1:2005, Clause 9.

Check compliance by testing in accordance with IEC 60601-1.

4.3 Risk management

The manufacturer of an anaesthetic system, or parts intended for use in an 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 alarm system;

d) safety and handling advice by way of 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 anaesthetic system;

— sufficient specification of such risk mitigation measures.

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

5 * Essential functions

The anaesthetic system shall include the following:

a) means of gas delivery;

b) a draw-over vaporizer complying with ISO/TS 18835;

c) means for the manual ventilation of the patient;

NOTE 1 This may be an operator–powered resuscitator complying with ISO 10651-4, or an inflating bellows.

NOTE 2 Additionally, an anaesthetic ventilator complying with ISO 80601-2-13 may be supplied.

d) means for delivering gas to the patient by either a continuous flow breathing system complying with ISO 80601-2-13 or a draw-over breathing system complying with ISO/TS 18835;

NOTE 3 Circle breathing systems are considered unsafe for use with these anaesthetic systems.

e) means to prevent hypoxic gas mixtures of oxygen and nitrous oxide if nitrous oxide can be delivered by the anaesthetic system.

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6 Oxygen concentrators

If an oxygen concentrator is used as a means to supply an increased concentration of oxygen in the anaesthetic gas mixture delivered to the patient, it shall comply with either ISO 8359 or ISO 10083.

7 Performance requirements

7.1 Electrical supply

Anaesthetic systems shall continue to function and allow the delivery of anaesthetic gases as specified by the manufacturer if the mains electricity supply fails, or the voltage increases or decreases.

Check compliance by functional testing.

Any change from mains to battery supply shall be indicated to the operator.

The anaesthetic system shall be provided with suitable protection against excessively high voltage, surges, and spikes.

NOTE See IEC 61000-4-5.

7.2 Gas supply

7.2.1 If a gas supply is available, the anaesthetic system shall be able to provide a minimum of 6 l/min of fresh gas flow.

7.2.2 Anaesthetic systems shall continue to function and allow the delivery of anaesthetic gases as specified by the manufacturer if the pressure within the medical gas supply fails, increases or decreases.

Any change in the gas supply status should be indicated to the operator.

7.3 Flammable anaesthetic agents

If the anaesthetic system is designed to be used with flammable anaesthetic agents, such as diethyl ether, it shall comply with the requirements of IEC 60601-1:2005, Annex G.

8 Construction requirements

8.1 Servicing

Anaesthetic systems shall be designed to take account of available communication, logistic supply and the electrical and mechanical skills available at the site of use.

Check compliance by inspection of the service manual.

8.2 Materials

The materials selected for manufacture shall not cause risk to the patient when in normal use and shall withstand the cleaning, disinfecting and sterilization procedures which are recommended by the manufacturer or available locally.

Check compliance by examination of the technical file.

9 Environmental conditions

Anaesthetic systems shall function normally under the following environmental conditions:

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— temperature 5 °C to 40 °C

— relative humidity 15 % to 95 %

— pressure 70,0 kPa to 106,0 kPa

The manufacturer of the anaesthetic system shall declare, in the instructions for use, how the anaesthetic system will respond if the environmental conditions are extended outside the range specified in the instructions for use.

10 Marking

Anaesthetic systems or their components shall be marked with the following:

a) name and address of the manufacturer/supplier;

b) lot, batch or serial number;

c) if a flow-sensitive component can be assembled incorrectly, an arrow indicating the direction of flow;

d) if applicable, an indication that the anaesthetic system or component thereof is suitable for use with flammable anaesthetic agents.

11 Information to be provided by the manufacturer

Manufacturers of anaesthetic systems shall provide the following information where applicable:

a) the method of assembly;

b) a pre-use checklist;

c) instructions for use, maintenance and servicing;

d) instructions for cleaning, disinfecting and sterilization;

e) any special warnings or instructions regarding suitability of use with flammable anaesthetic agents;

f) the intended purpose and any restrictions on its use;

g) a list of spare parts to maintain the equipment for a minimum of 5 years;

h) if applicable, contact details for a rapid response help-line;

i) if applicable, a statement recommending risk mitigation measures prior to the use of the anaesthetic system and sufficient specification of such risk mitigation measures (see 4.3).

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Annex A
(informative)

Rationale

A.1 General

This annex provides rationale for certain requirements of this part of ISO 8835 and is intended for those who are familiar with the subject of this part of ISO 8835 but who have not participated in its development.

An understanding of the reasons for these requirements is considered to be essential for their proper application and is provided to aid in the application of this part of ISO 8835. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this part of ISO 8835 that is necessitated by those developments.

A.2 Introduction and Clause 5

Monitoring is recognised as a very emotive subject. A conscious decision was made not to mandate the use of any monitor as it is generally accepted that the patient is constantly attended by the person administering the anaesthetic. The economic pressures and logistical problems with supply of spare and consumable parts in these countries are also factors.

Pressure monitoring was considered to be most important when an anaesthetic ventilator is part of the system. This is covered by compliance with ISO 80601-2-13.

Oxygen monitoring was also considered but it was thought that if a choice had to be made a pulse oximeter may be preferred to an oxygen monitor as air is often the main fresh gas. A pulse oximeter is generally considered to be a patient monitor, not an equipment monitor, and is therefore not included in this part of ISO 8835. However, monitoring the concentration of oxygen in the inspired mixture is strongly encouraged, if feasible, especially if pulse oximetry is not available.

Carbon dioxide and anaesthetic agent monitoring were considered not to be essential for the type of anaesthetic system covered by this part of ISO 8835.

A.3 Clause 1

Anaesthetic systems will need to withstand adverse environmental conditions, especially temperature and humidity, and might need to be designed for use with flammable anaesthetic agents such as diethyl ether, which is still in widespread use.

The scope is not restricted to adults as many anaesthetic systems are used on a variety of patients.

Any restrictions are left to the manufacturer's declaration [see 11 f)].

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