INTERNATIONAL STANDARD

ISO 8835-5

First edition
2004-05-15

Inhalational anaesthesia systems —

Part 5: Anaesthetic ventilators

Systèmes d'anesthésie par inhalation —

Partie 5: Ventilateurs d'anesthésie

Reference number
ISO 8835-5:2004(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.

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 8835-5 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 2: Anaesthetic breathing systems for adults*

— *Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

— *Part 4: Anaesthetic vapour delivery devices*

— *Part 5: Anaesthetic ventilators*

NOTE ISO 8835-1, *Medical electrical equipment — Part 1: Particular requirements for the safety of anaesthetic workstations,* was withdrawn in 1998 and replaced by the second edition of IEC 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems.*

Introduction

This part of ISO 8835 is a Particular Standard based on IEC 60601-1:1988, including Amendments 1 (1991) and 2 (1995), hereafter referred to as the General Standard. The General Standard is the basic standard for the safety of all medical electrical equipment used by or under the supervision of qualified personnel in the general medical and patient environment; it also contains certain requirements for reliable operation to ensure safety.

The General Standard has associated Collateral Standards and Particular Standards. The Collateral Standards include requirements for specific technologies and/or hazards and apply to all applicable equipment, such as medical systems, EMC, radiation protection in diagnostic X-ray equipment, software, etc. The Particular Standards apply to specific equipment types, such as medical electron accelerators, high frequency surgical equipment, hospital beds, etc.

NOTE Definitions of Collateral Standard and Particular Standard can be found in IEC 60601-1:1988, 1.5 and A.2, respectively.

To facilitate the use of this part of ISO 8835, the following drafting conventions have been applied.

This part of ISO 8835 uses the same main clause titles and numbering as the General Standard, for ease of cross-referencing of the requirements. The changes to the text of the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

— “Replacement” means that the indicated clause or subclause of the General Standard is replaced completely by the text of this Particular Standard.

— “Addition” means that the relevant text of this Particular Standard is a new element (e.g. subclause, list item, Note, table, figure) additional to the General Standard.

— “Amendment” means that an existing element of the General Standard is partially modified by deletion and/or addition as indicated by the text of this Particular Standard.

To avoid confusion with any amendments to the General Standard itself, a particular numbering has been employed for elements added by this part of ISO 8835: subclauses, tables and figures are numbered starting from 101; additional list items are lettered aa), bb), etc. and additional annexes are lettered AA, BB, etc.

In this part of ISO 8835, the following print types are used:

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

— notes and examples: smaller roman type;

— description of type of document change, and test methods: *italic type*;

— terms defined in the General Standard IEC 60601-1:1988, Clause 2 and terms defined in this part of ISO 8835: **bold type**.

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

Inhalational anaesthesia systems —

Part 5:
Anaesthetic ventilators

1 Scope

IEC 60601-1:1988, Clause 1 applies except as follows:

This part of ISO 8835 specifies particular requirements for the essential performance of **anaesthetic ventilators** (as defined in 3.1). This part of ISO 8835 is applicable to **anaesthetic ventilators** which are always a component of an **anaesthetic system** and are intended to be continuously attended by an **operator**.

This part of ISO 8835 is not applicable to **anaesthetic ventilators** intended for use with flammable anaesthetics, as determined by Annex BB.

The requirements of this part of ISO 8835 which replace or modify the requirements of IEC 60601-1:1988 and its Amendments 1 (1991) and 2 (1995) are intended to take precedence over the corresponding general requirements.

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 407, *Small medical gas cylinders — Pin-index yoke-type valve connections*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5145, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 7396-1, *Medical gas pipeline systems — Part 1: Pipelines for compressed medical gases and vacuum*

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

ISO 8835-3:1997, *Inhalational anaesthesia systems — Part 3: Anaesthetic gas scavenging systems — Transfer and receiving systems*

ISO 10524, *Pressure regulators and pressure regulators with flow-metering devices for medical gas systems*

IEC 60079-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature*

EC 60079-11:1999, *Electrical apparatus for explosive gas atmospheres — Part 11: Intrinsic safety "i"*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2:2001, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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

3 Terms and definitions

For the purposes of this part of ISO 8835, the terms and definitions given in IEC 60601-1, ISO 4135 and IEC 60601-2-13 and the following apply.

3.1
anaesthetic ventilator
lung ventilator designed for use during anaesthesia with an anaesthetic breathing system

3.2
breathing system connection port
port which connects the ventilator to the breathing system

3.3
legible
displayed qualitative or quantitative information, values, functions, and markings that can be discriminated and identified under a specific set of environmental conditions

NOTE See 6.101 for testing for legibility.

3.4
driving gas
gas which powers the ventilator but is not delivered to the **patient**

3.5
driving gas inlet port
port to which the **driving gas** is supplied

3.6
inflating gas
gas delivered to the **patient's** airway which is controlled by the **anaesthetic ventilator**

NOTE The **inflating gas** may also power the **anaesthetic ventilator**.

3.7
inflating gas inlet port
port to which the **inflating gas** is supplied

3.8
maximum limited pressure
$p_{\text{LIM max}}$
highest pressure at the **patient** connection port during **normal use** and under a **single fault condition**

NOTE Adapted from IEC 60601-2-12.

3.9
minimum limited pressure
$p_{LIM\ min}$
lowest pressure at the **patient** connection port during **normal use** and **under a single fault condition**

NOTE 1 Adapted from IEC 60601-2-12.

NOTE 2 This pressure may be sub-atmospheric.

3.10
maximum working pressure
$p_{W\ max}$
highest pressure which can be attained at the **patient** connection port during the inspiratory phase, with the ventilator operating normally

[ISO 4135]

3.11
minimum working pressure
$p_{W\ min}$
lowest (most negative) pressure which can be attained at the **patient** connection port during the expiratory phase, with the ventilator operating normally

[ISO 4135]

3.12
oxygen-rich environment
environment in which the partial pressure of oxygen is greater than 275 hPa

4 General requirements and general requirements for tests

IEC 60601-1:1988, Clauses 3 and 4 apply, except as follows.

Addition:

4.101 Other test methods

Test methods other than those specified in this part of ISO 8835, but of equal or greater accuracy, may be used to verify compliance with requirements.

5 Classification

IEC 60601-1:1988, Clause 5 applies.

6 Identification, marking and documents

IEC 60601-2-13 Clause 6 applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

Additions:

aa) If provided and **operator**-accessible, the following ports shall be legibly and durably marked:

— **driving gas inlet port;**

— **driving gas** exhaust port;

— **inflating gas** inlet port;

— **fresh gas** inlet;

— **anaesthetic breathing system** connection port;

— inspiratory port;

— expiratory port;

— exhaust port;

— bag port.

6.3 Marking of controls and instruments

Addition:

aa) The **operator**-adjustable means for pressure limitation shall be graduated in units or multiples of pascals and/or centimetres water.

6.8.2 Instructions for use

Additions:

aa) The instructions for use of the **anaesthetic ventilator**, shall contain a statement to the effect that the **anaesthetic ventilator** is intended to be used with

1) an **anaesthetic breathing system** in accordance with ISO 8835-2, and

2) an anaesthetic gas scavenging transfer and receiving system in accordance with ISO 8835-3.

Unless the **anaesthetic ventilator** is an integral part of an **anaesthetic system**, the manufacturer/supplier of the **anaesthetic ventilator** shall provide information on how to connect the **anaesthetic breathing system** and the **anaesthetic gas scavenging transfer and receiving system**.

bb) The manufacturer/supplier of an **anaesthetic ventilator** shall provide the following information:

1) an instruction on how to perform a leak test of the **anaesthetic ventilator**;

2) the supply pressure range required for the driving gas(es) of the **anaesthetic ventilator**;

3) set-up, gas flow(s) and technique recommended for testing the **anaesthetic ventilator** before use;

4) a warning that the **anaesthetic ventilator** is not intended to be used with flammable anaesthetic agents;

5) inspiratory flow and pressure characteristics.

cc) The instructions for use shall contain a statement to the effect that flammable anaesthetic agents such as diethyl ether and cyclopropane shall not be used with the **anaesthetic ventilator**. Only anaesthetic agents which comply with the requirements for non-flammable anaesthetic agents as specified in Annex BB of this part of ISO 8835 are suitable for use with the **anaesthetic ventilator**.

dd) The instructions for use shall contain a description of the functioning of the **anaesthetic ventilator** after interruption of the power supply and, where applicable, the functioning of the **anaesthetic ventilator** after a switch-over to a reserve power supply.

6.8.3 Technical description

Addition:

aa) The technical description shall provide the operational characteristics of the **anaesthetic ventilator**, including, if appropriate, the following:

— range of delivered volumes (tidal and minute);

— range of breathing frequency;

— range of I:E ratios;

— range of values to which the **maximum working pressure** can be set and the means by which the maximum pressure is controlled (e.g. pressure cycling, pressure limitation);

— inspiratory flow and pressure characteristics;

— modes of cycling;

— minimum limited pressure;

— positive end-expiratory pressure (PEEP) range;

— if there is a facility for sub-atmospheric pressure in the expiratory phase, the limiting pressure and generated pressure;

— if provided, characteristics of the means of triggering;

— if applicable, interdependance of controls;

— any restrictions on the location and/or sequence of components within the **anaesthetic breathing system** supplied or recommended by the manufacturer (e.g. where such components are flow-direction-sensitive);

— the range of internal volume of any breathing attachments or other components or subassemblies recommended by the manufacturer.

6.101 Test method for legibility

Legible indications are correctly perceived by an operator with a visual acuity of 0 on the log MAR scale or 6-6 (20/20) vision (corrected if necessary) from a distance of 1 m $\pm$ 0,1 m at a light level of 215 lux $\pm$ 65 lux, when viewing the information, markings, etc. perpendicular to and including 15° above, below, left and right of the line of sight of the **operator**.

7 Power input

IEC 60601-1:1988, Clause 7 applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8 applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9 applies.

10 Environmental conditions

IEC 60601-2-13, Clause 10 applies.

11 Not used

IEC 60601-1:1988, Clause 11 applies.

12 Not used

IEC 60601-1:1988, Clause 12 applies.

13 General

IEC 60601-1:1988, Clause 13 applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14 applies.

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15 applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16 applies.

17 Separation

IEC 60601-1:1988, Clause 17 applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18 applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19 applies.

20 Dielectric strength

IEC 60601-1:1988, Clause 20 applies.

21 Mechanical strength

IEC 60601-1:1988, Clause 21 applies.

22 Moving parts

IEC 60601-1:1988, Clause 22 applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23 applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24 applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25 applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26 applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27 applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28 applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29 applies.

30 Alpha, beta, gamma, neutron radiation and other particle radiation

IEC 60601-1:1988, Clause 30 applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31 applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32 applies.

33 Infra-red radiation

IEC 60601-1:1988, Clause 33 applies.

34 Ultraviolet radiation

IEC 60601-1:1988, Clause 34 applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35 applies.

36 Electromagnetic compatibility

IEC 60601-1:1988, Clause 36 applies.

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37 does not apply.

38 Marking and accompanying documents

IEC 60601-1:1988, Clause 38 does not apply.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39 does not apply.

NOTE AP = anaesthetic proof, APG = anaesthetic proof gas.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40 does not apply.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41 does not apply.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42 applies.

43 Fire prevention

IEC 60601-1:1988, Clause 43 applies.

44 Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility

IEC 60601-1:1988, Clause 44 applies, except as follows.

44.3 Spillage

Amendment to first and second sentences:

The **anaesthetic ventilator** and its components shall be so constructed that spillage does not wet component parts which when wetted can cause a **safety hazard**.

Compliance is checked by the test in IEC 60601-1:1988, 44.3.

44.7 Cleaning, sterilization and disinfection

Amend this subclause by replacing the entire second paragraph with the following:

All components not specified by the manufacturer as single-patient use, which come into contact with exhaled patient gas that may be rebreathed, shall be capable of being sterilized or disinfected or be provided with a bacterial/viral filter.

Compliance is checked by a review of the accompanying documents for methods of sterilization or disinfection.

44.8 Compatibility with substances used with the equipment

Addition:

The **anaesthetic ventilator** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the equipment or its components during **normal use**.

Evidence shall be held by the manufacturer and made available upon request.

Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during normal use.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45 applies.

46 Human errors

IEC 60601-1:1988, Clause 46 applies, except as follows.

Addition:

NOTE Attention is drawn to IEC 60601-1-6.

47 Electrostatic charges

IEC 60601-1:1988, Clause 47 applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48 applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49 applies, with the following changes.

Replace 49.101.2 of IEC 60601-2-13 with the following.

49.101.2 The anaesthetic ventilator shall be so designed that in the event of an electrical power supply failure, the supply of gas to the ventilator shall be unaffected. Under electrical power failure conditions, it shall be possible to ventilate the patient manually.

An alarm signal of at least medium priority shall be activated in the event of an electrical power supply failure (i.e. below the minimum supply specified by the manufacturer). See also 6.8.2 dd).

NOTE Electrical power supply failure includes both mains and reserve power.

Additions:

49.102.2 When a compressed gas supply is provided as a power supply to the anaesthetic ventilator, an alarm signal of at least medium priority shall be annunciated if a safety hazard arises from a failure of the compressed gas supply (i.e. below the minimum supply specified by the manufacturer).

49.101.3 There shall be a means to ensure that in the event of pneumatic power failure, the pressure in the anaesthetic breathing system shall be reduced so that the patient can be ventilated manually.

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50 applies.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51 applies, with the following additions.

Additions:

51.101 Operator-adjustable pressure limitation

The **anaesthetic ventilator** shall be equipped with an **operator**-adjustable means to limit the pressure applied to the **anaesthetic breathing system**.

The means of limitation shall ensure that the airway pressure does not deviate from the set value by more than ±1 kPa (10 cmH_2O) or 15 % of the set value, whichever is the greater.

NOTE * Because of the differing ways in which pressure limitation may be used in clinical practice, this device standard does not specify the relationship between the means of **operator**-adjustable pressure limitation and the pressure alarm system.

51.102 Failure-to-cycle alarm

If the **anaesthetic ventilator** is provided with a "failure-to-cycle" **alarm system**, the **alarm signal** shall be at least a medium priority.

51.103 Operator-adjustable pressure alarm

51.103.1 The **anaesthetic ventilator** shall be equipped with an **operator**-adjustable **alarm system** to indicate when the pressure in the **anaesthetic breathing system** has exceeded a set limit. This **alarm signal** shall be at least a medium priority **alarm signal**.

51.103.2 If the **anaesthetic ventilator** is equipped with a means to annunciate an **alarm signal** following failure of the pressure to reach the operator-set minimum pressure threshold, the **alarm signal** shall be at least a medium priority.

Test for compliance by visual inspection, and functional testing simulating the alarm condition in accordance with the accompanying documents.

52 Abnormal operation and fault conditions

IEC 60601-2-13:2003, Clause 52 applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53 applies.

54 General

IEC 60601-1:1988, Clause 54 applies.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55 applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56 applies.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57 applies.

58 Protective earthing — Terminals and connections

IEC 60601-1:1988, Clause 58 applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59 applies.

101 Additional requirements for anaesthetic ventilators

101.1 Medical gas supply

101.1.1 Connections for medical gas cylinders, if provided, shall comply with ISO 407 or ISO 5145.

101.1.2 Each medical gas supply inlet connection shall be equipped with a means to prevent particles greater than 100 µm from entering the **anaesthetic ventilator**.

101.2 Medical gas pipeline inlet connections

101.2.1 Pipeline inlet connectors for the **anaesthetic ventilator** shall be the gas-specific body fittings as specified in ISO 5359.

101.2.2 The **anaesthetic ventilator** shall be equipped with means to limit reverse gas flowrate between multiple gas input ports for the same gas to 100 ml/min (169 Pa · l/s) under normal conditions.

101.2.3 If the **anaesthetic ventilator** is fitted with pipeline inlet connectors for different gases, the **anaesthetic ventilator** shall be equipped with means to limit the flowrate of gas from one input port to an input port of a different gas to less than 10 ml/h (0,281 Pa · l/s) under **normal conditions**.

Evidence shall be held by the manufacturer and made available upon request.

101.3 Driving gas inlet port

101.3.1 If provided, and operator accessible, the **driving gas inlet port** shall not be compatible with any of the connectors specified in ISO 5356-1 or ISO 5356-2.

101.3.2 If the **driving gas** is supplied from a medical gas supply pipeline system complying with ISO 7396-1 or from cylinders via a pressure regulator complying with ISO 10524, the **driving gas inlet port** shall be fitted with the body of the appropriate gas-specific fitting complying with ISO 5359.

101.4 Inflating gas inlet port

If the **anaesthetic ventilator** has both a **driving gas inlet port** and an **inflating gas inlet port**, the **inflating gas inlet port** shall not be compatible with the **driving gas inlet port**.

101.5 Control(s) to change from automatic ventilation to spontaneous/manually assisted breathing or vice versa

If the **anaesthetic ventilator** is an integral part of the **anaesthetic system**, it shall not be necessary to operate more than one control to change from automatic ventilation to spontaneous or manually assisted breathing and vice versa.

101.6 Breathing system connection port

If a conical **operator**-accessible breathing system connection port is provided, it shall be a 22 mm male conical connector in accordance with ISO 5356-1 or ISO 5356-2.

102 Appendices of IEC 60601-1:1988

The Appendices of IEC 60601-1:1988 apply.

Addition: The subsequent annexes form an additional element of this part of ISO 8835.

Annex AA
(informative)

Rationale

AA.51.101 Pressure limitation

The means of pressure limitation may be used primarily as a protection device, in which case it will be set by the operator at a level above the anticipated working pressure. When the means of pressure limitation is used in this manner, the setting of the (operator-) adjustable alarm system will also be determined by the operator and may be at, below or above the pressure setting according to the clinical situation. On the other hand, when the means of pressure limitation is used to limit the peak pressure attained during each inspiratory cycle, then clearly the pressure alarm system will need to be set at a value above that at which the pressure is limited, in order to prevent nuisance alarms.

Annex BB
(normative)

Test for flammability of anaesthetic agents

BB.1 General

The following tests can be used to determine whether an anaesthetic agent shall be regarded as non-flammable.

NOTE Cyclopropane and diethyl ether are known to be flammable agents. Halothane, desflurane, sevoflurane, enflurane and isoflurane have been found to be non-flammable agents.

BB.2 Spark ignition tests

Spark ignition tests shall be carried out with the most ignitable concentration of the anaesthetic agent, mixed with the gases (oxygen and/or nitrous oxide) in which the anaesthetic agent is more ignitable, using the test apparatus described in IEC 60601-1:1988, Annex F and in IEC 60079-11. The following criteria shall be met.

With an ignition probability of less than 10^{-3}, ignition shall not occur

a) in a resistive circuit at a d.c. voltage of 20 V with a current of 1,0 A, and at a d.c. voltage of 100 V with a current of 0,15 A,

b) in an inductive circuit at a d.c. current of 200 mA with an inductance of 10 mH, and at a d.c. current of 60 mA with an inductance of 1 000 mH,

c) in a capacitive circuit at a d.c. voltage of 100 V with a capacitance of 1 µF and at a d.c. voltage of 20 V with a capacitance of 20 µF.

The measuring circuits are illustrated in Figures 29 and 31 of IEC 60601-1:1988.

BB.3 Surface-temperature ignition tests

Determination of the ignition temperature shall be carried out in accordance with IEC 60079-4, with the following additional instructions.

a) Fill the test vessel with a mixture of oxygen and nitrous oxide in different proportions in successive tests, and

b) cover the vessel with a lid which prevents diffusion but lifts easily if an explosion occurs.

The ignition temperature shall not be less than 300 °C.

Bibliography

[1] IEC 60601-1-1:2000, *Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems*

[2] IEC 60601-1-4:2000, *Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems*

[3] IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for safety — Collateral Standard: Usability*

[4] IEC 60601-1-8:2003, *Medical electrical equipment — Part 1-8: General requirements for safety — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

[5] ISO 5358:1992, *Anaesthetic machines for use with humans*

[6] NFPA 53M, *Fire hazards in oxygen-enriched atmospheres* [1)]

1) Available from the National Fire Protection Association, 1 Batterymarch Park, PO Box 9101, Quincy, MA 02269-9101, USA.

ICS 11.040.10

Price based on 16 pages