INTERNATIONAL STANDARD ISO 11196:1995
TECHNICAL CORRIGENDUM 1

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Anaesthetic gas monitors

TECHNICAL CORRIGENDUM 1

Dispositifs de contrôle de gaz d'anesthésie

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to International Standard ISO 11196:1995 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines.*

Page 18

Replace existing table 2 with new table 2 below, in which the value "5" has been added in column 2, row 3; the value "5" has been replaced with the value "15" in column 8, row 16; and in table footnote 1) the value "5 %" for desflurane has been replaced with the value "15 %".

ICS 11.040.10

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Descriptors: medical equipment, anaesthetic equipment, medical gases, gas analyzers, classification, specifications, safety requirements, tests, identification methods, marking, instructions for use.

Table 2 — Dry gas text mixtures % (*V/V*)

Oxygen	Carbon dioxide [1]	Nitrous oxide	Halothane	Isoflurane	Enflurane	Sevoflurane	Desflurane
100							
balance		65	0,5				
balance	5	65	1				
balance	5	65	4 [2]				
balance	5	65		0,5			
balance		65		1			
balance	5			5 [2]			
balance	5	65			0,5		
balance	5	65			1		
balance					5 [2]		
balance	5	65				0,5	
balance	5	65				1	
balance		65				5 [2]	
balance	5	65					5
balance	5	65					10
balance		65					15 [2]
balance		65					
balance	5	50					
		100					

1) To minimize the number of test gas mixtures and still evaluate the effect of CO_2, 5 % (*V/V*) CO_2 is used for all gas mixtures containing halogenated gases except for the mixtures containing 0,5 % (*V/V*) halothane, 1 % (*V/V*) isoflurane, 5 % (*V/V*) enflurane, 5 % (*V/V*) sevoflurane and 15 % (*V/V*) desflurane.

CO_2 may be excluded from the test gas mixture if the anaesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

2) Or full-scale reading, if lower than specified value.

Page 26

Annex M

In clause **M.1**, second dash, replace the final phrase "... with an inductance of 100 mH;" with the phrase "... with an inductance of 1 000 mH;".

Page 31

Annex N

Under the listing for inductive circuit, second item, replace "5,8 mH, 450 mA –" with "5,8 mH, 450 mA +".

INTERNATIONAL STANDARD

ISO 11196

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Anaesthetic gas monitors

Dispositifs de contrôle de gaz d'anesthésie

Reference number
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Contents

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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.

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.

International Standard ISO 11196 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

Introduction

The measurement of the concentration of inhalation anaesthetic gases is becoming common practice. This International Standard establishes requirements for anaesthetic gas monitors that are achievable within the limits of existing technology.

Calibration gases (i.e. gases with accurate molar concentrations of anaesthetic agents) generated by gravimetric methods defined in ISO 6142 are directly traceable to national mass standards.

Such gases may be used

a) to calibrate anaesthetic gas monitors directly, or

b) to calibrate intermediate methods used to verify secondary calibration gases which are then used to calibrate anaesthetic gas monitors.

For example, such intermediate methods may be the use of refractometry, mass spectrometry, etc.

Annex N contains rationales for the most important requirements and is included to provide additional insight for the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard.

INTERNATIONAL STANDARD © ISO ISO 11196:1995(E)

Anaesthetic gas monitors

Section 1: General

1.1 Scope

NOTE 1 See the rationale in annex N.

ISO 11196 is one of a series of International Standards based on IEC 601-1; in IEC 601-1 (the "General Standard"), this type of International Standard is referred to as a "Particular Standard". As stated in 1.3 of IEC 601-1:1988, the requirements of this International Standard take precedence over those of IEC 601-1.

The scope and object given in clause 1 of IEC 601-1:1988 apply except that **1.1** shall be replaced by the following:

This International Standard specifies requirements for anaesthetic gas monitors intended for use in determining the anaesthetic vapour and/or gas level(s) in breathing gas mixtures and/or fresh gas mixtures. Both diverting and non-diverting anaesthetic gas monitors are covered, irrespective of the measuring technology used. Also included are anaesthetic gas identifying monitors. The field of application includes monitoring patient breathing mixtures, the output of anaesthesia workstations, and the output of vaporizers as well as anaesthesia ventilators and breathing systems.

Anaesthetic gas monitors intended for use in laboratory research, non-human applications or for calibration of anaesthetic agent vaporizers are outside the scope of this International Standard.

Anaesthetic gases addressed in this International Standard include, but are not limited to, halothane, enflurane, isoflurane, sevoflurane, desflurane and nitrous oxide.

1.2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 4135:1995, *Anaesthesiology — Vocabulary.*

ISO 5356-1:1987, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 9703-1:1992, *Anaesthesia and respiratory care alarm signals — Part 1: Visual alarm signals.*

ISO 9703-2:1994, *Anaesthesia and respiratory care alarm signals — Part 2: Auditory alarm signals.*

IEC 79-3:1990, *Electrical apparatus for explosive gas atmospheres — Part 3: Spark test apparatus for intrinsically-safe circuits.*

IEC 79-4:1975, *Electrical apparatus for explosive gas atmospheres — Part 4: Method of test for ignition temperature.*

IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety.*

IEC 601-1-2:1994, *Medical electrical equipment — Part 1: General requirements for safety — Collateral standard — Electromagnetic compatibility requirements and tests.*

IEC 801-2:1991, *Electromagnetic compatibility for industrial process measurement and control equipment — Electrostatic discharge requirements.*

1.3 Definitions

For the purposes of this International Standard, the definitions given in clause 2 of IEC 601-1:1988 and ISO 4135, and the following definitions apply.

1.3.1 alarm set-point: Setting of the adjustment control, or display value which indicates the anaesthetic gas reading, at or beyond which the alarm is intended to be activated.

NOTE 2 Terms such as "alarm limits" or "alarm threshold" are frequently used to describe the same function.

1.3.2 alarm system: Those parts of the anaesthetic gas monitor which

a) establish the alarm set-point(s);

b) activate an alarm when the anaesthetic gas reading is less than or equal to the low alarm set-point, if provided, or is equal to or greater than the high alarm set-point.

1.3.3 anaesthesia workstation: System for administration of anaesthesia which includes, but is not limited to, an anaesthetic gas delivery system, its essential monitoring devices, and essential hazard protection devices.

1.3.4 anaesthetic gas monitor: Device for the measurement of the anaesthetic gas level in anaesthetic gas mixtures.

1.3.5 anaesthetic gas: Gas and/or vapour of a volatile agent used in anaesthesia.

1.3.6 anaesthetic gas level: Concentration in volume percent or partial pressure of anaesthetic gas in a gaseous mixture.

1.3.7 anaesthetic gas reading: Measured anaesthetic gas level as indicated by the anaesthetic gas monitor display.

1.3.8 applied part: Part of the anaesthetic gas monitor intended to be connected with the patient or with the anaesthetic breathing system.[1)]

1.3.9 delay time: Time from a step function change in anaesthetic gas level at the sampling site to the achievement of 10 % of the step change in the anaesthetic gas reading of the anaesthetic gas monitor (see figure 1).

1) See the rationale in Annex N.

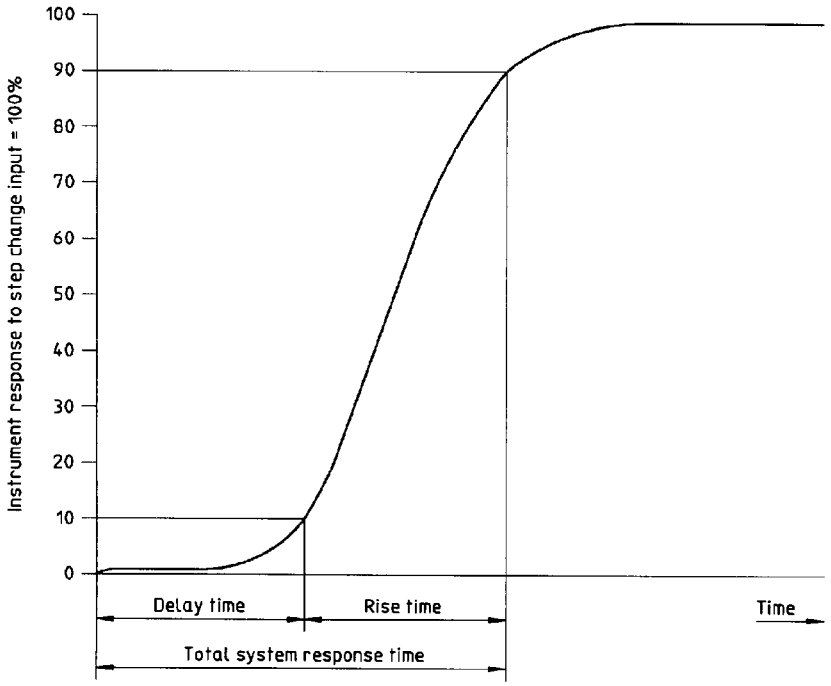

Figure 1 — Delay time, rise time and total system response time

1.3.10 display: Visual representation of output data.

1.3.11 diverting anaesthetic gas monitor: Anaesthetic gas monitor that transports a portion of ventilatory gases from the sampling site through a sampling tube to the sensor, which is remote from the sampling site.

1.3.12 fresh gas outlet; common gas outlet: That port through which the dispensed mixture from an anaesthetic apparatus is delivered to a breathing system.

1.3.13 enabled condition: Necessary, but not sufficient, condition to cause an action.

1.3.14 default conditions; default settings: Those operating parameters within the monitor, which are pre-set at the factory or by the operator and which the monitor itself sets, without further intervention, when it is turned on.

1.3.15 interference with measurement accuracy: Difference between the anaesthetic gas readings in the presence and absence of an interfering gas(es).

1.3.16 non-diverting anaesthetic gas monitor: Anaesthetic gas monitor that uses a sensor at the sampling site.

1.3.17 partial pressure: Pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature.

1.3.18 volume percent; % (*V/V*): Volume of an anaesthetic or other gas in a mixture, expressed as a percent of the total volume.

1.3.19 rise time: Time required to display a rise from 10 % to 90 % of the change in the anaesthetic gas reading by the anaesthetic gas monitor when a step function change in anaesthetic gas level occurs at the sampling site (see figure 1).

1.3.20 sampling site: Location at which ventilatory gases are diverted for measurement to a remote sensor in a diverting anaesthetic gas monitor or the location of the sensor area in a non-diverting anaesthetic gas monitor.

1.3.21 sampling tube: Conduit for transfer of gas from the sampling site to the sensor in a diverting anaesthetic gas monitor.

1.3.22 sensor: Part of the anaesthetic gas monitor which is sensitive to the presence of the anaesthetic gas.

1.3.23 total system response time: Sum of the delay time and rise time (see figure 1).

1.3.24 anaesthetic ventilator: Actuator device of an anaesthesia workstation which, when connected to the patient's airway, is designed to augment or provide ventilation of the patient's lungs.

1.3.25 accuracy: Quality which characterizes the ability of a device to give indications approximating to the true value of the quantity measured.

NOTE 3 Accuracy is an overall quality of a device from the point of view of errors. Accuracy is greater when the indications are closer to the true value (based on ISO 7504:1984).

1.3.26 drift: Change of the indications of a monitor, for a given level of concentration over a stated period of time, under reference conditions which remain constant.

NOTE 4 It is necessary to distinguish the zero drift which concerns the operation of the instrument with samples of zero or low concentration from the drift considered at one or several levels of concentration (based on ISO 7504:1984).

1.3.27 flammable anaesthetic agent: Anaesthetic agent which is ignited by the test specified in annex M.[1)]

1.3.28 non-flammable anaesthetic agent: Anaesthetic agent which is not ignited by the test specified in annex M.[1)]

1.3.29 respiratory gas conducting components: All components of the anaesthetic ventilator and the anaesthetic breathing system which are in contact with the patient's inhaled gas during any form of ventilation.

NOTES

5 Such components are for example anaesthetic breathing systems, anaesthetic breathing system attachments, ventilator bellows, particle filters, APL valves and CO_2 absorber assemblies.

6 When the sample gas is not returned to the anaesthetic breathing system, the gas sampling line is not considered to be a respiratory gas conducting component.

1.4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of IEC 601-1:1988 apply with the following additions.[1)]

All parts of an anaesthetic gas monitor and their devices should be designed and manufactured to minimize health risks due to toxic products and substances leached from the devices during use.

3.6 j) Applicable single fault conditions are:

a) short- and open-circuits of components or wiring which can

— cause sparks to occur, or
— increase the energy of sparks, or
— increase the temperature (see section 7);

b) incorrect output resulting from software error.

3.6 k) An oxidant leak which remains undetected shall be considered a normal condition and not a single fault condition.[1)]

3.10 Devices dependent on software shall be designed in such a way as to minimize the possibility of risks arising from errors in the software.

4.12 Test methods other than those specified in this International Standard but of equal or greater accuracy may be used to verify compliance with the requirements of this International Standard. However, in the event of dispute, the methods specified in this International Standard shall be used as the reference methods.

1.5 Classification

The requirements given in clause 5 of IEC 601-1:1988 apply with the following addition.

NOTE — An anaesthetic gas monitor may have applied parts of different types.

1.6 Identification, marking and documents

The requirements given in clause 6 of IEC 601-1:1988 apply together with the following amendments and additions.

6.1 j) Amend existing IEC 601-1:1988 text to read

The rated input shall be given in amperes for the anaesthetic gas monitor and for the sum of the current ratings for the anaesthetic gas monitor and the auxiliary mains socket outlet(s).[1)]

6.1 k) Amend existing IEC 601-1:1988 text to read

Each auxiliary mains socket outlet shall be marked with the maximum allowed output, which shall be given in amperes.[1)]

After **6.1 z)**, add the following:

6.1 aa) All operator-connectable components of the anaesthetic gas monitor which are flow-direction-sensitive shall be clearly and durably marked with an arrow showing the direction of gas flow.

6.1 ab) Each gas-specific inlet and outlet shall be identified by clear and durable marking using the gas name or chemical symbol in accordance with ISO 5359. If colour coding is used in addition, it shall be in accordance with ISO 32.

6.1 ac) Marking of packages.

Packages containing respiratory gas-conducting components shall be permanently and legibly marked with the following:

1) information about cleanliness and sterility of single use and reusable components as supplied by the manufacturer;
2) an indication of the time limit for using a device safely expressed in year/month, where applicable;
3) a description of the contents;
4) the name and/or trademark of the manufacturer and/or supplier;
5) an identification reference to the type, batch or serial number;
6) the necessary instructions in the event of the sterile pack being damaged and, where appropriate, details of appropriate methods of sterilization;
7) if appropriate the words "SINGLE USE" or "SINGLE PATIENT USE";

   NOTE — Symbol No. 1051 ("Do not re-use") given in ISO 7000:1989 may additionally be used.
8) the word "STERILE", and the method of sterilization, if applicable. Device packing and/or labelling shall differentiate between the same or similar products both sterile and non-sterile placed on the market by the same manufacturer.

6.1 ad) Marking of anaesthetic gas monitors

Anaesthetic gas monitors shall be durably and legibly marked with the following:

1) any particular instructions for use;
2) any particular warnings and/or cautions;
3) if a sampled gas inlet and outlet are present on the anaesthetic gas monitor, marking of the ports;
4) if the device is intended only for use with dry fresh-gas mixtures, a statement to that effect;
5) serial number and year of manufacture;

NOTE — The year of manufacture may be part of the serial number.

6) if not suitable for use in breathing systems, a statement to that effect.

6.2 Marking on the inside of equipment or equipment parts.

The requirements given in clause 6.2 of IEC 601-1:1988 apply.

6.3 Marking of controls and instruments.

The requirements given in clause 6.3 of IEC 601-1:1988 apply with the following additions.

6.3 g) If an anaesthetic gas monitor has more than one sampling site, the selection of a particular sampling site shall be clearly indicated on the anaesthetic gas monitor;

6.3. h) If a display or a calibrated scale or control measures or controls a variable within the anaesthetic gas monitor,

1) the display or scale shall be marked to indicate that it refers to a machine variable and not a patient variable,
2) anaesthetic gas reading display(s) shall be marked with kPa (partial pressure) or % (*V/V*) (volume percent) anaesthetic gas,
3) if abbreviations for anaesthetic agents are used, they shall be in compliance with column 2 of table 1.

Compliance shall be determined by inspection of marking and instructions for use.

Table 1 — Abbreviations for anaesthetic agents

Anaesthetic agent	Abbreviation
Desflurane	DES or D
Enflurane	ENF or E
Halothane	HAL or H
Isoflurane	ISO or I
Methoxyflurane	MET or M
Sevoflurane[1)]	SEV or S
1) Provisional.	

6.4 Symbols.

The requirements given in clause 6.4 of IEC 601-1:1988 apply.

6.5 Colours of insulation of conductors.

The requirements given in clause 6.5 of IEC 601-1:1988 apply.

6.6 Identification of medical gas cylinders and connections.

The requirements given in clause 6.6 of IEC 601-1:1988 apply.

6.7 Indicator lights and push-buttons.

The requirements given in clause 6.7 a) of IEC 601-1:1988 apply with the following modification.

On equipment, the colour red shall be used exclusively to indicate a warning of danger and/or a need for urgent action. Dot matrix, alphanumeric displays and computer-generated graphics are not considered to be indicator lights.

6.8 Accompanying documents.

6.8.1 General.

The requirements given in clause 6.8.1 of IEC 601-1:1988 apply.

6.8.2 Instructions for use.

The requirements given in clause 6.8.2 of IEC 601-1:1988 apply with the following additions.

6.8.2 a) General information.

— If gas diversion occurs, the range of gas diversion flows shall be given.

— If appropriate, a statement that equipment may be used in a magnetic resonance imaging (MRI) environment shall be given.

— Instructions for proper disposal of the diverted gas shall be provided.

— Delay time and rise time (see figure 1) shall be disclosed. In the case of diverting anaesthetic gas monitors, the sampling tube(s) used in determining these values shall be disclosed.

Instructions for use shall contain the conditions under which measured values are displayed, for example ambient temperature and pressure saturated (ATPS), body temperature and pressure saturated (BTPS), standard temperature and pressure dry (STPD).

6.8.2 i) The instructions for use of category APG anaesthetic gas monitors shall include statements to the effect of the following.

— This anaesthetic gas monitor has been constructed to comply with the requirements for category APG equipment.

— Any modification to the anaesthetic gas monitor may compromise its safety in the presence of flammable anaesthetic agents.

— Provided that the following precautions are strictly observed, this anaesthetic gas monitor is safe to use with flammable anaesthetic agents such as diethyl ether and cyclopropane.

1) The discharge of flammable anaesthetic agents or mixtures while the anaesthetic breathing system is disconnected is to be avoided.
2) Only equipment classified and marked APG should be used within 5 cm of any point of possible emission of flammable anaesthetic agents or mixtures.
3) Only equipment classified and marked as AP or APG should be used within 25 cm of any point of possible emission of flammable anaesthetic agents.

6.8.2 k) The instructions for use of anaesthetic gas monitors marked as APG but having parts which are not category APG shall include full information to identify such parts.[1)]

6.8.2 l) The instructions for use of category APG anaesthetic gas monitors shall include a warning statement to the effect of the following.

When using agents forming flammable mixtures, only antistatic or electrically conductive components shall be used in the anaesthetic breathing system. This does not apply to tracheal tubes, tracheal tube connectors and oropharyngeal airways.[1)]

6.8.2 m) The instructions for use of anaesthetic gas monitors not specified as category APG equipment shall include a statement to the effect of the following.

To avoid explosion hazards, flammable anaesthetic agents such as ether and cyclopropane shall not be used in this anaesthetic gas monitor. Only anaesthetic agents which comply with the requirements on non-flammable anaesthetic agents in this International Standard are suitable for use in this anaesthetic gas monitor.[1)]

6.8.2 n) The instructions for use of anaesthetic gas monitors not specified as category APG shall include a statement to the effect of the following.

The use of antistatic or electrically conductive breathing tubes when utilizing high-frequency electrosurgery equipment may increase the risk of burns and is therefore not recommended in any application of this anaesthetic gas monitor.[1)]

6.8.2 o) The instructions for use shall contain information about cleanliness and sterility upon delivery for single use and re-usable components, where applicable.

6.8.2 p) Information about monitoring, alarm and protection modules.

The instructions for use shall contain:

1) a description of the methods of verifying alarm functions;
2) details of any pressure relief valves fitted to the anaesthetic gas monitor that can affect the breathing system;
3) details of default alarm set-points and priorities.

6.8.2 q) The instructions for use shall include information about the connection of an anaesthetic gas scavenging system (AGSS) and/or return of the diverted gases to the breathing system.

6.8.3 Technical description.

The requirements given in clause 6.8.3 of IEC 601-1:1988 apply with the following amendments.

6.8.3 a) The technical description shall additionally include the following information.

a) General

The requirements given in clause 6.8.3 a) of IEC 601-1:1988 apply with the following additions.

— The technical description shall give accuracies, display resolutions and ranges of displayed values and calibrated controls.

Accuracies should be expressed as maximum zero error (bias) quoted directly in appropriate units plus a sensitivity error (linearity, precision), for example, quoted as a percentage of the reading.

— Interdependence of controls, if applicable, shall be disclosed.

— The ambient air ingression and internal gas leakage, if any, shall be disclosed.

— Information necessary to check that an anaesthetic gas monitor is installed correctly and is in safe and correct working order and on the nature and frequency of maintenance operations necessary to ensure continuing safety and correct operation shall be disclosed.

1.7 Power input

The requirements given in clause 7 of IEC 601-1:1988 apply.

Section 2: Environmental conditions

2.1 Basic safety categories

The requirements given in clause 8 of IEC 601-1:1988 apply.

2.2 Removable protective means

The requirements given in clause 9 of IEC 601-1:1988 apply.

2.3 Environmental conditions

The requirements given in clause 10 of IEC 601-1:1988 apply.

Section 3: Protection against electric shock hazards

3.1 General

The requirements given in clause 13 of IEC 601-1:1988 apply.

3.2 Requirements related to classification

The requirements given in clause 14 of IEC 601-1:1988 apply.

3.3 Limitation of voltage and/or energy

The requirements given in clause 15 of IEC 601-1:1988 apply.

3.4 Enclosures and protective covers

The requirements given in clause 16 of IEC 601-1:1988 apply.

3.5 Separation

The requirements given in clause 17 of IEC 601-1:1988 apply with the following additions.

17 h) Deterioration of parts due to oxygen shall be taken into account.

Compliance is checked by inspection, by measurements and/or test according to subclause 59.2 c) of IEC 601-1:1988.

17 j) Deterioration of parts due to anaesthetic agents shall be taken into account.

Compliance is checked via manufacturer certification.

3.6 Protective earthing, functional earthing and potential equalization

The requirements given in clause 18 of IEC 601-1:1988 apply.

3.7 Continuous leakage current and patient auxiliary currents

The requirements given in clause 19 of IEC 601-1:1988 apply with the following addition.

19.4 h) Measurement of the patient leakage current.[1)]

Addition:

19.4. h) 12) The patient leakage current shall be measured from parts which are defined as applied parts for the purposes of this International Standard. All these parts shall be connected together electrically with the exception of parts connected to the protective earth terminal which shall be tested separately from parts not so connected.

3.8 Dielectric strength

The requirements given in clause 20 of IEC 601-1:1988 apply.

Section 4: Protection against mechanical hazards

4.1 Mechanical strength

The requirements given in clause 21 of IEC 601-1:1988 apply.

4.2 Moving parts

The requirements given in clause 22 of IEC 601-1:1988 apply.

4.3 Surface, corners and edges

The requirements given in clause 23 of IEC 601-1:1988 apply.

4.4 Stability in normal use

The requirements given in clause 24 of IEC 601-1:1988 apply.

4.5 Expelled parts

The requirements given in clause 25 of IEC 601-1:1988 apply.

4.6 Vibration and noise

The requirements given in clause 26 of IEC 601-1:1988 apply with the following addition.

Vibration and noise shall be limited to non-hazardous levels.

4.7 Pneumatic and hydraulic power

The requirements given in clause 27 of IEC 601-1:1988 apply.

4.8 Suspended masses

The requirements given in clause 28 of IEC 601-1:1988 apply.

Section 5: Protection against hazards from unwanted or excessive radiation

5.1 X-radiation

The requirements given in clause 29 of IEC 601-1:1988 apply.

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

The requirements given in clause 30 of IEC 601-1:1988 apply.

5.3 Microwave radiation

The requirements given in clause 31 of IEC 601-1:1988 apply.

5.4 Light radiation (including lasers)

The requirements given in clause 32 of IEC 601-1:1988 apply.

5.5 Infrared radiation

The requirements given in clause 33 of IEC 601-1:1988 apply.

5.6 Ultraviolet radiation

The requirements given in clause 34 of IEC 601-1:1988 apply.

5.7 Acoustical energy (including ultrasonics)

The requirements given in clause 35 of IEC 601-1:1988 apply. See also 1.6, "6.8.2 p)".

5.8 Electromagnetic compatibility

Replace the requirements given in clause 36 of IEC 601-1:1988 with the following.

36.1 Electromagnetic compatibility.

The anaesthetic gas monitor shall continue to function and meet the requirements of this International Standard or shall not cause a safety hazard when tested in accordance with IEC 601-1-2.

36.2 Protection from electrostatic discharge.

Discharges shall be applied only to accessible parts and coupling planes (as defined in IEC 801-2).

If an anomaly occurs, such as display interrupt, alarm activation, etc., it shall be possible to restart normal operation within 30 s after the electrostatic discharges have been applied.

Silencing of an activated alarm should not be considered a failure.

Section 6: Protection against hazards of ignition of flammable anaesthetic mixtures

6.1 Locations and basic requirements

The requirements given in clause 37 of IEC 601-1:1988 apply with the following additional subclauses.

37.9 Anaesthetic agents which are ignited by the test in annex M shall be regarded as flammable anaesthetic agents.[1)]

Anaesthetic gas monitors specified for use with such flammable agents shall be classified and marked as category APG equipment and shall comply with the requirements of APG equipment in IEC 601-1:1988.

NOTE — Diethyl ether and cyclopropane are such agents in use.

37.10 Anaesthetic agents which are not ignited by the test in annex M shall be regarded as non-flammable anaesthetic agents.[1)]

Anaesthetic gas monitors specified for use only with such non-flammable agents shall comply with 7.2, "43".

NOTE — Such an agent in use is halothane.

6.2 Marking, accompanying documents

The requirements given in clause 38 of IEC 601-1:1988 apply.

6.3 Common requirements for categories AP and APG equipment

The requirements given in clause 39 of IEC 601-1:1988 apply, with the following additions.

39.3 k) An anaesthetic gas monitor specified and marked as APG shall provide a continuous current path for electrostatic charges from the applied part to earth with a resistance less than 1 MΩ.[1)]

Compliance is checked by the following test:

The resistance shall be measured between the applied part(s) and, in turn,

— a conductive plate on which the anaesthetic gas monitor is placed,

— any protective earth terminal,

— any terminal for potential equalization conductor.

6.4 Requirements and tests for category AP equipment, parts and components

The requirements given in clause 40 of IEC 601-1:1988 apply.

6.5 Requirements and tests for category APG equipment, parts and components

The requirements given in clause 41 of IEC 601-1:1988 apply.

Section 7: Protection against excessive temperatures and other safety hazards

7.1 Excessive temperatures

The requirements given in clause 42 of IEC 601-1:1988 apply.

7.2 Fire prevention

The requirements given in clause 43 of IEC 601-1:1988 apply with the following additional subclause.[1)]

In order to reduce the risk to patients, other persons or the surroundings due to fire, ignitable material, under normal and single fault conditions, shall not, at the same time, be subjected to conditions in which

— the temperature of the material is raised to its minimum ignition temperature, and

— an oxidant is present.

The minimum ignition temperature is determined in accordance with IEC 79-4 using the oxidizing conditions present under the normal and single fault condition.

Compliance is checked by determining the temperature the material is raised to under the normal and single fault condition.

If sparking can occur under normal or single fault conditions, the material subjected to the energy dissipation of the spark shall not ignite under the oxidizing conditions present.

Compliance is checked by observing if ignition occurs under the most unfavourable combination of normal conditions with a single fault.

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

The requirements given in clause 44 of IEC 601-1:1988 apply with the following addition.

44.7

44.7.1 In order to minimize the risk of infection to the patient from respiratory gas conducting components, all manufacturer-specified reusable components which come into contact with the respiratory gas shall be sterile or disinfected, or sterilizable or disinfectable, or be provided with a microbial filter.

44.7.2 If a claim is made in the labelling that the device is sterile, it shall have been sterilized using an appropriate validated method.

44.7.3 Non-sterile device packaging systems shall be designed to maintain products which are intended to be sterilized before use at the intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

7.4 Pressure vessels and parts subject to pressure

The requirements given in clause 45 of IEC 601-1:1988 apply.

7.5 Human errors

Replace the requirements of clause 46 of IEC 601-1:1988 with the following.

46.1 Connections for calibration gases for which Diameter Indexed Safety System (DISS) or Non-Interchangeable Screw Thread (NIST) fittings are not specified shall not be interchangeable with diameter or pin index safety systems.

46.2 Interchange of operator-accessible electrical connectors shall not cause a safety hazard.

7.6 Electrostatic charges

The requirements given in clause 47 of IEC 601-1:1988 apply.

7.7 Materials in applied parts in contact with body of patient

The requirements given in clause 48 of IEC 601-1:1988 apply.

7.8 Interruption of power supply

The requirements given in clause 49 of IEC 601-1:1988 apply with the following addition.

49.1 The anaesthetic gas monitor shall resume operation without operator intervention to reset the display(s) and alarm(s) after mains power supply failures of less than 180 s duration.

Section 8: Accuracy of operating data and protection against hazardous output

8.1 Accuracy of operating data

The requirements given in clause 50 of IEC 601-1:1988 apply with the following addition.

50.1 All accuracies, minimum and maximum levels required in this International Standard for the anaesthetic gas monitor shall include the accuracy of test equipment (e.g. pressure gauges, flow meters, test gases) required to perform the tests.

8.2 Protection against hazardous output

The requirements given in clause 51 of IEC 601-1:1988 apply with the following additions.

51.5 Measurement accuracy.

51.5.1 General

For halogenated anaesthetic gases, the difference between the mean anaesthetic gas reading and the anaesthetic gas level shall be within ± [0,15 % (*V/V*) + 15 % of anaesthetic gas level] over the full measurement range specified in the accompanying documents.

For nitrous oxide, the difference between the mean nitrous oxide reading and the nitrous oxide gas level shall be within ± [2 % (*V/V*) + 8 % of nitrous oxide gas level] over the full measurement range specified in the accompanying documents.

When the gas readings are outside of the manufacturer's specified range, the instrument shall so indicate.

Compliance shall be checked by the test given in 51.5.2.

51.5.2 Test method

51.5.2.1 Principle

Anaesthetic gas readings are determined at a number of anaesthetic gas levels spanning the anaesthetic gas monitor measurement range.

Test gases of an accuracy equal to or better than 0,2 of the tolerance stated in 51.5.1 as determined by gravimetric methods traceable to standards, e.g. ISO 6142 for weighing methods, shall be used for these tests.

Alternative methods of certifying gas composition accuracy may be substituted for the gravimetric method if the alternative method can be shown to be equivalent to or better than the gravimetric method.

51.5.2.2 Dry gas testing.[1)]

The anaesthetic gas monitor shall be set up in accordance with the accompanying documents and tested using dry test gas mixtures, given in table 2, at an ambient temperature of (23 ± 2) °C, a relative humidity within the range of 30 % to 75 %, and atmospheric pressure within the range of 86 kPa to 106 kPa (645 mmHg to 795 mmHg). Verify that the accuracy requirements of 51.5.1 are met.

Equipment designed to monitor anaesthetic agents not listed in table 2 shall be tested by similar methods using clinically significant values.

As noted in 1.4, "4.12" gas compositions different from those listed in table 2 may be used to verify that the accuracy requirements of 51.5.1 are met.

51.5.2.3 Water-saturated gas testing

This requirement does not apply to anaesthetic gas monitors intended solely for use in dry fresh-gas mixtures.

The anaesthetic gas monitor shall be set up in accordance with the accompanying documents and using ambient conditions described in 51.5.2.2. Connect the anaesthetic gas monitor to a simulated breathing system containing air saturated with water at (37 ± 3) °C, with the system cycling at a frequency of (10 ± 2) breaths per min at an inspired to expired time ratio (I:E ratio) of 1:1,5 to 1:2,5 between a pressure of ambient and (3,5 ± 0,5) kPa, [(35 ± 5) cmH_2O] above ambient.

Operate the monitor in accordance with the manufacturer's instructions with the sampling port connected to the breathing system and with condensate visible at the sampling site, for a minimum of 1 h.

Perform an accuracy test using the gas mixtures given in table 3 saturated at (37 ± 3) °C.

Anaesthetic gas monitors shall maintain the accuracy required in 51.5.1 after readings are corrected for humidity (if required) as specified in the accompanying documents.

Table 2 — Dry gas test mixtures % (*V/V*)

Oxygen	Carbon dioxide[1)]	Nitrous oxide	Halothane	Isoflurane	Enflurane	Sevoflurane	Desflurane
100							
balance		65	0,5				
balance		65	1				
balance	5	65	4 [2)]				
balance	5	65		0,5			
balance		65		1			
balance	5			5 [2)]			
balance	5	65			0,5		
balance	5	65			1		
balance					5 [2)]		
balance	5	65				0,5	
balance	5	65				1	
balance		65				5 [2)]	
balance	5	65					5
balance	5	65					10
balance		65					5 [2)]
balance		65					
balance	5	50					
		100					

1) To minimize the number of test gas mixtures and still evaluate the effect of CO_2, 5 % (*V/V*) CO_2 is used for all gas mixtures containing halogenated gases except for the mixtures containing 0,5 % (*V/V*) halothane, 1 % (*V/V*) isoflurane, 5 % (*V/V*) enflurane, 5 % (*V/V*) sevoflurane and 5 % (*V/V*) desflurane.

CO_2 may be excluded from the test gas mixture if the anaesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

2) Or full-scale reading, if lower than specified value.

Table 3 — Test gas mixtures (dry) for water-saturated testing and pressure cycling testing, % (*V/V*)

Oxygen	Carbon dioxide[1)]	Nitrous oxide	Halothane	Isoflurane	Enflurane	Sevoflurane	Desflurane
100							
balance	5	65	4 [2)]				
balance	5	65		0,5			
balance	5	65			1		
balance	5	65				1	
balance	5	65					5

1) CO_2 may be excluded from the test gas mixture if the anaesthetic gas monitor is not intended for use in gas mixtures containing CO_2.

2) Or full-scale reading, if lower than specified value.

51.6 Drift of measurement accuracy.

51.6.1 General

The anaesthetic gas monitor shall meet the requirements specified in 51.5.1 for a minimum of 6 h when used in accordance with the accompanying documents.

Compliance shall be checked by the test given in 51.6.2 or 5.6.3 as approriate.

51.6.2 Test method (water-saturated).

This requirement does not apply to anaesthetic gas monitors intended solely for use in dry fresh-gas mixtures.

Continue to operate the anaesthetic gas monitor as specified in 51.5.2.3, sampling the gas test mixtures in table 3 every 2 h for a minimum of 6 h.

51.6.3 Test method (dry gas).

If the anaesthetic gas monitor is tested by the method in 51.6.2, this clause does not apply.

The anaesthetic gas monitor shall be set up in accordance with the accompanying documents. Using the ambient conditions described in 51.5.2.2, connect the anaesthetic gas monitor to a simulated common gas outlet supplying dry air at (23 ± 2) °C into a simulated breathing system with the system cycling at a frequency of (10 ± 2) breaths per minute at an I:E ratio of 1:1,5 to 1:2,5 at a pressure between ambient and (3,5 ± 0,5) kPa [(35 ± 5) cm H_2O] above ambient.

Operate the monitor for a minimum of 1 h, then perform an accuracy test using the dry gas method as described in 51.5.2.2, using the test gas mixtures given in table 3.

Continue to operate the anaesthetic gas monitor for a minimum of 6 h, repeating the accuracy test every 2 h.

51.7 Pressure effects.

51.7.1 Anaesthetic gas monitors, if specified for use in breathing systems, shall meet the requirements given in 51.5.1 following exposure of the sampling site to a nominal positive pressure of 10 kPa (100 cm H_2O) and a nominal negative pressure of 1,5 kPa (15 cm H_2O) for 5 s each for 20 cycles.

Compliance shall be checked by the test given in 51.7.2.

The rate at which a diverting anaesthetic gas monitor withdraws gas flow from a breathing system should not exceed 1,15 times the maximum value stated in the accompanying documents.

51.7.2 Test for pressure effects.

51.7.2.1 Principle

The accuracy of the anaesthetic gas reading is determined after exposure of the sensor to pressure cycling.

51.7.2.2 Procedure

Cycle the pressure at the sampling site between a positive pressure with respect to ambient of (10 ± 1) kPa [(100 ± 10) cm H_2O] and a negative pressure with respect to ambient of (1,5 ± 0,2) kPa [(15 ± 2) cm H_2O] for not less than 5 s each. Repeat this procedure 20 times (i.e. a total of 21 times), then carry out the test for measurement accuracy using the dry gas method as described in 51.5.2.2 using the gases listed in table 2.

51.8 Alarms

51.8.1 Alarms shall comply with the requirements of ISO 9703-1 and ISO 9703-2, and with 51.8.2 to 51.8.13.

51.8.2 The set-points of adjustable alarms shall be indicated continuously or on operator demand.

51.8.3 The auditory indication shall reset automatically when the condition causing the alarm has cleared.

51.8.4 If a means of temporarily silencing the auditory alarm(s) is provided, this silencing shall not exceed 120 s.

51.8.5 If an auditory alarm(s) can be disabled by the operator, there shall be a visual indication that it has been disabled.

51.8.6 The anaesthetic gas monitor shall have both high and low alarm set-point(s) for halogenated anaesthetic gas(es).

51.8.7 Alarm set-points for high and low anaesthetic gas reading(s) shall be operator-adjustable.

51.8.8 When the anaesthetic gas monitor is switched on, the high anaesthetic gas reading alarm(s) for halogenated anaesthetic gas(es) shall be a medium priority alarm.

51.8.9 When the anaesthetic gas monitor is switched on, the low anaesthetic gas reading alarm(s) for halogenated anaesthetic gas(es) shall be a low priority alarm.

51.8.10 The difference between the alarm set-point and the anaesthetic gas reading when the alarm is activated shall not exceed 0,2 % (*V/V*) for halogenated anaesthetic gas(es) and 2 % (*V/V*) for nitrous oxide.

51.8.11 Means shall be provided to prevent unintentional change of adjustable alarm settings.

NOTE 7 Prevention of unintentional change may be achieved by a deliberate sequence of operator actions, a recess or guard over the control, or the requirement for more than one operator action, etc.

51.8.12 All alarms shall be provided with a default set-point(s) [see 1.6 "6.8.2 p) 3)"].

51.8.13 Compliance shall be checked by inspection and by simulation of the alarm conditions in accordance with the accompanying documents.

NOTE 8 In order that the test may be performed, some anaesthetic gas monitors may require the simulation of a cyclic breathing pattern.

Section 9: Abnormal operation and fault conditions; environmental tests

9.1 Abnormal operation and fault conditions

The requirements given in clause 52 of IEC 601-1:1988 apply.

9.2 Environmental tests

The requirements given in clause 53 of IEC 601-1:1988 apply.

Section 10: Constructional requirements

10.1 General

The requirements given in clause 54 of IEC 601-1:1988 apply.

10.2 Enclosures and covers

The requirements given in clause 55 of IEC 601-1:1988 apply.

10.3 Components and general assembly

The requirements given in clause 56 of IEC 601-1:1988 apply with the following addition.

56.12 Control function and position

If the anaesthetic gas monitor has a test mode, this shall be clearly distinguishable from normal operation.

Controls and their associated markings shall be visible and/or legible to an operator having a visual acuity (corrected if necessary) of at least 1 when the user is located in front of the anaesthetic gas monitor at a distance of 1 m under an illuminance of 215 lx. Calibration controls shall include a means to prevent unintended changes of adjustable settings.

10.4 Main parts, components and layout

The requirements given in clause 57 of IEC 601-1:1988 apply.

10.5 Protective earthing — Terminals and connections

The requirements given in clause 58 of IEC 601-1:1988 apply.

10.6 Construction and layout

The requirements given in clause 59 of IEC 601-1:1988 apply.

Section 11: Additional requirements specific to anaesthetic gas monitors

11.1 Interfering gas and vapour effects (other than water vapour)

60.1 The manufacturer shall disclose in the accompanying documents any known effect on anaesthetic gas readings caused by the gases given at the nominal concentrations listed in table 4. The manufacturer shall make available upon request the test methods used to make such determinations.

Table 4 — Test concentrations of interfering gases or vapours

Gas or vapour	Level % (*V/V*)
Nitrogen	78 (use medical air)
Nitrous oxide	80
Helium[1)]	50
Halothane	4
Enflurane	5
Isoflurane	5
Sevoflurane	5
Ethanol	Specified by manufacturer
Acetone	Specified by manufacturer
Methoxyflurane[1)]	1
Carbon dioxide[1)]	5
Desflurane	5

1) May be excluded from the test gas mixture if the anaesthetic gas monitor is not intended for use in gas mixtures containing this gas.

60.2 Sample gas exhaust port

60.2.1 For diverting anaesthetic gas monitors, an exhaust port shall be provided to collect or route the diverting gas from the anaesthetic gas monitor.

Compliance shall be checked by inspection.

11.2 Obstruction of sampling tube

61.1 A diverting anaesthetic gas monitor shall have a means to indicate obstruction of the sampling tube.

Compliance shall be checked by the test given in 61.2.

61.2 Test method

With the anaesthetic gas monitor operating according to the accompanying documents, totally obstruct the sampling tube, and verify that the requirement of 61.1 is met.

11.3 Breathing system connections

If an anaesthetic gas monitor is intended to be connected to the breathing system through a T-piece, the breathing system connection ports of the T-piece shall be 15 mm and/or 22 mm conical connectors in accordance with ISO 5356-1. The sampling gas inlet and outlet ports of a diverting anaesthetic gas monitor shall not directly mate with any 15 mm and/or 22 mm conical connectors of a breathing system.

11.4 Contamination of breathing systems

It shall not be possible to reverse the direction of flow through the sampling tube in a diverting anaesthetic gas monitor.

Annexes

Annexes A to L of IEC 601-1:1988 apply.

Annex M

(normative)

Test of anaesthetic agents for non-flammability

M.1 Spark ignition tests

Spark ignition tests[1] 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 most ignitable, using the test apparatus described in Appendix F of IEC 601-1:1988, and in IEC 79-3.

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

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

— 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 100 mH;

— 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 IEC 601-1:1988, figures 29 and 31.

M.2 Surface temperature ignition tests

Determination of the ignition temperature shall be carried out with apparatus and procedures based on IEC 79-4, with the following additional requirements.

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

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.

Annex N

(informative)

Rationale

The clause numbers below refer to the body of this International Standard.

1.1 The purpose of this International Standard is to establish requirements for the safety of anaesthetic gas monitors with particular reference to

— protection against electric shock,

— prevention of fires in oxygen- or nitrous oxide-enriched atmospheres,

— prevention of explosions of flammable anaesthetic agents such as ether and cyclopropane,

— protection against hazards from delivery of energy or substances to the patient.

The safety requirements of IEC 601-1:1988 against explosion of flammable anaesthetic agents are modified with less restrictive requirements on such anaesthetic gas monitors where exclusively anaesthetic agents which in this International Standard are defined as non-flammable anaesthetic agents, such as halothane and other halogenated compounds are used.

This International Standard recognizes that the restrictive and expensive requirements of section six of IEC 601-1:1988 for preventing explosions of flammable anaesthetic agents, such as ether and cyclopropane, are unnecessary when only agents defined as non-flammable anaesthetic agents, such as halothane are used.

Even if anaesthetic agents such as halothane are defined in this International Standard as non-flammable anaesthetic agents, they may form flammable mixtures with oxygen and/or nitrous oxide when tested with very high ignition energy. Annex M establishes a lower limit of flammability (based on tests of halothane) for agents to be classified as non-flammable. The requirements of this International Standard ensure that anaesthetic gas monitors not intended for use with flammable anaesthetic agents and therefore not classified as category AP or APG are nevertheless safe for use with non-flammable agents.

1.3.8 The definition of the applied part (1.3.8) is the base for clarification of requirements for, and measurement of, patient leakage current.

Antistatic tubing is required in anaesthetic gas monitors of category APG and cannot be excluded for use with any anaesthetic gas monitor. Such tubing has to be considered as conductive for the patient leakage current.

It is not possible, however, to include any requirements in this International Standard on leakage currents from electrically operated attachments such as humidifiers and heating elements which may be connected in the breathing system because the types of such attachments which will be used in clinical work with a specific type of anaesthesia workstation cannot be anticipated by a manufacturer or test house.

However, parts integrated with the anaesthesia workstation, such as temperature and carbon dioxide sensors, which are intended to come into contact with the breathing system and which are electrically connected to the anaesthesia workstation, are considered as parts for which requirements on leakage currents can be specified in this International Standard.

Such parts are therefore included in the definition of applied part (see figure 1 of IEC 601-1:1988).

3.1.3.27 and **3.1.3.28** See the rationale for 6.1 "37.9" and "37.10".

1.4 "3.6 k)" A fault which is not detected can exist for a long time. Under these circumstances it is not acceptable to regard a further fault as a second fault which can be disregarded. Such a first fault must be regarded as a normal condition.

An undetected oxygen leak is an important example. It should be considered as a normal condition if it is not detected by an alarm or by periodic inspection or unless the system is considered infallible.

1.6 "6.1 j)" and "6.1 k)" The marking of each auxiliary mains socket outlet with its output in amperes gives information on the current ratings of the fuses of each auxiliary mains socket outlet.

1.6 "6.8.2 k)" Anaesthetic gas monitors may have parts, e.g. electric control units, which are not APG. The discharge of flammable mixtures close to such parts must be prevented.

Subclause 38.7 of IEC 601-1:1988 requires a marking to indicate clearly which equipment parts are APG. It is considered important for this information also to be given in the instructions for use.

1.6 "6.8.2 l)" The use of antistatic and/or electrically conductive materials in the anaesthetic breathing system of anaesthesia workstations has proved to be an effective method of eliminating explosions of flammable anaesthetic agents caused by electrostatic sparks. For such parts as tracheal tubes and oropharyngeal airways, surface moisture provides the necessary conductivity and therefore antistatic materials are unnecessary.

1.6 "6.8.2 m)" It is very important that the operator of an anaesthesia workstation not specified as category APG is made aware that an explosion hazard exists when flammable anaesthetic agents are used. It is also important to inform the operator as to which anaesthetic agents are suitable for use in an anaesthesia workstation not specified as APG.

1.6 "6.8.2. n)" Antistatic or conductive anaesthetic breathing system components are not necessary if flammable anaesthetic agents are not used. As such components increase the risk of burns to the patient during electrosurgery, their use with non-APG anaesthesia workstations is not recommended.

3.7 "19.4 h)" See rationale to subclause 2.1.5 and figure 1 of IEC 601-1:1988.

Section 6 The opinion of the experts in clinical anaesthesia about the explosion risk of anaesthetic agents is reflected in the following resolution by ISO/TC 121 at the twelfth meeting held in Philadelphia, 8th to 12th October, 1979.

Resolution for Plenary Session:

> "The requirements for maximum electrical power and stored energy of electrical circuits in an anaesthetic breathing system for use with explosive anaesthetic gases are very restrictive. These restrictive requirements make it difficult or impossible to design electrical sensors and control circuits in or near an anaesthetic breathing system. Such sensors and control circuits are necessary for the design and function of monitoring devices, e.g. of oxygen detectors or servo-ventilation functions as well as measurement of physiological parameters during the use of equipment."
>
> The above-mentioned very restrictive requirements are fully justified on equipment specified for the use of highly explosive anaesthetic agents such as ether and cyclopropane. However, the situation is quite different when the much more frequently used halogenated anaesthetic agents such as halothane, methoxyflurane or enflurane are used.
>
> Flammability tests indicate that the electrical power and energy needed to bring these agents to ignition are sufficiently high that existing restrictive requirements for electrical circuits in the anaesthetic breathing system are not needed as with explosive agents.
>
> After a literature search and solicitation of personal communication, the members of ISO/TC 121 do not know of any injury to patients or operating room personnel caused by ignition of halothane, enflurane or methoxyflurane during anaesthesia irrespective of the use of electrosurgical units.

6.1 "37.9 and **37.10"** Anaesthetic agents do not fall readily into flammable and non-flammable categories. The possibility of ignition depends not only on the agent in use, its concentration and other simultaneously used gases but also on the electrical energy, power and surface temperature that may be available to cause ignition.

Halothane, though generally regarded as safe, will form flammable mixtures with oxygen and nitrous oxide when tested with very high ignition energy. It is therefore necessary to specify a lower ignition level of the agents under which the APG requirements on equipment apply and above which less restrictive requirements apply. Currently used anaesthetic agents such as halothane belong to the category above this level and may therefore, according to this International Standard, be used in anaesthesia workstations not marked as APG or AP.

Ignition tests on the most ignitable of the anaesthetic agent mixed with oxygen and/or nitrous oxide have been recommended in annex M. The reason for using the most ignitable concentration and not clinically used concentrations is that this method is common and recognized when determining the flammability level of gas mixtures and when comparing this level with the flammability of other gas mixtures. The most ignitable concentration is also a well-defined concentration which can be technically determined in test institutes specialized in such tests.

Ignition tests carried out in the resistive circuit according to annex M with the most ignitable mixture of halothane with nitrous oxide gave the following results.

NOTE — "–" indicates no ignition, "+" indicates ignition.

100 V, 0,22 A –

100 V, 0,25 A +

15 V, 2,7 A –

15 V, 2,8 A +

6.3 "39.3. k)" A continuous path for electrostatic charges to earth eliminates possible sparks which could ignite flammable gases.

6.4 "40" It is considered that in anaesthetic workstations specified for use with flammable anaesthetic agents there always exist parts, e.g. parts conducting the flammable anaesthetic agent, which only can be classified as APG and which shall be so marked. Such anaesthesia workstations, however, include parts, e.g. control units, so allocated in normal use that they can be classified as AP.

7.3 "43" Reports of fire caused by medical devices are unusual. However, when such fires occcur in the hospital environment they can have tragic consequences.

The risk of a fire is fundamentally determined by the three elements which are necessary in order to start a fire:

— ignitable material (fuel);

— temperature equal to or above the minimum ignition temperature of the material, or sparks with energy dissipation equal to or above the minimum ignition energy of the materials;

— an oxidant.

Therefore, following the basic safety concepts of IEC 601-1, the objective in the design of the equipment must be to ensure that under both normal and single fault conditions and under the oxidizing conditions to which the material may be exposed, the temperature of any material is not raised to its minimum ignition temperature or the spark energy does not exceed the material ignition energy level. Alternatively, contained ignition may occur provided it is self-limiting so that no hazard is created, e.g. a fuse or a resistor within a sealed compartment.

Minimum ignition temperatures for a large number of specific materials are well established in published literature, although usually only for ambient air and pure oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of oxidant present. If ignition temperatures for other materials or different oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 79-4.

In considering the ignitable materials, particular attention should be paid to materials which may accumulate during prolonged use, e.g. airborne particles of paper or cotton.

The risk of fire directly caused by sparking of electrical circuits is generally considered insignificant in medical equipment as temperature rise resulting from the power dissipation caused by a spark will not normally reach the ignition temperature of the solid materials generally used when following good design practice.

However, if materials with a low ignition temperature and a very low thermal capacity, e.g. cotton wool, paper or organic fibre accumulations, are present then it may not be possible to determine the surface temperatures attained during exposure to spark energy, and specific tests, such as ignition tests, may be necessary to assume safety under these conditions.

In certain standards currently in use the requirements to minimize fire risk are based on limitation of temperature, electrical energy and oxidant concentration to absolute values.

The temperature value is based on the minimum hotplate ignition temperature for fire-retardant cotton in 100 % oxygen which is given in the American NFPA Publication 53M as 310 °C. The assumption was therefore made that 300 °C was an acceptable temperature limit in medical equipment with oxygen-enriched atmospheres.

The origin of the electrical energy values which have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from other published standards. However, simple tests and detailed analysis of the known factors involved in causing an oxygen fire show that these figures can be either over-restrictive or potentially hazardous depending, in particular, on the manner in which the power may be dissipated and the proximity and type of any "fuel" present.

It is now generally accepted that there are no single or universally applicable ranges of temperatures, energy and concentration of oxidant which can ensure safety under all circumstances. Ultimately, electrical energy is only significant in respect of its ability to raise the temperature of ignitable materials and this in turn depends upon the particular configuration and the proximity of any ignitable materials.

Under single fault conditions in a typical electrical circuit, the possible number of failure modes is very high. In this case full assurance of safety may only be possible by the use of appropriate hazard and safety analysis procedures, taking into consideration the three basic elements, i.e. material, temperature and oxidant.

An appropriate design might limit the electrical energy in the circuit to ensure that temperatures remain below the minimum air ignition temperature under normal conditions, and seal compartments or add forced ventilation to ensure that the oxygen content does not exceed that of ambient air under a single fault condition.

Alternatively, it may be appropriate to limit the electrical energy to ensure temperatures below the minimum ignition temperature for a pure oxygen environment, even under a single fault condition.

It is the particular combination of material, oxidant and temperature which determines whether a fire will occur, not a single value of any one of these variables.

51.5.2.2 The requirement for dry gas testing applies to anaesthetic gas monitors intended for dry and wet gas use in order to establish deviations in accuracy.

10.4 "57" Emergency equipment such as defibrillators, cardiac monitors and routine equipment such as infusion pumps have to be capable of being used anywhere in a hospital. The provision of non-standard sockets on anaesthesia workstations would prevent the unrestricted interchange of equipment and would be unacceptable to the operator. More than one auxiliary mains socket outlet may be needed according to medical practice.

An unrestricted number would, however, increase leakage currents to unacceptably high levels. As any other routine equipment which is connected to the auxiliary mains socket outlets normally will comply with the requirements of IEC 601-1:1988, this problem of added leakage currents is considered to be of little significance for up to four auxiliary mains socket outlets, which is the number recommended by experts in IEC/SC 62D and ISO/TC 121, balancing the benefits of interchangeability against the incremental risk of exceeding tolerable leakage currents. A number of auxiliary mains socket outlets may be needed according to medical experts of ISO/TC 121.

Annex M See rationale to 6.1 subclauses "37.9" and "37.10".

Ignition tests with halothane were carried out according to annex M by Physikalisch-Technische Bundesanstalt, D-3300 Braunschweig, Germany.

Halothane proved to be more ignitable in nitrous oxide than in oxygen. The ignition test was therefore continued with halothane in nitrous oxide. The most ignitable concentration was investigated by variation of the halothane concentration when testing with the inductive circuit. This concentration was measured as 25 % (*V/V*) to 28 % (*V/V*). With 26 % (*V/V*) halothane in nitrous oxide, the following results were obtained.

NOTE — "–" indicates no ignition, "+" ignition.

Resistive circuit:

110 V, 0,22 A –
110 V, 0,25 A +
15 V, 2,7 A –
15 V, 2,8 A +

Inductive circuit:

5.8 mH, 400 mA –
5.8 mH, 450 mA –
105 mH, 220 mA –
105 mH, 240 mA +
1003 mH, 90 mA –
1003 mH, 95 mA +

Capacitive circuit:

1 µF, 178 V –
1 µF, 190 V +
20 µF, 38 V –
20 µF, 40 V +

When the cadmium disc in the test apparatus was oxidized by the reaction products resulting from explosions of the test mixture, the minimum energy for ignition decreased slightly. The tests were made with oxidized cadmium disc.

Literature reference: T. Redeker: *The flammability hazard when using halogenated agents*, Physikalisch-Technische Bundesanstalt (PTB), Braunschweig, Germany.

Annex P

(informative)

Bibliography

[1] ISO 6142:1981, *Gas analysis — Preparation of calibration gas mixtures — Weighing methods.*

[2] ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

[3] ISO 7504:1984, *Gas analysis — Vocabulary.*

[4] NFPA Publication 53M *Fire hazards in oxygen-enriched atmospheres*[2].

2) Available from the National Fire Prevention Association, 1, Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101, USA.

ICS 11.040.10

Descriptors: medical equipment, anaesthetic equipment, medical gases, gas analyzers, classification, specifications, safety requirements, tests, identification methods, marking, instructions for use.

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