INTERNATIONAL STANDARD

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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.

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.

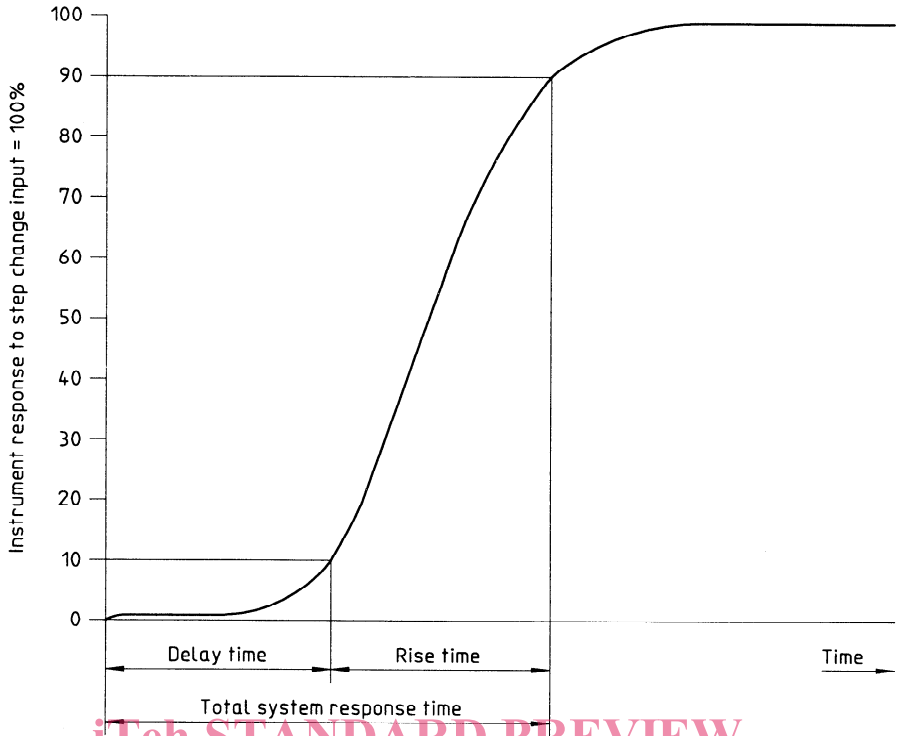

Figure 1 — Delay time, rise time and total system response time

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.