

Anaesthetic gas monitors

The European Standard EN ISO 11196:1997 has the status of a
British Standard

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National foreword

This British Standard is the English language version of EN ISO 11196:1997. It is identical with ISO 11196:1995 including Technical Corrigendum 1:1997.

The UK participation in its preparation was entrusted by Technical Committee CH/44, Anaesthetic machines, breathing attachments, medical gas pipeline systems and hose assemblies, to Subcommittee CH/44/1, Anaesthetic machines, breathing systems and anaesthetic gas scavenging systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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

Cross-references

Attention is drawn to the fact that CEN and CENELEC standards normally include an annex which lists normative references to international publications with their corresponding European publications. The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN ISO title page, page 2, the ISO title page, pages ii to iv, pages 1 to 26 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 October 1997

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English version

Anaesthetic gas monitors (ISO 11196:1995 including Technical Corrigendum 1:1997)

Dispositifs de contrôle de gaz d'anesthésie
(ISO 11196:1995 Rectificatif Technique 1:1997
inclus)

Überwachungsgeräte für Anästhesiegase
(ISO 11196:1995 einschließlich Technisches
Korrigendum 1:1997)

This European Standard was approved by CEN on 1996-11-08. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

The text of the International Standard from Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) has been taken over as a European Standard by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment”, the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 1998, and conflicting national standards shall be withdrawn at the latest by June 1998.

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11196:1995 has been approved by CEN as a European Standard without any modification.

NOTE Normative references to International Standards are listed in Annex ZB (normative).

INTERNATIONAL STANDARD

ISO 11196

First edition
1995-10-15

Anaesthetic gas monitors

Dispositifs de contrôle de gaz d'anesthésie



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

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*.

Section 1. General

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.

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 system¹⁾

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)

1.3.10

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⁾ See the rationale in Annex N.