

Medical electrical equipment —

Part 2: Particular requirements for safety —

Specification for oxygen monitors for monitoring patient breathing mixtures

ICS 11.040.10

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National foreword

This British Standard reproduces verbatim ISO 7767:1997 and implements it as the UK national standard. It supersedes BS 5724-2.27:1989 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/46, Lung ventilators and related equipment, to Subcommittee CH/46/2, Oxygen analyzers, 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

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or using the “Find” facility of the BSI Standards Electronic Catalogue.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ISO title page, pages ii to iv, pages 1 to 22 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.

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INTERNATIONAL STANDARD

**ISO
7767**

Second edition
1997-05-01

Oxygen monitors for monitoring patient breathing mixtures — Safety requirements

Analyseurs d'oxygène pour le contrôle des mélanges gazeux respirés par le patient — Exigences de sécurité



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Descriptors: Medical equipment, artificial breathing apparatus, anaesthetic equipment, monitoring equipment, accident prevention, oxygen, gas analyzers, classification, specifications, safety requirements, protection against mechanical hazards, protection against electric shocks, radiation protection, fire protection.

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 7767 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee 3, *Lung ventilators and related equipment*.

This second edition cancels and replaces the first edition (ISO 7767:1988), which has been technically revised.

Annex N forms an integral part of this International Standard. Annex O and Annex P are for information only.

Section 1. General

Introduction

ISO 7767 is one of a series of standards developed for specific medical electrical equipment (a Particular Standard) based on IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* (The General Standard). ISO 7767:1988 referenced the first edition of IEC 601-1 published in 1977 and this International Standard references the second edition, published late in 1988.

Annex O provides a rationale for specific requirements.

1.1 Scope

ISO 7767 is one of a series of International Standards based on 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 given in clause 1 of IEC 601-1:1988 applies except that 1.1 shall be replaced by the following:

This International Standard specifies safety requirements for oxygen monitors, as defined in clause 1.3.14, intended for use in determining the oxygen level in gas mixtures. Both diverting and non-diverting oxygen monitors are covered.

The field of application includes, but is not limited to:

- a) anaesthetic machines and breathing systems;
- b) ventilators;
- c) infant incubators;
- d) oxygen concentrators.

Devices that do not “measure and indicate” are not intended to be covered by this International Standard. For instance, a device that has no function other than to signal an alarm at a specific oxygen level would not be considered to be an oxygen monitor for use in direct patient monitoring applications.

The phrase “in a gaseous mixture” implies that devices that measure or monitor oxygen in a liquid phase (for example, blood gas analyzer or indwelling catheters) are not covered by this International Standard.

Oxygen monitors intended for use in laboratory research applications are outside the scope of this International Standard.

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 agreement based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the standards listed below:

ISO 5356-1:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*.

ISO 5356-2:1996, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw — threaded weight-bearing connectors*.

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 explosive gas atmospheres*.

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 601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety*.
2. Collateral standard: *Electromagnetic compatibility — Requirements and tests*.

1.3 Definitions

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

1.31.1 alarm

warning signal of an alarm system

1.31.2 alarm set-point

setting of the adjustment control or display value which indicates the oxygen level at or beyond which the alarm is intended to be activated (indicated alarm limit)

**1.3.3
alarm system**

those parts of the oxygen monitor which a) establish the alarm set point(s); b) activate an alarm when the oxygen level is less than or equal to the low alarm set-point, or is equal to or greater than the high alarm set-point

**1.3.4
default (alarm or setting)**

those operating parameters within the system which are preset at the factory or by the operator and which the system itself sets, without further intervention, when it is turned on

**1.3.5
delay time**

with respect to a step change in oxygen concentration or partial pressure at the sampling site, the time required for the monitor to register 10 % of the step change

**1.3.6
display**

device that visually indicates quantitative or qualitative information

**1.3.7
diverting oxygen monitor**

oxygen monitor which transports the gas mixture from the sampling site to the sensing area

**1.3.8
expected service life**

period during which the performance of an oxygen monitor or any of its components is expected to meet the requirements of this International Standard when used and maintained according to the accompanying documents

**1.3.9
high priority alarm**

combination of auditory and visual signals indicating that immediate operator response is required

**1.3.10
interference with measurement accuracy**
difference between the oxygen reading in the presence of an interfering gas mixture and the oxygen reading in a corresponding mixture in which the interfering gas or vapour fraction has been replaced by nitrogen

**1.3.11
low priority alarm**

visual signal, or combination of auditory and visual signals, indicating that prompt operator response is required

**1.3.12
medium priority alarm**

combination of auditory and visual signals indicating that prompt operator response is required

**1.3.13
oxygen level**

concentration of oxygen in a gaseous mixture expressed as volume fraction in percent (V/V) or as partial pressure (in kilopascals)

**1.3.14
oxygen monitor**

device that measures and indicates the oxygen level in a gaseous mixture

**1.3.15
oxygen reading**

measured oxygen level as indicated by the oxygen monitor

**1.3.16
oxygen (or other gases) % (V/V)**

level of oxygen (or other gas) in a mixture expressed as volume fraction in percent

**1.3.17
partial pressure**

pressure that each gas in a gas mixture could exert if it alone occupied the volume of the mixture at the same temperature

**1.3.18
response time**

time required for an oxygen monitor to achieve a 90 % change to a step function (delay response to a step change in oxygen level plus rise time)

**1.3.19
rise time**

time for an oxygen monitor to change from 10 % to 90 % of a step function

**1.3.20
sensing area**

part of the sensor at which oxygen is detected

**1.3.21
sensor**

part of the oxygen monitor which is sensitive to the presence of oxygen

**1.3.22
shelf life**

period during which the oxygen monitor or any of its components are stored in its original container under conditions in accordance with the accompanying documents