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Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors

Appareils électromédicaux — Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 21647 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines*.

This first edition of ISO 21647 cancels and replaces ISO 7767:1997, ISO 9918:1993 and ISO 11196:1995, which have been technically revised.

Introduction

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

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

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

To facilitate the use of this International Standard, the following drafting conventions have been applied.

The changes to the text of IEC 60601-1:1988, the General Standard, as supplemented by the Collateral Standards, are specified by the use of the following words.

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

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

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

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

In this International Standard, the following print types are used:

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

— notes and examples: smaller roman type;

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

— terms defined in Clause 2 of the General Standard IEC 60601-1:1988 or in this Particular Standard: **bold.**

Throughout this Particular Standard, text for which a rationale is provided in Annex AA, is indicated by an asterisk (*).

Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors

1* Scope

IEC 60601-1:1998, Clause 1, applies, except as follows.

Amendment (add at the end of 1.1):

This International Standard specifies particular requirements for the basic safety and essential performance of respiratory gas monitors (RGM) (as defined in 3.15) intended for continuous operation for use with humans.

This International Standard specifies requirements for

aa) anaesthetic gas monitoring,

bb) carbon dioxide monitoring,

cc) oxygen monitoring.

This International Standard is not applicable to monitors intended for use with flammable anaesthetic agents.

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

Environmental aspects are addressed in Annex CC.

NOTE Additional aspects of environmental impact are addressed in ISO 14971.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

ISO 23328 (all parts), *Breathing system filters for anaesthetic and respiratory use*

IEC 60068-2-27, *Environmental testing. Part 2: Tests. Test Ea and guidance: Shock*

IEC 60068-2-32:1975, *Environmental testing. Part 2: Tests. Test Ed: Free fall*,
Amendment 1:1982,
Amendment 2:1990

IEC 60068-2-64 *Environmental testing. Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance*

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

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety,*
Amendment 1:1991
Amendment 2;1995

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

IEC 60601-1-6, *Medical electrical equipment — Part 1: General requirements for safety — Collateral standard: 6, Usability: Analysis, test and validation of human factors compatibility*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 and the following apply.

NOTE For convenience, the sources of all defined terms used in this International Standard are given in Annex DD.

3.1
applied part
Amendment to IEC 60601-1:1988 subclause 2.1.5 (add between first and second dashes):

— is intended to be connected with the breathing system, e.g. for a **non-diverting respiratory gas monitor**, the **sensor**, or for a **diverting respiratory gas monitor**, the **sample gas** inlet at the **RGM**

3.2
clearly legible
capable of being read by the **operator** or other relevant person with normal vision

[IEC 60601-1:—[1)], definition 3.14]

NOTE See 6.101 for further information.

3.3
delay time
time from a step-function change in **gas level** at the **sampling site** to the achievement of 10 % of the final **gas reading** of the **RGM**

3.4
displayed
⟨output data on the **RGM**⟩ visually represented

1) To be published (revision of IEC 60601-1:1988).

3.5
diverting respiratory gas monitor
sidestream monitor
RGM that transports a portion of respiratory gases from the **sampling site** through a **sampling tube** to the **sensor**, which is remote from the **sampling site**

3.6
drift
change in the **gas reading** of an **RGM**, for a given **gas level** over a stated period of time, under reference conditions that remain constant

3.7
gas level
content of a specific gas in a gaseous mixture

3.8
gas reading
measured **gas level** as **displayed** by the **RGM**

3.9
measurement accuracy
quality which characterizes the ability of an **RGM** to give indications approximating to the true value of the quantity measured

3.10
***minimum alveolar concentration**
MAC
alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50 % of subjects from moving in response to a standard surgical stimulus

NOTE For the purposes of this International Standard, **MAC** is calculated from the end-tidal gas content.

3.11
non-diverting respiratory gas monitor
mainstream monitor
RGM that uses a **sensor** at the **sampling site**

3.12
oxygen-rich environment
environment in which the partial pressure of oxygen is greater than 27,5 kPa

NOTE Adapted from IEC 60601-1:—[1)], definition 3.76.

3.13
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

3.14
reserve electrical power source
part of the **medical electrical equipment** that temporarily supplies power to the electrical system in the event of an interruption of the primary electrical supply

3.15
respiratory gas monitor
RGM
medical electrical equipment intended to measure the **gas level(s)** or **partial pressure(s)** in respiratory gases

NOTE The **RGM** consists of a complete monitor including accessories, **sensor**, and **sampling tube** (in the case of a **diverting respiratory gas monitor**) specified by the manufacturer in the **accompanying documents** for the intended use of the **RGM**.

3.16
sampling site
〈**diverting respiratory gas monitor**〉 location at which respiratory gases are diverted for measurement to a remote **sensor**

3.17
sampling site
〈**non-diverting respiratory gas monitor**〉 location of the **sensor**

3.18
sampling tube
conduit for transfer of gas from the **sampling site** to the **sensor** in a **diverting respiratory gas monitor**

3.19
sensor
part of the **RGM** that is sensitive to the presence of the respiratory gas

3.20
total system response time
time from a step function change in **gas level** at the **sampling site** to the achievement of 90 % of the final **gas reading** of the **RGM**

3.21
use-by
〈time frame〉 describing last date during which the **RGM** or any of its components, when stored in its original container under conditions in accordance with the **accompanying documents**, is intended to be put into service

3.22
volume fraction
volume of a gas in a mixture, expressed as a percentage of the total volume

4 General requirements and general requirements for tests

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

Addition:

4.101 Other test methods

The manufacturer may use type tests different from those detailed within this International Standard, if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified in this International Standard shall be used as the reference methods.

4.102 Acceptance criteria

Many of the test clauses within this International Standard establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the manufacturer chooses to specify in the **accompanying documents** performance levels better than those specified within this International Standard, these manufacturer-specified levels become the acceptance levels and shall also be met (e.g. see Clauses 50 and 101).

5 Classification

IEC 60601-1:1988, Clause 5, applies.

6 Identification, marking and documents

IEC 60601-1:1988, Clause 6, applies, except as follows.

6.1 Marking on the outside of equipment or equipment parts

Replacement:

d) If the size of the **RGM** does not permit the complete marking as specified throughout this clause, at least the following shall be marked on the **RGM**:

— the name and address of the manufacturer or authorized representative, if applicable;

— a serial (or Symbol 3.16 from ISO 15223:2000) or lot or batch (or Symbol 3.14 from ISO 15223:2000) identifying number; and

— Symbol ISO 7000-0434.

Addition:

aa) All **operator**-interchangeable components of an **RGM** that are flow-direction sensitive shall be marked with a **clearly legible** arrow showing the direction of gas flow.

bb) Each **RGM** sampling gas inlet shall be marked either with the **clearly legible** text “Gas sample” or with the Symbol ISO 7000-0794.

cc) Each **RGM** sampling gas outlet shall be marked either with the **clearly legible** text “Gas exhaust” or with the Symbol ISO 7000-0795.

dd) Packages for single-use components shall be marked with the following words: “Single use” or “Single patient use” or the Symbol ISO 7000-1051.

ee) If the **RGM** contains any latex based components it shall be marked with the following word: “Latex”.

ff) If appropriate, the **use-by** date or Symbol 3.12 from ISO 15223:2000.

gg) All **sampling tubes** shall be marked either with the **clearly legible** text “Gas sample” or with the Symbol ISO 7000-0794.

hh) Any gas exhaust tube for a **diverting respiratory gas monitor** shall be marked either with the **clearly legible** text “Gas exhaust” or with the Symbol ISO 7000-0795.

ii) The **RGM** and its parts shall be marked with regard to proper disposal, as appropriate.

6.3 Markings of controls and instruments

g)

Amendment. Add at the beginning:

Gas reading should be marked in kilopascals (kPa).

Amendment. Add after last dash:

Units outside the International System, which alternatively may be used on an RGM:

— **gas reading**

  — % (**volume fraction**, see 3.22);

  — millimetres of mercury;

— **gas reading of anaesthetic agents**

  — % (**volume fraction**, see 3.22)

  — **MAC** (**minimum alveolar concentration**) can be displayed additionally (see Table 107).

6.8.2* Instructions for use

Addition:

aa) Description of the intended use of the **RGM**;

bb) A description of the principles of operation of the **RGM**;

It is recommended that illustrated service information be provided that includes the following: instructions for preventive maintenance and service calibration, and those adjustments that are necessary to maintain the **RGM** in the correct operating condition, as well as a description of those adjustments and replacements that can be performed by the **user**.

cc) The instructions for use shall include the following where applicable:

1) performance specifications:

  i) in a **diverting respiratory gas monitor**, the sampled gas flowrates and their tolerances;

  ii) the **gas reading alarm limit** range and its discrimination;

  iii) the detection threshold for a single halogenated anaesthetic gas in a gas mixture, and the detection threshold(s) for multiple halogenated anaesthetic gases in a gas mixture;

  iv) the ranges of temperature, atmospheric pressure and humidity for operation and for storage;

  v) the time from turning on the **RGM** to obtaining specified operating performance;

  vi) the maximum specified interval (expressed in hours) between any necessary **operator** interventions to the water-handling system, based on a sample gas temperature of 37 °C, a room temperature of 23 °C and sample relative humidity of 100 %. This interval shall be stated for both the specified minimum and maximum sample flowrates;

  vii) a statement indicating whether or not the **RGM** is equipped with automatic barometric pressure compensation;

  viii) if **MAC gas readings** are provided, the **MAC** values or algorithms used to determine the **MAC** values displayed by the **RGM**;

  ix) total system response time (see 51.102);

  x) drift of measurement accuracy (see 51.101.2).

2) known adverse effects on stated performance due to the following:

   i) quantitative effects of humidity or condensate;

   ii) leaks or internal venting of sampled gas;

   iii) cyclical pressure of up to 10 kPa (100 cmH_2O);

   iv) quantitative effects of barometric pressure;

   v) return of the sampled gas to the breathing system;

   vi) quantitative effects of fluctuation in **supply mains** or battery voltage;

   vii) interfering gases and vapours; and

   viii) other sources of interference.

3) operation and maintenance:

   i) procedures for calibration before or during use, including advice for the proper disposal of calibration gases;

   ii) description of the functional checks required before or during use;

   iii) methods and frequency of routine inspection and testing;

   iv) methods for cleaning, disinfecting or sterilizing and any limitations on the number of these cycles;

   v) method for connecting the exhaust port of the **RGM** to an **anaesthetic gas scavenging system**, including advice for the proper disposal of sampled gases;

   vi) method of verifying all **operator-**adjustable **alarm system** functions;

   vii) for normal operation, the **rated** voltage range of any external electrical power source;

   viii) the minimum value for normal operation of any **internal electrical power source**;

   ix) the operation of the **RGM** after the **supply mains** has been interrupted when the “on-off” switch remains in the “on” position and is restored after a period of time that is longer than 30 s;

   x) advice for the proper disposal of accumulated fluids, e.g. fluids in reusable water traps.

dd) A diagrammatic illustration of the features of the **RGM**, indicating the function and location of all operating controls, adjustments, and system components necessary for correct operation.

ee) A description of the correct installation of the **RGM** and a description of sampling arrangements and any connecting tubing, if applicable.

ff) Information concerning the disposal of the **RGM** or components thereof.

gg) The location of all latex-based components, if applicable.

hh) If applicable, a statement that the **RGM** is suitable for use in a magnetic resonance imaging (MRI) environment, including the maximum magnetic field (gauss) line in which the **RGM** will function normally.