BRITISH STANDARD

BS EN ISO
21647:2009

Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

ICS 11.040.10

BSI
British Standards

National foreword

This British Standard is the UK implementation of EN ISO 21647:2009. It is identical to ISO 21647:2004. It supersedes BS EN ISO 21647:2004 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2009.

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EUROPEAN STANDARD

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Supersedes EN ISO 21647:2004

English Version

Medical electrical equipment - Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

Appareils électromédicaux - Prescriptions particulières relatives à la sécurité et aux performances de base des moniteurs de gaz respiratoires (ISO 21647:2004, Cor 1:2005 inclus)

This European Standard was approved by CEN on 21 March 2009.

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 CEN Management Centre or to any CEN member.

This European Standard exists 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 21647:2009: E

Foreword

The text of ISO 21647:2004, including Cor 1:2005 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 21647:2009 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 October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document supersedes EN ISO 21647:2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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

Endorsement notice

The text of ISO 21647:2004, including Cor 1:2005 has been approved by CEN as a EN ISO 21647:2009 without any modification.

Annex ZA
(Informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 – Correspondence between this European Standard and EU Directives

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
-	6a)	This relevant Essential Requirement is not addressed in this European Standard
-	7.5 (1st paragraph, 2nd sentence and 2nd and 3rd paragraphs)	These relevant Essential Requirements are not addressed in this European Standard
-	12.1a)	This relevant Essential Requirement is not addressed in this European Standard
6.1 d)	13.3a)	This relevant Essential Requirement is only partly addressed in this European Standard
6.1 d)	13.2, 13.3 a)	
6.1 aa) to 6.1 hh)	13.2	
6.1 dd)	13.3 f)	The relevant Essential Requirement 13.3 f) is partly addressed
6.1 ee)	13.3 k)	
6.1 ff)	13.3 e)	
6.8.2 aa)	13.4	
6.8.2 cc) 1)	6.8.2 hh), 13.6 b)	
6.8.2 cc) 2)	13.6 a), 13.6 b)	
6.8.2 cc) 3)	13.6 a), 13.6 d), 13.6 i)	
6.8.2.cc) 3	13.6.h)	The relevant Essential Requirement 13.6 h) is partly addressed

Clause(s)/sub-clause(s) of this EN	**Essential Requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**
-	13.6 q)	This relevant Essential Requirement is not addressed in this European Standard
6.8.2 cc) 3) iv)	13.6 a), 13.6 h)	The relevant Essential Requirement 13.6 h) is partly addressed
6.8.2 dd)	13.6 a), 13.6 c)	
6.8.2 ee)	13.6 c)	
6.8.2 ff) to 6.8.2 hh)	13.6 a)	
Table BB.1 also applies.		

WARNING: Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 – Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard
(according to article 3 of amended Directive 93/42/EEC)

Clause(s)/sub-clause(s) of this EN	**Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC**	**Qualifying remarks/Notes**
-	1.1.4	This relevant Essential Requirement is not addressed in this EN
6.2, 101.3	1.5.4	This relevant Essential Requirement is not fully addressed in this EN
-	1.6.1	This relevant Essential Requirement is not completely addressed in this EN; see also reference to IEC 60601-1
-	1.6.2	This relevant Essential Requirement is not addressed in this EN
-	1.6.3	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1
-	3.6.2	This relevant Essential Requirement is not completely addressed in this EN; see reference to IEC 60601-1

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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 (*).

INTERNATIONAL STANDARD **ISO 21647:2004(E)**

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.

Addition:

6.101* Test for legibility

*Position the **RGM** or its part so that the viewpoint is the **operator's** intended position; or the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the center of the plane of the marking and indications and at a distance of 1 m ± 0,025 m. The ambient illuminance shall be in the range of 100 lx to 1 500 lx.*

The observer shall have a visual acuity of 0 on the log Mean Angle Resolvable (log MAR) scale or 6/6 (20/20), corrected if necessary. The observer shall correctly identify the marking from the viewpoint.

7 Power input

IEC 60601-1:1988, Clause 7, applies.

8 Basic safety categories

IEC 60601-1:1988, Clause 8, applies.

9 Removable protective means

IEC 60601-1:1988, Clause 9, applies.

10 Environmental conditions

IEC 60601-1:1988, Clause 10, applies, except as follows.

10.1 Transport and storage

Amendment: add following sentence:

Consideration should be given to the disposal of packaging waste.

10.2.2 Power supply

Addition:

aa) When the **RGM** is intended for use during patient transport outside a healthcare facility, it shall be suitable for a power supply having

- DC voltage: −15 % to +25 % of nominal value, or
- AC voltage: −25 % to +15 % of nominal value, and
- AC frequency: −5 % to +5 % of nominal value, and
- AC waveform: sine, square and others specified by the manufacturer in the **accompanying documents**.

11 Not used

12 Not used

13 General

IEC 60601-1:1988, Clause 13, applies.

14 Requirements related to classification

IEC 60601-1:1988, Clause 14, applies

15 Limitation of voltage and/or energy

IEC 60601-1:1988, Clause 15, applies.

16 Enclosures and protective covers

IEC 60601-1:1988, Clause 16, applies.

17 Separation

IEC 60601-1:1988, Clause 17, applies.

18 Protective earthing, functional earthing and potential equalization

IEC 60601-1:1988, Clause 18, applies.

19 Continuous leakage currents and patient auxiliary currents

IEC 60601-1:1988, Clause 19, applies.

20 Dielectric strength

IEC 60601-1:1988, Clause 20, applies.

21* Mechanical strength

IEC 60601-1:1988, Clause 21, applies, except as follows.

Addition:

21.101 Shock and vibration

An **RGM** or its parts not intended for use during **patient** transport outside a healthcare facility shall have adequate mechanical strength when subjected to mechanical stress caused by **normal use,** pushing, impact, dropping, and rough handling. **Stationary equipment** is exempt from the requirements of this subclause.

After the following tests, the **RGM** shall not cause a **safety hazard** and shall function normally.

a) Shock, in accordance with IEC 60068-2-27

- peak acceleration: 150 m/s^2 (15,3 g);
- duration: 11 ms;
- pulse shape: half-sine;
- number of shocks: 3 shocks per direction per axis (18 total).

NOTE A **hand-held RGM** tested and complying with the requirements in 21.5 of IEC 60601-1:1988 is considered to comply with this requirement.

b) Broad-band random vibration, in accordance with IEC 60068-2-64

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration amplitude:
  - 10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz,
  - 100 Hz to 200 Hz: –3 db/octave,
  - 200 Hz to 2 000 Hz: 0,5 (m/s^2)^2/Hz;
- duration: 10 min per each perpendicular axis (3 total).

21.102 Shock and vibration for transport

An **RGM** or its parts, intended for use during **patient** transport outside a healthcare facility, shall have adequate mechanical strength when subjected to mechanical stress caused by **normal use,** pushing, impact, dropping, and rough handling.

After the following tests, the **RGM** shall not cause a **safety hazard** and shall function normally.

NOTE **Equipment** tested and complying with the requirements in 21.102 in total or part, is considered to comply with the corresponding requirements of 21.101.

a) Shock, in accordance with IEC 60068-2-27:1987

- peak acceleration: 1 000 m/s^2 (102 g);
- duration: 6 ms;
- pulse shape: half-sine;
- number of shocks: 3 shocks per direction per axis (18 total).

b) Broad-band random vibration, in accordance with IEC 60068-2-64

- frequency range: 10 Hz to 2 000 Hz;
- resolution: 10 Hz;
- acceleration spectral density:
  - 10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$,
  - 100 Hz to 200 Hz: –7 db/octave,
  - 200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$;
- duration: 30 min per each perpendicular axis (3 total).

c) For mobile equipment, free fall, in accordance with IEC 60068-2-32:1975, using Procedure 1:

- height: 0,1 m;
- number of falls: 1;
- direction: vertical, (normal operating position).

d) For portable equipment, free fall, in accordance with IEC 60068-2-32:1975, using Procedure 2:

- height: 0,25 m;
- number of falls: 1;
- direction: on each of the six surfaces.

NOTE For **portable equipment**, which is intended to be used with a carrying case, that case may be applied to the **equipment** during this test.

22 Moving parts

IEC 60601-1:1988, Clause 22, applies.

23 Surfaces, corners and edges

IEC 60601-1:1988, Clause 23, applies.

24 Stability in normal use

IEC 60601-1:1988, Clause 24, applies.

25 Expelled parts

IEC 60601-1:1988, Clause 25, applies.

26 Vibration and noise

IEC 60601-1:1988, Clause 26, applies.

27 Pneumatic and hydraulic power

IEC 60601-1:1988, Clause 27, applies.

28 Suspended masses

IEC 60601-1:1988, Clause 28, applies.

29 X-Radiation

IEC 60601-1:1988, Clause 29, applies.

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

IEC 60601-1:1988, Clause 30, applies.

31 Microwave radiation

IEC 60601-1:1988, Clause 31, applies.

32 Light radiation (including lasers)

IEC 60601-1:1988, Clause 32, applies.

33 Infra-red radiation

IEC 60601-1:1988, Clause 33, applies.

34 Ultraviolet radiation

IEC 60601-1:1988, Clause 34, applies.

35 Acoustical energy (including ultrasonics)

IEC 60601-1:1988, Clause 35, applies.

36* Electromagnetic compatibility

IEC 60601-1:1988, Clause 36, applies, except as follows.

Addition:

Respiratory gas monitors shall not be considered **life-supporting equipment** or **systems** as defined in IEC 60601-1-2:2001. An **RGM** shall meet the appropriate requirements of IEC 60601-1-2:2001.

In addition to these requirements, an **RGM** intended for use during patient transport outside a healthcare facility shall comply with IEC 60601-1-2:2001, 36.202.3 a) 1) at the immunity test level of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2 500 MHz (see IEC 60601-1-2:2001, Table 209).

37 Locations and basic requirements

IEC 60601-1:1988, Clause 37, applies.

38 Marking and accompanying documents

IEC 60601-1:1988, Clause 38, applies.

39 Common requirements for category AP and category APG equipment

IEC 60601-1:1988, Clause 39, does not apply.

40 Requirements and tests for category AP equipment, parts and components thereof

IEC 60601-1:1988, Clause 40, does not apply.

41 Requirements and tests for category APG equipment, parts and components thereof

IEC 60601-1:1988, Clause 41, does not apply.

42 Excessive temperatures

IEC 60601-1:1988, Clause 42, applies.

43* Fire prevention

IEC 60601-1:1988, Clause 43, applies, except as follows.

Addition:

43.101 RGM used in conjunction with oxidants

a) In order to reduce the risk to **patients**, to other persons or to 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.

EXAMPLE Nitrous oxide.

NOTE For partial pressures of oxygen up to 27,5 kPa, when no other oxidants are present, the requirements in IEC 60601-1:1988 are considered to be sufficient.

The minimum ignition temperature is determined in accordance with IEC 60079-4 using the oxidizing conditions present under **normal** and **single fault condition**.

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

b) 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 shall be checked by observing if ignition occurs under the most unfavorable combination of **normal conditions** with a single fault.*

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

IEC 60601-1:1988, Clause 44, applies, except as follows.

44.3 Spillage

Amendment (replace the first sentence with the following):

An **RGM** and its components shall be so constructed that spillage does not wet component parts which when wetted can cause a **safety hazard**.

44.7 Cleaning, sterilization and disinfection

Amendment:

All components not specified by the manufacturer as for single **patient** use, which come into contact with exhaled **patient** gas that may be rebreathed, shall be capable of being sterilized or disinfected, or shall be provided with a breathing system filter compliant with ISO 23328 (all parts).

*Compliance shall be checked by a review of the **accompanying documents** for methods of sterilization and disinfection [see 6.8.2 cc) 3) iv)], and by inspection of the relevant validation reports.*

44.8 Compatibility with substances used with the equipment

Addition:

The **RGM** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the **RGM** or its components during **normal use**.

Particular attention should be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during normal use or routine procedures.

Compliance shall be checked by inspection of the relevant validation reports.

45 Pressure vessels and parts subject to pressure

IEC 60601-1:1988, Clause 45, applies.

46 Human errors

IEC 60601-1:1988, Clause 46, applies, except as follows.

Replacement:

IEC 60601-1-6 applies.

47 Electrostatic charges

IEC 60601-1:1988, Clause 47, applies.

48 Biocompatibility

IEC 60601-1:1988, Clause 48, applies.

49 Interruption of the power supply

IEC 60601-1:1988, Clause 49, applies, except as follows.

Addition:

49.101 Power failure alarm conditions

The **RGM** shall provide at least a **medium priority alarm signal** when the power falls below the minimum value for normal operation.

NOTE After the loss of power, the **alarm system** is not expected to repeat **alarm signals** indefinitely.

If the **RGM** is provided with an **internal electrical power source**, it shall generate at least a **low priority alarm signal** prior to the power source falling below the minimum value for normal operation. This **low priority alarm signal** shall have an auditory component and shall repeat. The **alarm signal** should occur while there is sufficient time to replace the **internal electrical power source**.

The **RGM** shall not display the **respiratory gas reading** when the external electrical power source falls below the minimum value for normal operation.

Compliance shall be checked by functional testing.

49.102 Settings and data storage following short interruptions or automatic switchover

When the **supply mains** to the **RGM** is interrupted for less than 30 s or when automatic switchover to an **internal electrical power source** occurs, all settings and all stored **patient** data shall not be changed.

NOTE 1 The **RGM** does not have to be operating during the interruption of the **supply mains**.

NOTE 2 Settings includes **operator settings**, **user settings**, and the mode of operation.

Compliance shall be checked by functional testing.

49.103 Reserve electrical power source

There shall be a continual visual indication when the **RGM** is operating from the **reserve electrical power source**.

When the **RGM** is equipped with a **reserve electrical power source** it shall provide at least 30 min normal operation of the **RGM** under the conditions specified in the instructions for use.

Compliance shall be checked by functional testing.

49.104 Reserve electrical power source for use outside the healthcare facility

An **RGM** intended for use during **patient** transport outside a healthcare facility shall be provided with either an **internal electrical power supply** or a **reserve electrical power source** that shall provide at least 1 h of normal operation of the **RGM**.

*Compliance shall be checked by determining that normal operation can be maintained by either the **reserve electrical power source** or **internal electrical power supply** for a period of at least 1 h following disconnection of the primary power source.*

50 Accuracy of operating data

IEC 60601-1:1988, Clause 50, applies.

51 Protection against hazardous output

IEC 60601-1:1988, Clause 51, applies, except as follows.

Addition:

51.101* Measurement accuracy

51.101.1 General

For each respiratory gas that an **RGM** is intended to monitor, the **measurement accuracy** levels given in Table 101 shall be achieved. The **gas reading** range, the **measurement accuracy**, and the minimum sample flowrate at which the **RGM** will meet **measurement accuracy** specifications shall be disclosed in the instructions for use.

Table 101 — Measurement accuracy

Gas levels in % volume fraction

Gas	Measurement accuracy
Halogenated agent	± (**volume fraction** of 0,2 % + 15 % of **gas level**)
CO_2	± (**volume fraction** of 0,43 % + 8 % of **gas level**)
Nitrous oxide	± (**volume fraction** of 2,0 % + 8 % of **gas level**)
O_2	± (**volume fraction** of 2,5 % + 2,5 % **gas level**)

Compliance shall be checked by inspection of the instructions for use and with the following test:

*After exposing the **sampling site** 10 times to a cyclical pressure in accordance with Figure 101, **gas readings** shall be determined at a number of **gas levels** spanning the **RGM** measurement range.*

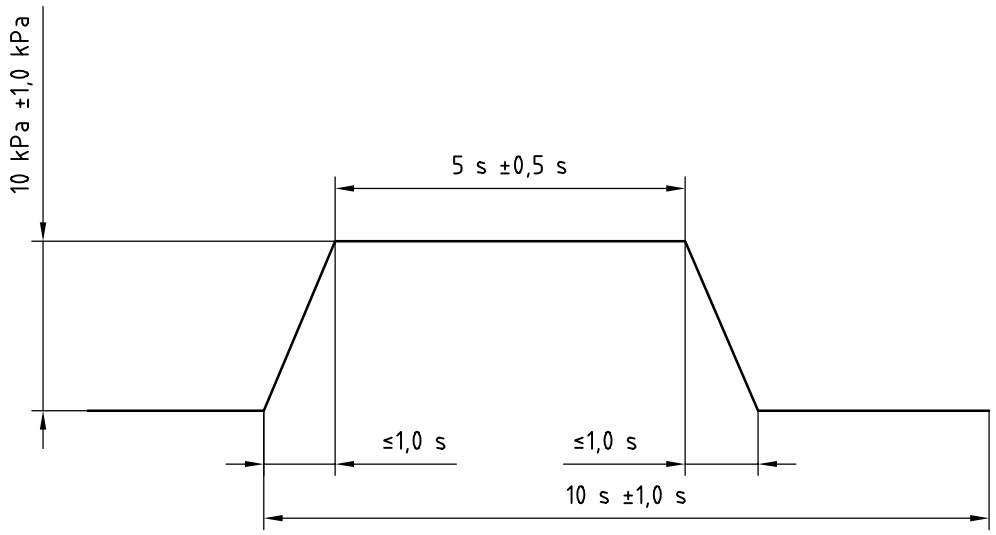


Figure 101 — Cyclical ambient pressure waveform

*Use test gas with a **gas level** as indicated in Table 102 and a tolerance of less than 0,2 times the error tolerance given in Table 101.*

Table 102 — Mixtures for measurement accuracy, drift, and total system response time measurement

Gas levels in % **volume fraction**

Nitrogen	Nitrous oxide[a]	Halothane[a]	Enflurane[a]	Isoflurane[a]	Sevoflurane[a]	Desflurane[a]	Oxygen	Carbon dioxide
Balance	30							
Balance	65[c,d]							
Balance		0,5						
Balance		1,0[c]						
Balance		4,0[b,d]						
Balance			0,5					
Balance			1,0[c]					
Balance			5,0[b,d]					
Balance				0,5				
Balance				1,0[c]				
Balance				5,0[b,d]				
Balance					0,5			
Balance					1,0[c]			
Balance					5,0[b,d]			
Balance						5		
Balance						10[c]		
Balance						15[b,d]		
Balance								0,0
Balance								2,5
Balance								5, 0[c,d]
Balance								10,0
Balance							15,0	
Balance							21,0	
Balance							40,0	
Balance							60,0[c,d]	
Balance							100,0	

[a] Included if the **RGM** is intended for use with this gas.
[b] Or full scale reading, if lower than specified value.
[c] This mixture to be used for **drift** of **measurement accuracy** test (If applicable).
[d] This mixture to be used for the **total system response time** testing (If applicable).

*NOTE Test gases with the aforementioned accuracy may be obtained from manufacturers of test gases or by in-house production of the required test gas mixtures with **gas levels** verified by other methods (e.g. mass spectrometry or refractometry).*

The proper disposal of test gas mixtures should be considered.

*Set up and calibrate the **RGM** in accordance with the instructions for use, and test it using the test gas mixtures as indicated in Table 102. For each numerically **displayed** respiratory **gas level**, verify that the **measurement accuracy** requirements of Table 101 are met.*

51.101.2 Drift of measurement accuracy

For each respiratory gas that an **RGM** is intended to monitor, the **drift** of **measurement accuracy** shall meet the **accuracy** requirements specified in Table 101 for not less than 6 h when used in accordance with the instructions for use with mixtures of gases as indicated in Table 102. The **drift** of **measurement accuracy** shall be disclosed in the instructions for use. See also 6.8.2 cc) 1) x).

Compliance shall be checked by inspection of the instructions for use and with the following test:

*With the **RGM** set up, calibrated and operated in accordance with the instructions for use, perform the tests of 51.101.1 using the test gases for **drift** of **measurement accuracy** testing as indicated in Table 102 and sample all of the identified test gas mixtures every 3 h at least 3 times (total of 6 h). Between the sampling points allow the **RGM** to sample ambient air. The proper disposal of test gas mixtures should be considered.*

*Verify that the **measurement accuracy** requirements of Table 101 are met at each sample point at each test **gas level**.*

51.101.3 Measurement accuracy of gas readings for gas mixtures

For each respiratory gas that an **RGM** is intended to monitor, the **measurement accuracy** of **gas readings** in gas mixtures as specified in Table 101 shall be achieved with the gas mixtures of Table 103.

Compliance shall be checked by inspection of the instructions for use and with the following test:

*Set up and calibrate the **RGM** in accordance with the instructions for use, and test it using the test gases given in Table 103, at an ambient temperature of 23 °C ± 2 °C. For each numerically **displayed** respiratory **gas level**, verify that the **measurement accuracy** requirements of Table 101 are met. The proper disposal of test gas mixtures should be considered.*

*Use test gas mixtures with **gas levels** as indicated in Table 103 and a tolerance of less than 0,2 times the error tolerance given in Table 101.*

Table 103 — Mixtures for combined gas measurement accuracy testing

Gas levels in % **volume fraction**

Carbon dioxide	Nitrous oxide[b]	Oxygen	Nitrogen[b]	Halothane[a]	Enflurane[a]	Isoflurane[a]	Sevoflurane[a]	Desflurane[a]
5	30	40	Balance	2,0				
5	30	40	Balance		2,0			
5	30	40	Balance			2,0		
5	30	40	Balance				2,0	
5	30	40	Balance					8,0
5	Balance[c]	30						
5	Balance[c]	60						

[a] Included if the **RGM** is intended for use with these gas mixtures.

[b] For test gases prepared in-house, nitrous oxide can be increased to “balance” and nitrogen eliminated.

[c] If not for use with nitrous oxide, use nitrogen.

51.102 Total system response time

Total system response time shall be disclosed in the instructions for use.

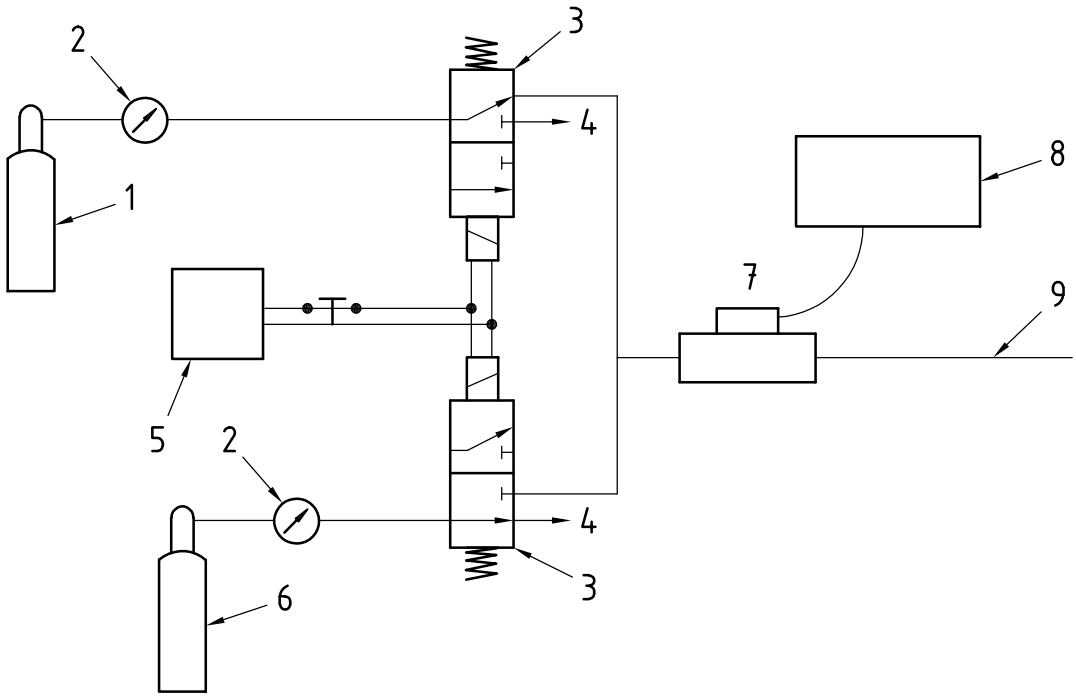
For a **diverting respiratory gas monitor**, the manufacturer shall disclose **total system response time** at each of its specified gas diversion flowrates. See also 6.8.2 cc) 1) ix).

Compliance shall be checked by inspection of the instructions for use and with the following test:

*Set up the **RGM** in accordance with the instructions for use and attach it to the test apparatus arranged as in Figure 102. The proper disposal of test gas mixtures should be considered.*

*Connect the **RGM** to a suitable recording device.*

*With the respective gas mixture from Table 102 (see footnote d of Table 102) at a flowrate of 60 l/min for bore size of 20 mm (or the equivalent average linear gas velocity for other bore sizes), cycle the valve(s) and record the **total system response time**. Repeat the procedure for this single gas mixture 20 times, and determine the average **total system response time**.*



Key

1 calibrated test gas
2 flowmeter
3 two 3-way valves (non-mixing), power supply controlled
4 open to room
5 power supply
6 compressed air or calibrated test gas
7 **sensor/sampling site**
8 **RGM** under test
9 tube (preventing back flow)

Figure 102 — Respiratory gas monitor — Test apparatus for total system response time

51.103 Indication of gas readings units of measure

Units of measure of **gas readings** shall be indicated either continuously or on **operator** demand. If the **operator** has changed the units of measure from the manufacturer- or **user**-selected default units of measure, the units of measure shall be **displayed** continuously.

Compliance shall be checked by inspection of markings and instructions for use.

51.104 Indication of operating mode

Modes, other than normal operating modes (e.g. demonstration, self-test, setup, standby, etc.), shall be indicated continuously. After 1 min without **operator** interaction, other modes should return automatically to normal operating mode.

Compliance shall be checked by inspection.

52 Abnormal operation and fault conditions

IEC 60601-1:1988, Clause 52, applies.

53 Environmental tests

IEC 60601-1:1988, Clause 53, applies.

54 General

IEC 60601-1:1988, Clause 54, applies.

55 Enclosures and covers

IEC 60601-1:1988, Clause 55, applies.

56 Components and general assembly

IEC 60601-1:1988, Clause 56, applies, except as follows.

56.7 Batteries

Replacement:

3) Battery state

See also Clause 49.

57 Mains parts, components and layout

IEC 60601-1:1988, Clause 57, applies, except as follows.

57.3 Power supply cords

Addition:

aa) Any **detachable power supply cord** of an **RGM** shall be protected against accidental disconnection at the **appliance inlet**.

Compliance shall be checked by the following test:

*Subject the **detachable power supply cord** for 1 min to an axial pull force as given in Table 104.*

*During the test, a failure occurs if the **mains connector** becomes disconnected from the **appliance inlet**.*

Table 104 — Pull force as a function of RGM mass

Mass of RGM kg	**Pull** N
Up to and including 1	30
Over 1 up to and including 4	60
Over 4	100

58 Protective earthing — terminals and connections

IEC 60601-1:1988, Clause 58, applies.

59 Construction and layout

IEC 60601-1:1988, Clause 59, applies.

Addition:

101 Additional requirements specifically related to respiratory gas monitors

101.1 Interfering gas and vapour effects

The quantitative effects (if any) on **gas readings** caused by the interfering gases given by the **gas levels** listed in Table 105 shall be disclosed in the instructions for use [see 6.8.2 cc) 2) vii)].

Compliance shall be checked by inspection of the instructions for use.

Table 105 — Test gas levels of interfering gases and vapours

Gas levels in % volume fraction

Gas or vapour	Gas level
Nitrous oxide	60[a]
Halothane	4[a]
Enflurane	5[a]
Isoflurane	5[a]
Sevoflurane	5[a]
Xenon	80[b]
Helium	50[c]
Metered dose inhaler propellants	Specified by the manufacturer
Desflurane	15[a]
Ethanol	Specified by the manufacturer
Isopropanol	Specified by the manufacturer
Acetone	Specified by the manufacturer
Methane	Specified by the manufacturer

Test gas levels shall be ± 20 % of the specified level.

[a] If intended for use with inhalation halogenated agents.

[b] If intended for use with Xenon.

[c] If intended for use with Helium.

101.2 Gas leakage

The rate of leakage from the **sensor** of a **non-diverting respiratory gas monitor** shall not be greater than 10 ml/min at a pressure of 6 kPa (60 cmH_2O).

*Compliance shall be checked by using a pressure gauge having a **measurement accuracy** to within ± 0,3 kPa (3 cmH_2O) and a flowrate metering device having a **measurement accuracy** to within ± 2 ml/min. Assemble the **RGM** so that the **sensor** is installed in a dimensionally suitable port of a test apparatus containing an inlet fitting to which a test gas and air-flowrate metering device are attached. Connect the pressure gauge to a third port of the test apparatus. Slowly adjust the flowrate to raise the pressure in the test apparatus to 6 kPa (60 cmH_2O). Determine the flowrate necessary to maintain this pressure.*

101.3* Exhaust port connector for diverting respiratory gas monitor

A **diverting respiratory gas monitor** shall not be equipped with an exhaust port connector that connects with a connector complying with ISO 594-2.

Compliance shall be checked by inspection.

101.4 Minimum sampling flowrate

A **diverting respiratory gas monitor** shall have a means to indicate when the flowrate through the **sampling tube** has fallen below the value specified in the instructions for use for normal operation. See also 6.8.2 cc) 1) i).

Compliance shall be checked by functional testing.

101.5 Contamination of breathing systems

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

Compliance shall be checked by inspection and functional testing.

102 Alarm systems

IEC 60601-1-8:2003 applies, except as follows.

201.1.2* Alarm condition priority

Amendment (add after the note):

NOTE For the purposes of this International Standard, **minimum alveolar concentration** (**MAC**) values are those listed in the drug package insert for each inhalational agent.

For each respiratory gas that an **RGM** is designed to monitor, the RGM shall provide a means to detect each **gas reading alarm condition**, with its minimum priority, as given in Table 106.

If the **RGM** is capable of detecting the presence of more than one halogenated anaesthetic agent within a gas mixture, but not of quantifying **gas levels** and displaying the **gas readings**, it shall generate at least a **medium priority alarm signal** in the presence of such a mixture (see Table 106).

If the RGM is capable of detecting, quantifying and displaying a mixture of halogenated agents, the RGM shall

a) generate at least a **low priority alarm signal** whenever it detects a mixture of halogenated agents of less than three **MAC** (see Table 107); and

b) generate at least a **medium priority alarm signal** whenever it detects a mixture of halogenated agents of equal to or greater than three **MAC**.

Table 106 — RGM alarm condition priorities

Row number	Gas	Alarm condition priority for low gas level	Alarm condition priority for high gas level
1	Inspired halogenated anaesthetic agent	low priority[a]	medium priority
2	Exhaled CO_2	medium priority	medium priority
3	Inspired CO_2		medium priority
4	Inspired nitrous oxide	low priority[a]	medium priority[a]
5	Inspired O_2	medium priority	medium priority[a]
6	Inspired $O_2 < 18$ %	high priority	
7	Multiple halogenated anaesthetic agents present[b]	medium priority	
8	Multiple halogenated anaesthetic agents value < 3 **MAC**[c]	low priority	
9	Multiple halogenated anaesthetic agents value > 3 **MAC**[c]	medium priority	

NOTE 1 The priorities listed are the minimum priority.

NOTE 2 Exhaled **gas level alarm conditions** may also be provided.

[a] This alarm condition is optional.

[b] When the RGM is capable of detecting but not capable of quantifying and displaying the mixture of halogenated anaesthetic agents.

[c] When the RGM is capable of detecting, quantifying and displaying the mixture of halogenated anaesthetic agents.

Table 107 — Examples of minimum alveolar concentration (MAC) values

Halogenated agent	**MAC** (in oxygen) % volume fraction
Halothane	0,77
Enflurane	1,7
Isoflurane	1,15
Desflurane	7,3 (25-year-old patient)
Sevoflurane	2,1
Nitrous oxide	105[a]

At the time of publication of this International Standard, the MAC values shown in this table are those published by the U.S. Food and Drug Administration for a healthy 40-year-old adult male patient.

Other MAC values may be used. MAC values may be determined by algorithms. See also 6.8.2 cc) viii).

[a] 1 MAC nitrous oxide can only be reached in a hyperbaric chamber.

201.2 Disclosures for intelligent alarm system

Amendment (add as the last sentence in the subclause before the compliance test):

If the **alarm system** has a means to change **alarm condition** priority, without **operator** intervention, it shall not allow a change to a priority lower than that specified in this International Standard.

201.5 Alarm presets

201.5.1 General requirements

Amendment (add as the last sentence in the subclause before the compliance test):

Means shall be provided to prevent the low **alarm limit** of the inspired oxygen **gas reading** of an **RGM** from being set below 18 % in an **alarm preset**.

201.6.2 Adjustable alarm limit

Addition:

201.6.2.101 Operator-adjustable alarm limit

For each **gas reading alarm condition** with which the **RGM** is equipped, the **alarm limit(s)** shall be **operator**-adjustable. The high **gas level** for inspired nitrous oxide shall be exempt from this requirement. Deliberate action shall be required on the part of the **operator** to adjust **alarm limits**.

Compliance shall be checked by inspection.

201.6.2.102 Low alarm limit of the oxygen gas reading

It shall not be possible to set the low **alarm limit** of the inspired oxygen **gas reading** below 18 %.

Compliance shall be checked by inspection.

201.8 Alarm signal inactivation states

201.8.3 Indication and access

Amendment (add at the end of the second paragraph):

Means shall be provided to prevent unintentional activation of **audio off** and **alarm off**.

Amendment (add at the end of the third paragraph):

The manufacturer-configured **alarm preset** for the **audio-paused** or **alarm-paused** interval shall be no greater than 2 min.

103 Appendices of IEC 60601-1:1988

The Appendices of IEC 60601-1:1988 apply.

Addition: The subsequent annexes form an additional element of this part of ISO 10651.

Annex AA
(informative)

Rationale

This annex provides a rationale for some requirements of this International Standard, and is intended for those who are familiar with the subject of this International Standard but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change, it is believed that a rationale will facilitate any revision of this International Standard necessitated by those developments.

The numbering of the following rationale corresponds to the numbering of the clauses in this International Standard. The numbering is, therefore, not consecutive.

AA.1 Scope

An **RGM** used in laboratory research applications is often experimental or intended primarily for non-medical uses. Imposition of the requirements of this International Standard on an **RGM** used for research might unduly limit development of beneficial new techniques or **RGM** designs.

AA.3.10 Minimum alveolar concentration

MAC can vary according to the **patient's age**, so it should be possible for the **operator** to indicate to the **RGM** the **patient's** age and for the **RGM** to use that information to adjust the **MAC threshold** appropriately.

AA.6.8.2 Test method for legibility

The Minimum Angle of Resolution (MAR) is a visual acuity measurement method developed as an improvement on the long-used Snellen scale. The values are express as a logarithm of the Minimum Angle of Resolution. Log MAR can be calculated from the Snellen scale, i.e. log MAR = log(6/6) = 0 for normal vision.

AA.6.8.2 Instructions for use

The need to know the basic workings of the **RGM**, its principles of operation, and many of its detailed specifications should be self-evident, but frequently such information is not available in the instructions for use. It is necessary that the **operators** have this information available, and that they know about any possible adverse effect on the claimed function of the monitor due to any of a number of different conditions, for example condensation from excess humidity, interfering gases, sensitivity to mechanical shocks, fluctuations in barometric pressure or supply voltage, etc. It should be equally self-evident that the **operator** needs to be provided with instructions for proper operation of the **RGM**.

AA.21 Mechanical strength

Equipment, including an **RGM,** in **normal use** is subject to mechanical stresses (e.g. vibration, shock) and could randomly be subject to additional stresses. Therefore **equipment** needs to be robust enough to withstand the vibration, shock, bumps and drops that it will encounter in **normal use**.

These tests were chosen by first qualitatively assessing the relative severity of the scenarios within various environments, [home, hospital and transport] on various sizes and types of **equipment** (i.e., **hand-held, portable** and **mobile equipment**). The result of the committee's analysis is shown in Table AA.1 for the various types of shocks and vibrations which can be experienced.

Table AA.1 — Qualitative assessment of RGM shock and vibration environment

Category	Location															
	Standard environment								Ground transport				Air transport			
	Home				Hospital											
Mobile equipment	D1	S1	V1	B1	D1	S2	V1	B1	D1[a]	S3	V2	B3	D1[a]	S3	V3	B1
Portable equipment	D1	S2	V0	B0	D1	S2	V1	B1	D1[a]	S3	V2	B3	D1[a]	S3	V3	B1
Hand-held equipment	D3	S0	V0	B0	D3	S0	V1	B0	D3	S3	V2	B3	D3	S3	V3	B1
Stationary equipment	None				None				N/A							

S = shock; V = vibration; D = drop; B = bump

Rating: 0 = No test; 1 = Least severe, 2 = Moderate severity, 3 = Most severe

[a] A portion of the committee held that this environment was D3.

Rationale for combining home and hospital environments: the committee recognized that for the case of shock, vibration and bump, the environment in the home should be slightly less severe than levels expected in the hospital. The committee chose to combine these two categories both for simplicity and because many pieces of **equipment** are routinely moved from the hospital to the home environment and vice versa.

After qualitative assessment, the committee assessed the relevant particular standards for environmental testing in the IEC 60068 series and their respective rationales, as well as the IEC 60721 series of guidance documents.

In selecting the requirements, the committee reviewed other sources for material related to these tests (e.g. FDA reviewers guidance[13] for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with IEC 60721-3-7. This standard mapped well to the requirements defined in the above table. There is also a guidance document, IEC/TR 60721-4-7, that helps to correlate environmental condition classes of IEC 60721-3 to environmental tests according the IEC 60068 series. The aforementioned standards specify 3 classes of mechanical conditions, 7M1, 7M2 and 7M3. The committee found the classes 7M1 and 7M3 to best represent the conditions seen during **patient** transport within healthcare facilities and **patient** transport outside healthcare facilities, respectively. The committee agreed different tests and test levels should be applied to **equipment** intended for use in a healthcare facility versus **equipment** intended for use during **patient** transport outside the healthcare facility.

Verifying that the **equipment** is functioning within the **manufacturer's** specifications while the vibration (random and sinusoidal) tests are being conducted is not believed necessary. This line of thought was considered and it was decided that the test done in this manner would be overly burdensome and would only add a minimum additional level of safety to the **equipment** that would not outweigh the costs. Verifying proper functioning after completion of the tests is believed adequate.

AA.21.101 Shock and vibration

Equipment, including an **RGM**, in **normal use**, within a healthcare facility or home environment will be subjected to these mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, **equipment** intended to be used in healthcare and home environments should be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M1. IEC 60721-3-7 indicates that this class applies to use at, and direct transfer between, locations with only low-level vibrations or with medium-level shocks. Careful handling and transfer of products is expected in these environments.

AA.21.102 Shock and vibration for transport

Equipment, including an **RGM**, in **normal use** for **patient** transport outside a healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock, bump, and drop) and could randomly be subjected to additional stresses. Therefore, **equipment** intended to used for **patient** transport outside a healthcare facility should be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7 level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high-level shocks. Rough handling and transfer of **equipment** is expected in these environments.

There are no established generalized test programmes that exactly reproduce the range of vibration and shock conditions that **equipment** might meet when installed in a range of land vehicles and aircraft. Therefore the dynamic tests specified in this clause have been chosen on the basis that **equipment** tested to these levels are likely to withstand the normal dynamic disturbances that they will meet when used in the range of vehicles and aircraft (including helicopters) likely to be used for carrying **patients**.

The use of **equipment** in road ambulance, fixed wing and rotary wing aircraft, naval vessels, etc. can require additional tests and verification of safety when used in these different environments.

For free fall testing described in 60068-2-32, the committee used the rationale for the various levels to gauge the severity of the test based on the Table AA.1. The description of the test level chosen for **portable equipment** was portable cases. The committee agreed that an **RGM** should be required to meet a level of drop testing for the transport environment. The committee also agreed that many **RGM** are likely to be supplied with a protective or carrying case for use in transport environments. It was agreed among the committee that an adequate test would be for **portable equipment** to be dropped while in their carrying cases, as this would be most like the actual environment. For **mobile equipment**, a less severe level was chosen since wheeled **equipment** is typically heavier.

AA.36 Electromagnetic compatibility

The radiated immunity environment during **patient** transport outside a healthcare facility (e.g. land and air ambulances) is harsher than the typical healthcare environment. The main cause of this difference is the presence of multiple two-way radio communication systems that **intentionally** radiate electromagnetic energy. In both of these environments, an **RGM** meeting the requirements of IEC 60601-1-2 is adequately protected from **unintentional** sources of EMI. The additional testing to qualify an **RGM** that is intended for use during **patient** transport outside a healthcare facility need address only this additional source of interference.

Two-way communication devices are used to transmit both voice and patient data. Experience has shown that typical field strengths[13] measured in this environment can be as high as 20 V/m. Voice and patient data typically have modulation bandwidths that exceed 1 kHz with a centre-point of voice modulation of 1 kHz. The committee chose a single test point to represent the typical information modulation band. A signal with 80 % amplitude modulation at 1 000 Hz was chosen, and is consistent with the base radiated-immunity standard IEC 61000-4-3 that also uses 80 % amplitude modulated signal at 1 000 Hz. A 20 V_{RMS}/m 80 % amplitude-modulated signal has a peak-to-peak amplitude of 90,5 V.

The change to 20 V/m is also compatible with the requirements of the FDA reviewer's guidance[12].

AA.43 Fire prevention

Reports of fire caused by **medical electrical equipment** are unusual. However, when such fires occur in the healthcare environment they can have tragic consequences.

The risk of fire is fundamentally determined by the three elements that 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 the IEC 60601-1:1988, 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 **safety 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 normally only in ambient air and 100 % oxygen environments. The minimum ignition temperature may be critically dependent upon the concentration of the oxidant present. If ignition temperatures for other materials or oxygen concentrations are required, these may be determined using the methods and apparatus described in IEC 60079-4.

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

The effect of sparks in environments containing oxidants is quite different from that in explosive gas mixtures. Spark energy is the most potent form of energy in igniting explosive gas mixtures, whilst in environments containing oxidants thermal energy is more fundamental. It is possible that at higher power levels sufficient spark energy can be dissipated in the interface between sparking conductors or their surroundings so that sustained burning occurs, but there is at present no documented evidence as to the power level at which this might occur for different materials and environments. If the potential spark power dissipation deviates from well established safe practice, therefore, specific spark tests should be conducted simulating the most unfavorable environment that can be reasonably foreseen.

The accumulating materials mentioned above are particularly susceptible to ignition by spark energy, because of their low ignition temperatures and very low thermal capacity coupled with poor conductance.

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 NFPA publication 53M[11] 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 that have been used is less clear and it would seem that, in the absence of specific controlled tests, figures have been adopted from accepted working practices or from tests performed in other environments. 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 can be dissipated and the proximity and type of any “fuel” present.

It is therefore now generally accepted that there are no single or universally applicable ranges of temperature, energy and concentration of oxidant which can ensure safety under all circumstances whilst not being unduly restrictive. 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 with 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 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 single fault condition.

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

AA.51.101 Measurement accuracy

Measurement accuracy of an **RGM** is essential performance.

The paragraph immediately following is a reprint of the rationale from ASTM F-1452[10], when halothane, enflurane and isoflurane were the only halogenated agents clinically available. Currently, there are two additional halogenated agents available, sevoflurane and desflurane. The committee addressed establishing the **measurement accuracy** for these new halogenated agents in the same way that was applied by the original committee. Testing for **measurement accuracy** is spread over the entire range of measurement capabilities of a **respiratory gas monitor**, and verified using halogenated agent test gases at the low, medium and high values of the clinically utilized **gas levels**.

Rationale **measurement accuracy**, from ASTM F-1452[11]

NOTE The JWG has reviewed this historical rationale and has determined that it is still valid.

> The required measurement accuracy for halogenated anaesthetic gases and nitrous oxide was probably the single most extensively discussed subject during committee deliberations. The JWG furthermore had before it the results of extensive deliberations at the international level on the same subject. The final figures were arrived at after clinicians both nationally and internationally stated their “clinical requirements” for deviation from actual values at different gas levels of halogenated anaesthetics and nitrous oxide (that is, clinically permissible inaccuracy of the readout).

The resultant values, when an **RGM** is operating within these specifications, are compared in Table AA.2 below, with the statement of clinical requirements.

Table AA.2 — Actual respiratory gas clinical requirement for resultant performance

Gas levels (%)	**Clinical requirement for measurement accuracy**	**RGM specified measurement accuracy** (%)
	Halogenated agent (%)	
0,50	± 0,20	± 0,23
1,00	± 0,30	± 0,30
1,50	± 0,30	± 0,38
2,30	± 0,50	± 0,53
4,00	± 1,00	± 0,75
	Nitrous oxide (%)	
40	± 5,0	± 5,2
50	± 5,0	± 6,0
60	± 6,0	± 6,8
80	± 8,0	± 8,4

AA.101.3 Exhaust port connector for diverting respiratory gas monitor

In view of the work being done by CEN[2)] and in consideration of the reported incidents of misconnection, the use of Luer connectors might no longer be considered prudent. Consideration of the specific risks involved led the JWG to the conclusion that the inlet port on the RGM presented an acceptable risk to the **patient**. If the **patient's** IV system is connected to the **RGM** inlet port, it might cause problems for the **RGM** but not a significant risk for the **patient**. If the **RGM**-end of the sample tube from the breathing circuit to the **RGM** is connected to the **patient's** IV system, a **patient** risk might occur, but the probability is considered very low. It was agreed therefore to have no requirement for the sample inlet port, allowing manufacturers the freedom to choose an appropriate connector.

Misconnection of the exhaust or return port can present a significant risk to the **patient** if it were connected to, for example, an IV line. The JWG decided to mitigate this risk by requiring that the exhaust port not be compatible with Luer lock connectors complying with ISO 594-2.

AA.201.1.2 Alarm condition priority

This International Standard has a requirement that the **RGM** have a means to detect an **alarm condition** for the presence of more than one halogenated anaesthetic agent in the respired gas. This means is needed to help identify cross-filled vaporizers and to detect a failure in vaporizer “lockout” systems. Multiple anaesthetic gases in a mixture can also occur when agents are deliberately changed during the course of an anaesthetic. The **alarm condition** monitoring requirements were established in two parts. A **low priority alarm condition** is required for an **RGM** with automatic identification of individual halogenated agents in a gas mixture containing more than one halogenated agent, and when the total **MAC** is less than 3. For an **RGM** that is not capable of automatically quantifying the **gas levels** of individual halogenated agents but which can detect when a mixture is present, the **alarm condition** is required to be at least at **medium priority**. These requirements were created to provide the capability of changing between halogenated agents without creating nuisance **alarm signals**.

MAC values are defined to be the values listed by the Manufacturers' Package Insert (for healthy adults) that is mandated and reviewed by the US FDA, or via any algorithm that a manufacturer might choose to implement. The actual **MAC** value for an individual can be affected by age, health and other factors. Mandating age compensation would be design-restrictive, especially for anaesthetic workstations that could deliver only one halogenated anaesthetic agent. The 3 **MAC** level was chosen by the entire JWG to be a reasonable level. In fact, most manufacturers set the default high halogenated anaesthetic agent **alarm limit** to 3 **MAC**. **MAC** was chosen in order to effectively compare halogenated anaesthetic agents and allow for any future such agents.

Table AA.3 classifies anaesthetic agent monitors by features. The following requirements apply for the six different classification numbers:

1 single agent monitor, Table, row 1;

2 multiple agent monitor with manual selection of the anaesthetic agent, Table 106, row 1;

3 multiple agent monitor with manual selection of the agent with the capability to indicate the sum of the individual halogenated agents, e. g. using silicone as the absorbent, Table 106, row 8;

4 multiple agent monitor with automated agent selection, via e. g. vaporizer identification, but without mixed agent detection, Table 106, row 1;

5 multiple agent monitor with automatic agent identification and mixed agent detection, but without resolution of the mixture concentrations, Table 106, row 7;

6 multiple agent monitor with automatic agent identification, mixed agent detection and resolution of the mixture concentration, Table 106, rows 8 and 9.

2) Comité Européen de Normalisation, rue Stussart, Brussels, Belgium.

Table AA.3 — Classification of anaesthetic agent monitors

Classification No.	Single agent	Multiple concentration monitor	Silicone MAC	Agent ID	Agent mixture detection	Resolve mixed agent concentrations	Examples
1	X						RIKEN
2		X					Manual agent select monitor
3		X	X				ELSA Narkotest
4		X		X			Automatic agent select monitor via vaporizer identification, etc.
5		X		X	X		Sophisticated monitor
6		X		X	X	X	Mass spectroscopy Raman spectroscopy RASCAL advanced monitor

Annex BB
(informative)

Reference to the Essential Principles

This International Standard has been prepared to support the essential principles of safety and performance of **respiratory gas monitors** as medical devices according to ISO/TR 16142. This International Standard is intended to be acceptable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142. Other means are possible.

Table BB.1 — Correspondence between this International Standard and the Essential Principles

Clause/Subclause of this International Standard	Corresponding Essential Principle	Comments
all	1, 2, 3	
4	1, 2, 3	Via IEC 60601-1, Clause 4
4.101	1, 2, 3	
4.102	1, 2, 3	
5	1, 2, 3	Via IEC 60601-1, Clause 5
6	13.1	Via IEC 60601-1, Clause 6
6.1	2,13.1	Via IEC 60601-1, Clause 6.1
6.1 d)	13.1	
6.1 aa)	9.1, 13.1	
6.1 bb)	9.1, 13.1	
6.1 cc)	9.1, 13.1	
6.1 dd)	8.3, 8.7	
6.1 ee)	7.1, 7.2	
6.2	12.6, 13.1	Via IEC 60601-1, Clause 6.2
6.3	10.1, 10.3	Via IEC 60601-1, Clause 6.3
6.3 g)	10.3	
6.5	12.6	Via IEC 60601-1, Clause 6.5
6.6	9.1	Via IEC 60601-1, Clause 6.6
6.8.2 cc) 2)	9.2	
6.8.2 gg)	7.1, 7.2	
6.8.2 hh)	9.2	
6.101	10.2	
7	12.6	Via IEC 60601-1, Clause 7
8	12.6	Via IEC 60601-1, Clause 8
9	12.6	Via IEC 60601-1, Clause 9

Table BB.1 (*continued*)

Clause/Subclause of this International Standard	Corresponding Essential Principle	Comments
10	4	
10.2.2	5	
13	12.6	Via IEC 60601-1, Clause 13
14	12.6	Via IEC 60601-1, Clause 14
15	12.6	Via IEC 60601-1, Clause 15
16	12.6	Via IEC 60601-1, Clause 16
17	12.6	Via IEC 60601-1, Clause 17
18	12.6	Via IEC 60601-1, Clause 18
19	12.6	Via IEC 60601-1, Clause 19
20	12.6	Via IEC 60601-1, Clause 20
21	4, 5, 9.2, 12.7.1	Via IEC 60601-1, Clause 21
21.101	4, 5	
21.102	4, 5	
22	12.7.1	Via IEC 60601-1, Clause 22
23	9.2 1st dash, 12.7.1	Via IEC 60601-1, Clause 23
24	12.7.1	Via IEC 60601-1, Clause 24
25	12.7.1	Via IEC 60601-1, Clause 25
28	12.7.1	Via IEC 60601-1, Clause 28
29	11.3.1	Via IEC 60601-1, Clause 29
36	9.2, 12.5	
38	13	Via IEC 60601-1, Clause 38
42	12.7.5	Via IEC 60601-1, Clause 42
43	7.1	Via IEC 60601-1, Clause 43
43.101	7.1, 7.3, 9.3	
44	7.6, 12.6	Via IEC 60601-1, Clause 44
44.3	7.6, 12.6	
44.7	7.6, 8.1	
44.8	7.3, 7.5	
45	9.2	Via IEC 60601-1, Clause 45
46	10.2	Via IEC 60601-1, Clause 46
48	1, 7.1	Via IEC 60601-1, Clause 48
49	9.2	Via IEC 60601-1, Clause 49
49.101	12.2, 12.3	
49.102	10.1	
49.103	12.2	
49.104	12.2	

Table BB.1 (*continued*)

Clause/Subclause of this International Standard	Corresponding Essential Principle	Comments
51	10.1	Via IEC 60601-1, Clause 51
51.101.1	10.1	
51.101.2	10.1	
51.101.3	7.3, 10.1	
51.102	10.1	
51.103	10.2, 12.8.1, 12.8.3	
51.104	10.1, 12.8.2, 12.8.3	
52	1, 2, 7.2, 7.5, 9.2, 9.3, 12.6, 12.7.1, 12.7.5	Via IEC 60601-1, Clause 52
53	4	Via IEC 60601-1, Clause 53
56	2, 9.1, 12.6, 12.7	Via IEC 60601-1, Clause 56
56.7	12.2	
57	12.6, 12.7.4	
57.3	12.7.4	
58	12.6	Via IEC 60601-1, Clause 58
59	9.3, 12.6	Via IEC 60601-1, Clause 59
101.1	10.1	
101.2	7.5	
101.3	9.1	
101.4	12.8.2	
101.5	1, 2, 8.1	
102	2, 10.1, 12.2, 12.3, 12.4, 12.8.2	

Annex CC
(informative)

Environmental aspects

Planning and design of products applying to this International Standard should consider the environmental impact from the product during its life cycle. The environmental impact generated by an RGM performing analysis of respiratory gases is mainly restricted to the following occurrences:

— impact at local environment during **normal use**;

— disposal of contaminated sampled gases and biologic fluids during **normal use**;

— use, cleaning and disposal of consumables during testing and **normal use**;

— scrapping at the end of the life cycle.

To highlight the importance of reducing the environmental burden, this International Standard addresses requirements or recommendations intended to decrease environmental impact caused by those aspects during different stages of the **RGM**.

See Table CC.1 for a mapping of the life cycle of an **RGM** to aspects of the environment.

Table CC.1 — Environmental aspects addressed by clauses of this International Standard

Environmental aspects (Inputs and Outputs)		Product Life Cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in subclause	Addressed in subclause	Addressed in subclause	Addressed in subclause
1	Resource use	1.2	1.2	1.2	1.2
2	Energy consumption	1.2	1.2	1.2 42	—
3	Emission to air	1.2	1.2	1.2 6.1 6.8.2 29 36 42 43 44 45 51.101 51.102 56.7 57 59 101.2 201	1.2

Table CC.1 (*continued*)

Environmental aspects (Inputs and Outputs)		Product Life Cycle			
		Production and preproduction Stage A	Distribution (including packaging) Stage B	Use Stage C	End of life Stage D
		Addressed in subclause	Addressed in subclause	Addressed in subclause	Addressed in subclause
4	Emission to water	1.2	1.2	1.2 6.8.2 44	1.2
5	Waste	1.2	1.2 10.1	1.2 6.1 6.8.2 44 51.101 51.102 56.7	1.2 6.1 6.8.2
6	Noise	—	—	1.2 35 201	—
7	Migration of hazardous substances	1.2	—	1.2 6.1 6.8.2 25 44 45 48 51.101 56.7 101.2 101.5	1.2
8	Impacts on soil	—	—	—	1.2 6.8.2
9	Risks to the environment from accidents or misuse	1.2	—	1.2 6.8.2 44 45 56 57 101.3 101.4 101.5 201	1.2

Annex DD
(informative)

Vocabulary — Index of defined terms

Bibliography

[1] ISO 7767, *Oxygen monitors for monitoring patient breathing mixtures — Safety requirements*

[2] ISO 9918, *Capnometers for use with humans — Requirements*

[3] ISO 11196, *Anaesthetic gas monitors*

[4] ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

[5] ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[6] IEC 60721-3-7, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Section 7: Portable and non-stationary use*

[7] IEC/TR 60721-4-7, *Classification of environmental conditions — Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 — Portable and non-stationary use*

[8] EN 864, *Medical electrical equipment — Capnometers for use with humans — Particular requirements*

[9] EN 12598, *Oxygen monitors for patient breathing mixtures — Particular requirements*

[10] ASTM F 1452:1992, *Standard Specification for Minimum Performance and Safety Requirements for Anesthetic Gas Monitors*

[11] NFPA 53M[3)], *Fire Hazards in Oxygen-Enriched Atmospheres*, 1990 Edition

[12] US Food and Drug Administration, *Excerpts Related to EMI* from Anesthesiology and Respiratory Devices Branch, November 1993[4)] See Section (i)(7), on page 17

[13] BOIVIN, W. *et. al. Measurement of Radiofrequency Electromagnetic Fields in and around Ambulances*

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

4) Available from FDA at http://www.fda.gov/cdrh/ode/638.pdf.

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