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BSI Standards Publication

Medical electrical equipment

Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

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National foreword

This British Standard is the UK implementation of EN ISO 80601-2-55:2011. It supersedes BS EN ISO 21647:2009 which is withdrawn.

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

A list of organizations represented on this subcommittee 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.

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

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30 November 2015	Implementation of CEN Correction Notice 25 January 2012: Supersession information updated

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-55

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English Version

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)

Appareils électromédicaux - Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO 80601-2-55:2011)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO 80601-2-55:2011)

This European Standard was approved by CEN on 2 December 2011.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 80601-2-55:2011) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with 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 June 2012, and conflicting national standards shall be withdrawn at the latest by December 2014.

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 21647:2009.

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 EU Directive.

For relationship with EU 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, Croatia, 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 80601-2-55:2011 has been approved by CEN as a EN ISO 80601-2-55:2011 without any modification.

Annex ZA
(informative)

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

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union 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 Directive 93/42/EEC

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11.6.4 to 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed
201.11.6.4, 201.11.6.8	7.3	Only the part of the first sentence relating to design is addressed
201.11.6.4	7.5	
201.11.6.5, 201.101	7.6	
201.11.6.6, 201.11.6.7 , 201.105	8.1	The part of ER 8.1 relating to easy handling is not addressed
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137
201.7.2.17.101	8.7	
201.7.2.101, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.12.1.102, 201.102, 201.103, 208	9.1	
201.9, 201.101, 202, 206	9.2	The 4th indent of ER 9.2 is not addressed

Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	9.3	
201.12.1, 201.101	10.1	
201.7, 201.12.1.103, 201.12.1.104, 206, 208	10.2	
201.7.4.3	10.3	
201.10	11.1.1	
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.11.8.101, 208	12.2	
201.11.8.101, 208	12.3	
208	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.15, 201.103	12.7.4	
201.11	12.7.5	
201.104	12.8.2	Only the first sentence of ER 12.8.2 is covered
201.7, 201.12.1, 206	12.9	
201.7, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.1	
201.7, 201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.2	
201.7.9.1	13.3 a)	
201.7, 201.7.2.17.101, 201.7.2.101	13.3 b)	
201.7, 201.7.2.17.101	13.3 c)	
201.7.2.17.101, 201.7.2.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT
201.7.2.101	13.3 e)	
201.7.2.4.101, 201.7.2.17.101 b)	13.3 f)	Distinction between “single use“ and “single-patient use” taken into account
201.7.2.101 a)	13.3 i)	
201.7, 201.7.2	13.3 j)	

Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7, 201.7.9.2.2.101	13.3 k)	
201.7, 201.7.2.17 a)	13.3 m)	Presumption of conformity is only provided if symbols 5.21 to 5.24 are utilized
201.7.9.2.1.101 a), 201.7.2.17.101, 201.7.2.101	13.4	
201.7.2.17.101 a), 201.7.2.101 b)	13.5	Is only covered if the batch number is preceded by the word LOT
201.7, 201.7.9.1, 201.7.9.2.1.101, 201.7.9.2.2.101	13.6 a)	
201.7, 201.7.9.2.1.101, 201.7.9.2.2.101, 201.7.9.2.9.101 c), 201.7.9.2.9.101 d)	13.6 b)	
201.7, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.9.101 e)	13.6 c)	
201.7, 201.7.9.2.13.101	13.6 d)	
201.7, 201.7.9.2.9.101 g), , 201.7.9.2.9.101 k)	13.6 f)	
201.7.9.2.14.101 b)	13.6 g)	
201.7, 201.7.9.2.9.101 l) , 201.7.9.2.14.101 b)	13.6 h)	
201.7	13.6 i)	
201.7.9.2.1.101 c)	13.6 j)	
201.7	13.6 k)	
201.7	13.6 l)	
201.7, 201.7.9.2.14.101 c), 201.7.9.2.15.101	13.6 n)	
201.12.1.101.1	13.6 p)	
201.7.9.2.9.101 m)	13.6 q)	

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 health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this International 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)/subclause(s) of this European Standard	Essential health and safety requirements (ERs) of EU Directive 2006/42/EC	Qualifying remarks/Notes
201.7, 201.12.1	1.1.4	Only the first sentence of EHSR 1.1.4 is addressed
201.12.1, 201.12.1.104, 206, 208.6.5.1, 208.6.6.2.101	1.2.2	Only the parts of EHST 1.2.2 relevant to the RGM are addressed
201.7.2.101 d), 201.7.2.101 e), 201.7.2.101 f), 201.7.2.101 g) 201.7.2.101 h), 201.103, 201.105	1.5.4	
201.7	1.6.2	
201.8	1.6.3	
201.7, 201.7.2.101 i)	3.6.2	

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

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Introduction

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

— Requirements and definitions: roman type.

— *Test specifications: italic type*.

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this International Standard, the term

— "clause" means one of the 17 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are all subclauses of Clause 201.7).

References to clauses within this International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this International Standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

The verbal forms used in this International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "may" is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or a rationale related to that item in Annex AA.

The attention of Member Bodies and National Committees is drawn to the fact that equipment MANUFACTURERS and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

INTERNATIONAL STANDARD **ISO 80601-2-55:2011(E)**

Medical electrical equipment —

Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors

1 Scope

201.1 Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard specifies particular requirements for the BASIC SAFETY and ESSENTIAL PERFORMANCE of a RESPIRATORY GAS MONITOR (RGM), hereafter referred to as ME EQUIPMENT, intended for CONTINUOUS OPERATION for use with a PATIENT.

This International Standard specifies requirements for

— anaesthetic gas monitoring,

— carbon dioxide monitoring, and

— oxygen monitoring.

NOTE 1 An RGM can be either standalone ME EQUIPMENT or integrated into other equipment, e.g. an anaesthetic workstation or a ventilator.

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

Environmental aspects are addressed in Annex BB.

NOTE 2 Additional aspects of environmental impact are addressed in ISO 14971 and IEC 60601-1-9.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this particular standard, except in 7.2.13 and 8.4.1 of the general standard (IEC 60601-1).

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an RGM (as defined in 201.3.210) and its ACCESSORIES.

NOTE ACCESSORIES are included because the combination of the RGM and the ACCESSORIES needs to be safe. ACCESSORIES can have a significant impact on the BASIC SAFETY and ESSENTIAL PERFORMANCE of an RGM.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Subclause 1.4 of the general standard is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2:2007 collateral standard, 206.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-6:2010 collateral standard, etc.).

The changes to the text of the general standard are specified by the use of the following words:

“Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2:2007, 203 for IEC 60601-1-3:2008, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 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.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

Addition:

ISO 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 15223-1:—[1)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
Amendment 1:2008

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO/IEC 80601-2-13:2011 [2)], *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

1) To be published.

2) Cancels and replaces ISO 8835-2:2007, ISO 8835-3:2007, ISO 8835-4:2004, ISO 8835-5:2004 and IEC 60601-2-13:2003.

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment type specimens*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Test methods — Test Fh: Vibration, broad band random and guidance*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*
Corrigendum 1:2003
Corrigendum 2:2007
Corrigendum 3:2009

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2010*, Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006, IEC 60601-1-11:2010 and ISO/IEC 80601-2-13:2011 apply, except as follows:

NOTE An alphabetized index of defined terms is found beginning on page 50.

Addition:

201.3.201
DIVERTING RGM
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

201.3.202
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

201.3.203
GAS LEVEL
content of a specific gas in a gaseous mixture

201.3.204
GAS READING
measured GAS LEVEL as displayed by the RGM

201.3.205
MEASUREMENT ACCURACY
quality which characterizes the ability of an RGM to give indications approximating to the true value of the quantity measured

201.3.206

*** 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 LEVEL.

201.3.207

NON-DIVERTING RGM
MAINSTREAM MONITOR
RGM that uses a SENSOR at the SAMPLING SITE

201.3.208

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

201.3.209

RESERVE ELECTRICAL POWER SOURCE
part of the ME EQUIPMENT that temporarily supplies power to the electrical system in the event of an interruption of the primary electrical supply

201.3.210

RGM
RESPIRATORY GAS MONITOR
ME EQUIPMENT intended to measure the GAS LEVEL or PARTIAL PRESSURE of one or more gases in respiratory gas

NOTE The RGM consists of equipment, as specified in the ACCOMPANYING DOCUMENTS for the INTENDED USE of the RGM, including a SENSOR, display, ALARM SYSTEM, ACCESSORIES and, for a DIVERTING RGM, the SAMPLING TUBE and exhaust tube.

201.3.211

SAMPLING SITE
location of the SENSOR for a NON-DIVERTING RGM or location at which respiratory gases are diverted for measurement to a remote SENSOR for a DIVERTING RGM

201.3.212

SAMPLING TUBE
conduit for the transfer of gas from the SAMPLING SITE to the SENSOR in a DIVERTING RGM

201.3.213

SENSOR
part of the RGM that is sensitive to the presence of the respiratory gas

201.3.214

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

201.3.215

VOLUME FRACTION
volume of a gas in a mixture, expressed as a percentage of the total volume

201.4 General requirements

IEC 60601-1:2005, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

Additional ESSENTIAL PERFORMANCE requirements are found in the subclauses listed in Table 201.101.

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
MEASUREMENT ACCURACY[a] and GAS READING ALARM CONDITION	201.12.1.101 208.6.1.2
or generation of a TECHNICAL ALARM CONDITION	201.11.8.101.1
[a] Methods of evaluating MEASUREMENT ACCURACY as acceptance criteria following specific tests required by this International Standard are found in 202.6.2.1.7.	

201.4.3.102 Additional requirements for 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 specifies in the ACCOMPANYING DOCUMENT performance levels better than those specified within this International Standard, these MANUFACTURER-specified levels become the acceptance levels.

EXAMPLE For a specified level of MEASUREMENT ACCURACY of 3 %, the RGM is required to have 3 % MEASUREMENT ACCURACY for all requirements, e.g. during IMMUNITY tests.

201.4.6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Addition:

Parts and ACCESSORIES of an RGM intended to be connected with the breathing system shall be subject to the requirements for APPLIED PARTS according to this subclause.

201.4.10.2.101 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For an RGM intended for use during professional transport of a PATIENT outside a healthcare facility, the characteristics of the SUPPLY MAINS specified in IEC 60601-1:2005, 4.10.2 apply, except as follows:

— DC voltage: –15 % to +25 % of NOMINAL value, or

— AC voltage: –15 % to +10 % of NOMINAL value, and

— AC frequency: –5 % to +5 % of NOMINAL value, and

— AC waveform: sine, square and others as specified in the ACCOMPANYING DOCUMENTS.

Check compliance by means of inspection and, where necessary, functional testing.

201.5 General requirements for testing ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

IEC 60601-1:2005, Clause 7 applies, except as follows:

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

The RGM shall be marked with the safety sign for the mandatory action: “Follow instructions for use”, ISO 7010-M002 (see IEC 60601-1:2005, Table D.2, Number 10).

201.7.2.101 * Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts

ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked as follows:

a) with any particular storage and/or handling instructions;

b) with a serial number (or Symbol 5.16 from ISO 15223-1:—) or lot identifying number or batch identifying number (or Symbol 5.14 from ISO 15223-1:—);

c) for the RGM, its parts and ACCESSORIES, with information for proper disposal, as appropriate;

d) for an OPERATOR-interchangeable component of an RGM that is flow-direction sensitive, with an arrow showing the direction of gas flow;

e) for an RGM sampling gas inlet, either with the text “Gas sample” or the Symbol ISO 7000-0794;

f) for an RGM sampling gas outlet, either with the text “Gas exhaust” or the Symbol ISO 7000-0795;

g) for a SAMPLING TUBE, either with the text “Gas sample” or the Symbol ISO 7000-0794;

h) for an exhaust tube for a DIVERTING RGM, either with the text “Gas exhaust” or the Symbol ISO 7000-0795;

i) for a TRANSPORTABLE RGM, the mass of the most usual configuration of the ME EQUIPMENT.

ME EQUIPMENT, parts or ACCESSORIES with a use-by date shall be CLEARLY LEGIBLY marked with an indication of the date after which it should not be used, expressed as the year and month. Symbol 5.12 of ISO 15223-1:— may be used.

Check compliance by means of inspection.

201.7.2.4.101 Additional requirements for ACCESSORIES

For an ACCESSORY intended for single PATIENT use, the package or the ACCESSORY itself shall be marked with an indication that the ACCESSORY is for single PATIENT use.

Check compliance by means of inspection.

201.7.2.13.101 * Additional requirements for physiological effects (safety signs and warning statements)

ME EQUIPMENT, parts or ACCESSORIES containing natural rubber latex shall be CLEARLY LEGIBLY marked as containing natural rubber latex. Symbol ISO 7000-2725 may be used. All components containing natural rubber latex shall be disclosed as such in the instructions for use.

Check compliance by means of inspection.

201.7.2.17.101 Additional requirements for protective packaging

Packages of ME EQUIPMENT, parts or ACCESSORIES shall be CLEARLY LEGIBLY marked:

a) with the following:

- a description of the contents;
- an identification reference to the batch, type or serial number or Symbols 5.14, 5.15, 5.16 from ISO 15223-1:—;
- for packages containing natural rubber latex, the word “LATEX”, or symbol ISO 7000-2725;
- if applicable, the word “STERILE” or one of the Symbols 5.20 to 5.24 from ISO 15223-1:—; packaging of sterile ME EQUIPMENT, parts or ACCESSORIES shall ensure sterile conditions until opened or damaged or until its expiration date is reached;

b) for those parts intended for single use, with the words “SINGLE USE”, “DO NOT REUSE”, “NOT FOR REUSE”, Symbol ISO 7000-1051 or Symbol 5.25 from ISO 15223-1:—; for a specific MODEL or TYPE REFERENCE, the indication of single use shall be consistent.

Consideration should be given to the disposal of packaging waste.

Check compliance by means of inspection.

201.7.4.3 Unit of measure

Amendment:

Add to the bottom as new rows in Table 1 units outside the SI units systems that may be used on ME EQUIPMENT:

Base quantity	Unit	
	Name	**Symbol**
GAS READING[b]	% (VOLUME FRACTION)	-
	millimetres of mercury	mmHg
GAS READING of anaesthetic agents	% (VOLUME FRACTION)	-
	MINIMUM ALVEOLAR CONCENTRATION[c]	MAC

[b] The GAS READING of respiratory gases may be expressed as a PARTIAL PRESSURE.

[c] MINIMUM ALVEOLAR CONCENTRATION may be utilized as an additional unit.

201.7.9.1 General requirements

Amendment:

Replace the first dash with:

— name or trade name and address of

  — the MANUFACTURER, and

  — where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer;

201.7.9.2.1.101 * Additional general requirements

The instructions for use shall include the following information.

a) For each RGM and ACCESSORY, the specified use of the RGM and ACCESSORY regarding

  — PATIENT population,

  — part of the body or type of tissue to which it is applied,

    EXAMPLE 1 Direct contact via nasal cannula or face mask.

    EXAMPLE 2 Indirect contact via gas passing through SENSOR/SAMPLING SITE.

  — application;

    EXAMPLE 3 Environment, frequency of use, location, mobility.

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

c) if automatic compensation is not provided, the quantitative effect of barometric pressure on the GAS READING.

Check compliance by means of inspection.

201.7.9.2.2.101 * Additional requirements for warnings and safety notices

The instructions for use of a DIVERTING RGM that is equipped with a gas exhaust connection shall include a warning regarding the RISK of PATIENT cross-infection if the sampled gas is returned to the breathing system. Additional requirements are found in 201.105.2.

Check compliance by means of inspection.

201.7.9.2.5.101 Additional requirements for ME EQUIPMENT description

The instructions for use shall include:

a) a diagram illustrating the features of the RGM, indicating the function and location of all operating controls, adjustments, and system components necessary for correct operation;

b) a description of the correct installation of the RGM and a description of sampling arrangements and any connecting tubing, if applicable;

c) the location of all natural-rubber-latex-based components, if applicable.

Check compliance by means of inspection.

201.7.9.2.8.101 * Additional requirements for start-up procedure

The instructions for use shall include:

a) a method of verifying all OPERATOR-adjustable ALARM SYSTEM functions;

b) the time duration from start-up to providing ESSENTIAL PERFORMANCE.

Check compliance by means of inspection.

201.7.9.2.9.101* Additional requirements for operating instructions

The instructions for use shall include the following:

a) the range of adjustment of the ALARM LIMITS;

b) 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);

c) 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;

d) if MAC GAS READINGS are provided, the MAC values or algorithms used to determine the MAC values displayed by the RGM;

e) method for connecting the exhaust port of a DIVERTING RGM to an ANAESTHETIC GAS SCAVENGING SYSTEM;

f) for a DIVERTING RGM, the sampled gas flowrates and their tolerances;

g) 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;

h) for a DIVERTING RGM intended to permit the return of the sampled gas to the breathing system in which the GAS LEVEL has changed from that at the SAMPLING SITE, an indication that the returned GAS LEVEL has changed;

EXAMPLE 1 Adding room air as a result of automatic zeroing.

EXAMPLE 2 Reference gas used by a gas SENSOR.

i) the RATED respiration rate;

j) any degradation in MEASUREMENT ACCURACY of the end-tidal GAS READING as a function of respiratory rate and I/E ratio (inspiratory/expiratory time ratio) over their RATED ranges;

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

— quantitative effects of gas sample humidity or condensate;

— leaks or internal venting of sampled gas;

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

— other sources of interference;

l) if the RGM, its parts or ACCESSORIES are intended for single use, information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if the RGM, its parts or ACCESSORIES were re-used;

m) date of issue or revision of the instructions for use;

n) highest GAS LEVEL for a single halogenated anaesthetic gas in a gas mixture that is concealed when the anaesthetic concentration falls.

Check compliance by means of inspection.

201.7.9.2.13.101 * Additional requirements for maintenance

The instructions for use shall include the following:

a) PROCEDURES for calibration before or during use;

b) methods and frequency of routine inspection and testing.

Check compliance by means of inspection.

201.7.9.2.14.101 * Additional requirements for ACCESSORIES, supplementary equipment, used material

The instructions for use shall include the following:

a) all known information regarding toxicity and/or the effect on tissues of any materials that can come into contact with the PATIENT or any other person;

b) if an ACCESSORY delivered in sterile packaging is permitted to be re-sterilized, the necessary information regarding how to re-sterilize in the event of damage to the sterile packaging;

c) advice on the proper disposal of accumulated fluids.

EXAMPLE Fluids in reusable water traps.

Check compliance by means of inspection.

201.7.9.2.15.101* Additional requirements for environmental protection

The instructions for use shall include:

a) advice on the proper disposal of calibration gases;

b) advice on the proper disposal of sampled gases.

Check compliance by means of inspection.

201.7.9.3.101 * Additional requirements for technical description

The technical description shall include:

a) a summary of the test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate as required in 201.7.9.2.9 i) and j);

b) the data sample rate;

c) a description of the method used to calculate end-tidal GAS READINGS.

Check compliance by means of inspection.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005, Clause 8 applies.

201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005, Clause 11 applies, except as follows:

201.11.6.4 Leakage

Addition (add after existing text):

The MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with the leaching or leaking of substances into the gas pathway from

aa) the SAMPLING SITE, and

bb) for a DIVERTING RGM which permits the return of the sampled gas to the breathing system, the gas pathways through the RGM and ACCESSORIES.

Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction.

If these parts or ACCESSORIES contain phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction, it shall be marked on the device itself or on the packaging that it contains phthalates. If, in addition, the INTENDED USE of the RGM and these parts or ACCESSORIES includes treatment of children or treatment of pregnant or nursing women, a specific justification for the use of these items shall be included in the RISK MANAGEMENT FILE. The instructions for use shall contain information on RESIDUAL RISKS for these PATIENT groups and, if applicable, on appropriate precautionary measures.

Check compliance by inspecting the RISK MANAGEMENT FILE to determine whether it addresses the RISK of leaching or leaking of substances during NORMAL USE and whether materials are potentially carcinogenic, mutagenic or toxic to reproduction.

201.11.6.5 * Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS

Replacement:

The ENCLOSURE of an RGM shall provide a degree of protection from the harmful ingress of water of

— at least IPX1, and

— for an RGM or its parts intended for use during professional transport of a PATIENT outside a healthcare facility, at least IPX2.

Check compliance in accordance with the tests of IEC 60529, with the RGM placed in the least favourable position of NORMAL USE. After these procedures, verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.11.6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS

Amendment (add additional requirement as new first paragraph):

Gas pathways through the RGM and its ACCESSORIES not specified as for single PATIENT use, which can become contaminated with body fluids or expired gases during NORMAL CONDITION or SINGLE FAULT CONDITION and in which gases can be re-breathed, shall be designed to allow for cleaning and disinfection or cleaning and sterilization (additional requirements are found in IEC 60601-1:2005, 11.6.7 and in 201.105). The RGM or ACCESSORIES may be dismantled for this purpose.

Amendment (add additional requirement and replace the compliance test):

RGM ENCLOSURES shall be designed to allow for surface cleaning or cleaning and disinfection to reduce the RISK of cross-infection to acceptable levels.

Processing and/or reprocessing PROCESS instructions for the RGM and its ACCESSORIES shall comply with ISO 17664 and ISO 14937 and shall be disclosed in the instructions for use.

NOTE ISO 14159 provides guidance for the design of enclosures.

Where compliance with this International Standard could be affected by the cleaning or disinfection of the RGM or its parts or ACCESSORIES, clean and disinfect 30 times in accordance with the methods indicated in the instructions for use, including any cooling or drying period. After these PROCEDURES, ensure that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained. Inspect the RISK MANAGEMENT FILE to verify that the MANUFACTURER has evaluated the effects of multiple PROCESS cycles and the effectiveness of those cycles.

201.11.6.7 Sterilization of ME EQUIPMENT or ME SYSTEMS

Amendment (add note before compliance test):

NOTE Additional requirements are found in IEC 60601-1:2005, 11.6.6.

201.11.6.8 Compatibility with substances used with ME EQUIPMENT

Amendment (add before compliance test):

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. Additional requirements are found in 201.11.6.4.

201.11.8.101 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

201.11.8.101.1 * Supply failure TECHNICAL ALARM CONDITION

When the power supply falls outside the values for normal operation, an RGM shall:

a) generate a MEDIUM PRIORITY TECHNICAL ALARM CONDITION;

NOTE After the loss of power, the ALARM SYSTEM is not expected to repeat ALARM SIGNALS indefinitely.

b) stop displaying the respiratory GAS READING.

If the function of the RGM is maintained by the switchover to an INTERNAL ELECTRICAL POWER SOURCE, the supply failure MEDIUM PRIORITY TECHNICAL ALARM CONDITION shall not be generated. Any such switchover to an INTERNAL ELECTRICAL POWER SOURCE shall be indicated by an INFORMATION SIGNAL or a LOW PRIORITY TECHNICAL ALARM CONDITION.

Check compliance by means of functional testing.

201.11.8.101.2 * 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 automatic switchover to an INTERNAL ELECTRICAL POWER SOURCE occurs, all settings and all stored PATIENT data shall be maintained.

NOTE 1 The RGM does not have to provide GAS READINGS during the interruption of the SUPPLY MAINS.

NOTE 2 Settings include OPERATOR settings, RESPONSIBLE ORGANIZATION settings, and the mode of operation.

Check compliance by observing the RGM settings and stored PATIENT data and then interrupting the SUPPLY MAINS for 25 s and 30 s by disconnecting the POWER SUPPLY CORD. After re-establishment of power, verify that the settings and stored data are the same.

201.11.8.101.3 * Operation following long interruptions

The ACCOMPANYING DOCUMENT shall disclose 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 30 s or longer.

Check compliance by inspecting the ACCOMPANYING DOCUMENTS.

201.11.8.101.4 * 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 under the conditions specified in the instructions for use.

Check compliance by means of functional testing.

201.11.8.101.5 * RESERVE ELECTRICAL POWER SOURCE for transport outside a healthcare facility

An RGM intended for use during professional transport of a PATIENT outside a healthcare facility shall be provided with either an INTERNAL ELECTRICAL POWER SOURCE or a RESERVE ELECTRICAL POWER SOURCE capable of supporting at least 1 h of normal operation.

Check compliance by determining that normal operation can be maintained by either the RESERVE ELECTRICAL POWER SOURCE or INTERNAL ELECTRICAL POWER SOURCE for a period of at least 1 h following disconnection of the primary power source.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

IEC 60601-1:2005, Clause 12 applies, except as follows:

201.12.1 Accuracy of controls and instruments

Amendment (add after existing sentence):

The controls of an RGM shall be CLEARLY LEGIBLE under the conditions of IEC 60601-1:2005, 7.1.2.

Check compliance by applying the tests of IEC 60601-1:2005, 7.1.2.

Additional subclauses:

201.12.1.101 * Measurement accuracy

201.12.1.101.1 General

For each respiratory gas that an RGM is intended to monitor, the MEASUREMENT ACCURACY levels given in Table 201.102 shall be achieved. The GAS READING range, the MEASUREMENT ACCURACY and, for a DIVERTING RGM, the minimum sample flowrate at which the RGM meets its MEASUREMENT ACCURACY specifications shall be disclosed in the instructions for use.

Table 201.102 — 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 % of GAS LEVEL)

Check compliance by inspecting the instructions for use and using the following test:

a) Set up and calibrate the RGM in accordance with the instructions for use.

b) Use the appropriate test gas mixture specified in Table 201.103 with a tolerance of less than 0,2 times the error tolerance given in Table 201.102.

NOTE Test gases with the appropriate accuracy can 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). Additional information is found in Annex CC.

c) Take GAS READINGS at the specified GAS LEVELS for each gas that the RGM is intended to measure.

d) Verify that the MEASUREMENT ACCURACY for each gas that the RGM is intended to measure is within the limits of Table 201.102.

The proper disposal of test gas mixtures should be considered.

201.12.1.101.2 * 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 201.102 for not less than 6 h when used in accordance with the instructions for use with mixtures of gases as indicated in Table 201.103. The DRIFT of MEASUREMENT ACCURACY shall be disclosed in the instructions for use.

Table 201.103 — Mixtures for measurement of MEASUREMENT ACCURACY, DRIFT, and TOTAL SYSTEM RESPONSE TIME

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 the specified value.

[c] This mixture is to be used for DRIFT of MEASUREMENT ACCURACY test (if applicable).

[d] This mixture is to be used for TOTAL SYSTEM RESPONSE TIME testing (if applicable). For TOTAL SYSTEM RESPONSE TIME testing, a lower accuracy of the test gas mixture is acceptable.

Check compliance by inspecting 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 201.12.1.101.1 using the test gases for DRIFT of MEASUREMENT ACCURACY testing as indicated in Table 201.103. 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 201.102 are met at each sample point for each test GAS LEVEL.

201.12.1.101.3 * 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 201.102 shall be achieved with the gas mixtures of Table 201.104.

Check compliance by inspecting the instructions for use and using 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 201.104, at an ambient temperature of (23 ± 2) °C. For each numerically displayed respiratory GAS LEVEL, verify that the MEASUREMENT ACCURACY requirements of Table 201.102 are met. The proper disposal of test gas mixtures should be considered.

Use test gas mixtures with GAS LEVELS as indicated in Table 201.104 and a tolerance of less than 0,2 times the error tolerance given in Table 201.102.

Table 201.104 — 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.

201.12.1.102 * TOTAL SYSTEM RESPONSE TIME and rise time

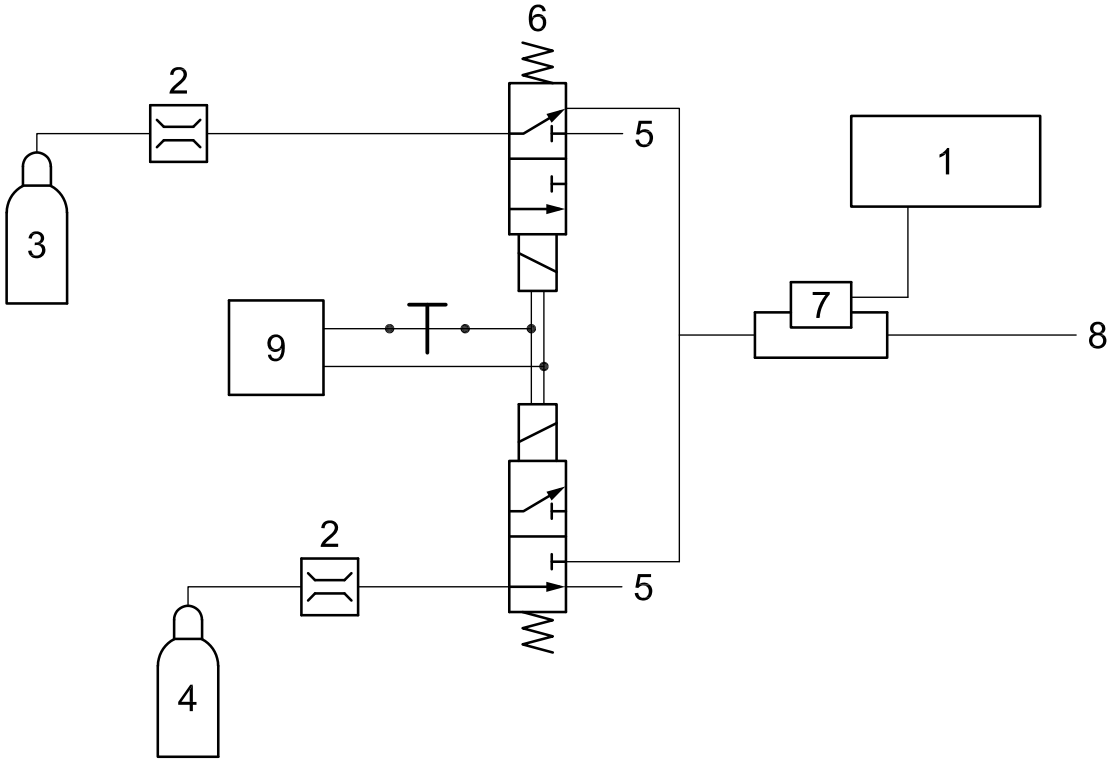
The TOTAL SYSTEM RESPONSE TIME shall be disclosed in the instructions for use. For a DIVERTING RGM, the TOTAL SYSTEM RESPONSE TIME and the 10 % to 90 % rise time, both over the RATED gas diversion flowrate, shall be disclosed in the instructions for use. The TOTAL SYSTEM RESPONSE TIME and rise time may be reported separately, as appropriate, by breathing system configuration.

Check compliance by inspecting the instructions for use and using 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 201.101. The proper disposal of test gas mixtures should be considered.

Connect the RGM to a suitable recording device.

With the relevant gas mixture from Table 201.103 (additional information is found in footnote d of Table 201.103) at a flowrate of 60 l/min for a bore size of 20 mm (or the equivalent average linear gas velocity for other bore sizes), where bore size is measured at the SAMPLING SITE, cycle the valve(s) and record the TOTAL SYSTEM RESPONSE TIME and, for a DIVERTING RGM, the 10 % to 90 % rise time. Repeat the PROCEDURE for this single gas mixture 20 times, and determine the average TOTAL SYSTEM RESPONSE TIME. For a DIVERTING RGM, repeat at every specified gas diversion flowrate. Repeat for each breathing system configuration indicated in the instructions for use.



Key

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

NOTE Care should be taken to minimize the tubing length between the valves and SAMPLING SITE.

Figure 201.101 — Test apparatus for the TOTAL SYSTEM RESPONSE TIME of an RGM

201.12.1.103 * Indication of units of measure for GAS READINGS

Units of measure of GAS READINGS shall be indicated either continuously or on demand from the OPERATOR. If the OPERATOR changes the units of measure from the default units of measure selected by the MANUFACTURER or RESPONSIBLE ORGANIZATION, the units of measure shall be displayed continuously.

Check compliance by inspecting markings and instructions for use.

201.12.1.104 * Indication of operating mode

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

Check compliance by functional testing.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5.101 * Additional requirements for rough handling

201.15.3.5.101.1 * Shock and vibration

An RGM or its parts not intended for use during professional transportation of a PATIENT 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 ME EQUIPMENT is exempt from the requirements of this subclause.

After the following tests, the RGM shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by performing the following tests.

a) Shock test in accordance with IEC 60068-2-27:2008, using the conditions given below.

NOTE 1 This represents IEC/TR 60721-4-7:2003, Class 7M2.

1) Test type: Type 1

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

2) Test type: Type 2

- *peak acceleration: 300 m/s^2 (30g);*
- *duration: 6 ms;*
- *pulse shape: half-sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

NOTE 2 A HAND-HELD RGM that complies with the requirements of IEC 60601-1:2005, 15.3.4.1 is considered to comply with this requirement.

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the conditions given below.

NOTE 3 This represents IEC/TR 60721-4-7:2003, Classes 7M1 and 7M2.

1) Acceleration amplitude:

- *10 Hz to 100 Hz: 1,0 $(m/s^2)^2/Hz$;*
- *100 Hz to 200 Hz: –3 db per octave;*
- *200 Hz to 2 000 Hz: 0,5 $(m/s^2)^2/Hz$.*

*2) * Duration: 10 min per perpendicular axis (3 total).*

A duration of 30 min per perpendicular axis (3 total) is recommended.

c) Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.15.3.5.101.2 * Shock and vibration for professional transportation

An RGM or its parts intended for use during professional transportation of a PATIENT 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 maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 1 ME EQUIPMENT tested and complying with the requirements in 201.15.3.5.101.2 in total or in part is considered to comply with the corresponding requirements of 201.15.3.5.101.1.

Check compliance by performing the following tests.

a) Shock test in accordance with IEC 60068-2-27:2008, using the conditions given below.

NOTE 2 This represents IEC/TR 60721-4-7:2003, Class 7M3.

1) Test type: Type 1

- *peak acceleration: 300 m/s^2 (30g);*
- *duration: 11 ms;*
- *pulse shape: half-sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

2) Test type: Type 2

- *peak acceleration: 1 000 m/s^2 (100g);*
- *duration: 6 ms;*
- *pulse shape: half-sine;*
- *number of shocks: 3 shocks per direction per axis (18 total).*

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the conditions given below.

NOTE 3 This represents IEC/TR 60721-4-7:2003, Class 7M3.

1) Acceleration amplitude:

- *10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$;*
- *100 Hz to 200 Hz: –7 db per octave;*
- *200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$.*

2) Duration: 30 min per perpendicular axis (3 total).

c) Free-fall to IEC 60068-2-31:2008, using PROCEDURE 1 and the conditions given below.

NOTE 4 This represents IEC/TR 60721-4-7:2003, Class 7M2.

1) Fall height:

- *for mass <1 kg: 0,25 m;*
- *for mass between 1 kg and <10 kg: 0,1 m;*
- *for mass between 10 kg and <50 kg: 0,05 m;*
- *for mass ≥50 kg: 0,01 m.*

*2) * Number of falls: 1 in each specified attitude.*

Two falls in each specified attitude is recommended.

For a PORTABLE RGM which is intended to be used with a carrying case, that case may be applied to the ME EQUIPMENT during this test.

d) Verify that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

201.15.101 * Mode of operation

An RGM shall be suitable for CONTINUOUS OPERATION.

Check compliance by inspecting the instructions for use.

201.16 ME SYSTEMS

IEC 60601-1:2005, Clause 16 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 17 applies.

New clauses:

201.101 * 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 201.105 shall be disclosed in the instructions for use.

Check compliance by inspecting the instructions for use.

Table 201.105 — 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.

201.102 * Gas leakage

The rate of leakage from the SENSOR of a NON-DIVERTING RGM shall not be greater than 10 ml/min at a pressure of 60 hPa (60 cmH_2O).

Check compliance by using a pressure gauge that has a MEASUREMENT ACCURACY of ±3 hPa (3 cmH_2O) and a flowrate metering device that has a MEASUREMENT ACCURACY of ± 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 (see Figure 201.101) to 60 hPa (60 cmH_2O). Determine the flowrate necessary to maintain this pressure.

201.103 * Port connector for DIVERTING RGM

The port connectors of a DIVERTING RGM and its ACCESSORIES shall comply with ISO 80369-1:2010.

Check compliance by means of inspection.

201.104 * Minimum sampling flowrate

A DIVERTING RGM shall indicate when it is not able to maintain the NORMAL USE flowrate.

Check compliance by means of functional testing.

201.105 * Contamination of breathing systems

201.105.1 Sampling tube

Reversal of the direction of flow through the SAMPLING TUBE in a DIVERTING RGM shall not be possible.

Check compliance by means of inspection and functional testing.

201.105.2 Exhaust tube

If there is an unacceptable RISK of cross-infection under NORMAL CONDITIONS and SINGLE FAULT CONDITIONS, the RGM shall be designed so that the sample gas is not returned to the breathing system.

Check compliance by means of inspection and by inspecting the RISK MANAGEMENT FILE.

202 Electromagnetic compatibility — Requirements and tests

IEC 60601-1-2:2007 applies except as follows:

202.6.2.1.7 * PATIENT simulation

Amendment (additional paragraph):

To verify the IMMUNITY of the RGM with each SENSOR indicated in the instructions for use, the RGM shall be tested with the gas mixture which generates the signal-to-noise ratio simulating a worst-case PATIENT physiological signal. If the RGM does not display instantaneous GAS READINGS in normal operating mode, the test may be conducted in a special mode or with special software where instantaneous values are displayed.

202.6.2.1.10 Compliance criteria

Replacement:

Under the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2007, 6.2, the RGM shall continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE For the purposes of this International Standard, an RGM is not considered to be a LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM.

The following conditions associated with BASIC SAFETY and ESSENTIAL PERFORMANCE shall apply:

aa) no permanent degradation or unrecoverable loss of function, due to damage of ME EQUIPMENT (components) or software, or loss of data shall be observed at any IMMUNITY TEST LEVEL specified in IEC 60601-1-2:2007, 6.2 and in 202.6.2.3.1 a);

bb) no change of operating mode;

cc) operation within the specified MEASUREMENT ACCURACY limits or generation of a TECHNICAL ALARM CONDITION;

dd) in the event of disruption during IMMUNITY tests of IEC 60601-1-2:2007, 6.2.2, 6.2.4, 6.2.5 and 6.2.7, the RGM shall recover from any disruption within 30 s without OPERATOR intervention.

202.6.2.3.1 * Requirements

Addition [add to a)]:

In addition to these requirements, an RGM intended for use during professional transportation of a PATIENT outside the healthcare facility shall comply with IEC 60601-1-2:2007, 6.2.1.10 at the IMMUNITY TEST LEVEL of 20 V/m (80 % amplitude-modulated at 1 000 Hz) over the range of 80 MHz to 2,5 GHz (see IEC 60601-1-2:2007, Table 9).

Check compliance by applying the tests in IEC 60601-1-2:2007, 6.2. Evaluate the response of the RGM during and after these tests in accordance with the above.

206 Usability

IEC 60601-1-6:2010 applies, except as follows:

206.6.2.2.2 Primary operating functions

For an RGM, the following shall be considered PRIMARY OPERATING FUNCTIONS:

aa) observing the GAS READING;

EXAMPLES FiO_2, CO_2, anaesthetic agent concentration.

bb) setting ALARM LIMITS;

cc) deactivating ALARM SIGNALS;

dd) for a DIVERTING RGM, adjusting the sampled gas flowrates, if so equipped;

ee) connecting the SENSOR or SAMPLING SITE to or into the breathing system;

ff) starting the RGM from power-off;

gg) starting the RGM from standby mode.

208 General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

IEC 60601-1-8:2006 applies except as follows:

208.6.1.2 * ALARM CONDITION priority

Amendment (add before the compliance test):

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 ALARM SYSTEM shall generate each GAS READING ALARM CONDITION, with its minimum priority, as given in Table 201.106.

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 of that mixture, it shall be capable of generating a MEDIUM PRIORITY ALARM CONDITION in the presence of such a mixture (see Table 201.106).

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

— generate a LOW PRIORITY ALARM CONDITION whenever the RGM detects a mixture of halogenated agents of less than 3 MAC (see Table 201.107), and

— generate a MEDIUM PRIORITY ALARM CONDITION whenever the RGM detects a mixture of halogenated agents equal to or greater than 3 MAC.

An ALARM SYSTEM that automatically changes ALARM CONDITION priority without OPERATOR intervention shall not change to a priority lower than that specified in this International Standard.

Table 201.106 — GAS READING ALARM CONDITIONS and priorities

Row number	GAS READING	ALARM CONDITION priority for low GAS READING	ALARM CONDITION priority for high GAS READING
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 The priorities listed are the minimum priority.

Exhaled GAS LEVEL ALARM CONDITIONS may also be provided.

[a] If this optional ALARM CONDITION is provided, it is required to be of the level of priority indicated.

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

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

Table 201.107 — Examples of MINIMUM ALVEOLAR CONCENTRATION (MAC) values

Anaesthetic agent	MAC (in oxygen) % VOLUME FRACTION
Halothane	0,77
Enflurane	1,7
Isoflurane	1,15
Desflurane	6,0
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 US 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. [a] 1 MAC nitrous oxide can only be reached in a hyperbaric chamber.	

208.6.5.1 * General requirements

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

It shall not be possible to set the ALARM LIMIT for the low inspired oxygen GAS READING below 18 % in an ALARM PRESET.

Additional subclauses:

208.6.6.2.101 * Additional requirements for adjustable ALARM LIMIT

The ALARM LIMIT(S) for every provided GAS READING ALARM CONDITION, except for the high GAS LEVEL for inspired nitrous oxide, shall be OPERATOR adjustable. The OPERATOR shall be required to take deliberate action to adjust ALARM LIMITS. An additional deliberate action shall be required to set the low ALARM LIMIT for the inspired oxygen GAS READING below 18 %.

Check compliance by means of inspection and functional testing.

208.6.8.5.101 * Additional requirements for ALARM SIGNAL deactivation states, indication and access

The MANUFACTURER-configured default AUDIO PAUSED or ALARM PAUSED interval of the RGM shall not exceed 2 min.

Check compliance by means of functional testing.

209 Requirements for environmentally conscious design

IEC 60601-1-9:2007 applies.

210 Requirements for the development of physiologic closed-loop controllers

IEC 60601-1-10:2007 applies.

211 Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare environment

IEC 60601-1-11:2010 applies.

Addition:

The annexes of IEC 60601-1:2005 apply, except as follows:

Annex C
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Additional requirements for marking on the outside of an RGM or their parts or ACCESSORIES are found in Table 201.C.101.

Table 201.C.101 — Marking on the outside of an RGM or its parts

Description of marking	Subclause
Any particular storage and/or handling instructions	201.7.2.101 a)
Follow “instructions for use” safety sign	201.7.2.3
For a TRANSPORTABLE RGM, the mass of the most usual configuration of the ME EQUIPMENT	201.7.2.101 i)
For an RGM sampling gas inlet, the text “Gas sample” or the Symbol ISO 7000-0794	201.7.2.101 e)
For an RGM sampling gas outlet, the text “Gas exhaust” or the Symbol ISO 7000-0795	201.7.2.101 f)
For a SAMPLING TUBE, the text “Gas sample” or the Symbol ISO 7000-0794	201.7.2.101 g)
For an ACCESSORY for single PATIENT use, so indicated on the ACCESSORY or package	201.7.2.4.101
For an exhaust tube for a DIVERTING RGM, the text “Gas exhaust” or the Symbol ISO 7000-0795	201.7.2.101 h)
For an OPERATOR-interchangeable component that is flow-direction sensitive, an arow showing direction of gas flow	201.7.2.101 d)
For packages containing natural rubber latex, so indicated	201.7.2.17.101 a)
For packaging containing parts intended for single use, so indicated	201.7.2.17.101 b)
For packaging, a description of the contents	201.7.2.17.101 a)
For packaging, reference to batch, type or serial number	201.7.2.17.101 a)
For parts or ACCESSORIES that contain phthalates, so indicated on part or packaging	201.11.6.4
If applicable for packaging, indicate sterile contents	201.7.2.17.101 a)
If applicable, date after which it should not be used	201.7.2.101
If containing natural rubber latex, so indicated	201.7.2.13.101
Proper disposal	201.7.2.101 c)
Serial number or lot identifying number or batch identifying number	201.7.2.101 b)

201.C.4 ACCOMPANYING DOCUMENTS, general

Additional requirements for the ACCOMPANYING DOCUMENT of an RGM are found in Table 201.C.102.

Table 201.C.102 — ACCOMPANYING DOCUMENTS

Description of disclosure	Subclause
Name or trade name and address of the MANUFACTURER or an authorized representative	201.7.9.1
Operation of the RGM after the SUPPLY MAINS has been interrupted for 30 s or longer	201.11.8.101.3

201.C.5 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for the instructions for use of an RGM are found in Table 201.C.103.

Table 201.C.103 — ACCOMPANYING DOCUMENTS, instructions for use

Description of disclosure	Subclause
Advice on the proper disposal of accumulated fluids	201.7.9.2.14.101 c)
Advice on the proper disposal of calibration gases	201.7.9.2.15.101 a)
Advice on the proper disposal of sampled gases	201.7.9.2.15.101 b)
Any degradation in MEASUREMENT ACCURACY of the end-tidal GAS READING as a function of respiratory rate and I/E ratio over their RATED ranges	201.7.9.2.9.101 j)
Date of issue or revision of the instructions for use	201.7.9.2.9.101 m)
Detection threshold for halogenated anaesthetic gas(es) in a gas mixture	201.7.9.2.9.101 c)
Diagram illustrating the features of the RGM, indicating the function and location of all operating controls, adjustments, and system components necessary for correct operation	201.7.9.2.5.101 a)
DRIFT of MEASUREMENT ACCURACY	201.12.1.101.2
For a DIVERTING RGM with a gas exhaust connection, a warning regarding the RISK of PATIENT cross-infection if the sampled gas is returned to the breathing system	201.7.9.2.2.101
For a DIVERTING RGM, method for connecting the exhaust port of the RGM to an ANAESTHETIC GAS SCAVENGING SYSTEM	201.7.9.2.9.101 e)
For a DIVERTING RGM, the rise time	201.12.1.102
For a DIVERTING RGM, the sampled gas flowrates and their tolerances	201.7.9.2.9.101 f)
For a DIVERTING RGM intended to permit the return of the sampled gas to the breathing system in which the GAS LEVEL has changed from that at the SAMPLING SITE, an indication that the returned GAS LEVEL has changed	201.7.9.2.9.101 h)
For an RGM without automatic compensation, the quantitative effect of barometric pressure on the GAS READING	201.7.9.2.1.101 c)
For single use, information on known characteristics and technical factors known to the MANUFACTURER that could pose a RISK if re-used	201.7.9.2.9.101 l)
For ACCESSORIES delivered sterile, the necessary information regarding how to re-sterilize in the event of damage to the sterile packaging, if re-sterilization is permissible	201.7.9.2.14.101 b)
GAS READING range	201.12.1.101.1
Highest GAS LEVEL for a single halogenated anaesthetic gas in a gas mixture that is concealed when anaesthetic concentration falls	201.7.9.2.9.101 n)
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	201.7.9.2.9.101 g)
If applicable, correct installation of the RGM and a description of sampling arrangements and any connecting tubing	201.7.9.2.5.101 b)
If applicable, location of all natural-rubber-latex-based components	201.7.9.2.5.101 c)
If containing natural rubber latex, so indicated	201.7.2.13.101
If MAC GAS READINGS are provided, the MAC values or algorithms used	201.7.9.2.9.101 d)
Information, as regards toxicity and/or action on tissues, about materials with which the PATIENT or any other person can come into contact	201.7.9.2.14.101 a)
Known adverse effects on stated performance	201.7.9.2.9.101 k)
Maximum specified interval between any necessary OPERATOR interventions to the water-handling system	201.7.9.2.9.101 b)
MEASUREMENT ACCURACY	201.12.1.101.1

Table 201.C.103 (*continued*)

Description of disclosure	Subclause
Method of verifying all OPERATOR-adjustable ALARM SYSTEM functions	201.7.9.2.8.101 a)
Methods and frequency of routine inspection and testing	201.7.9.2.13.101 b)
Minimum sample flowrate at which the DIVERTING RGM will meet MEASUREMENT ACCURACY specifications	201.12.1.101.1
PROCEDURES for calibration before or during use	201.7.9.2.13.101 a)
Processing and/or reprocessing PROCESS instructions for the RGM and its ACCESSORIES	201.11.6.6
Quantitative effects (if any) on GAS READINGS caused by the interfering gases given by the GAS LEVELS listed in Table 201.105	201.101
Range of adjustment of the ALARM LIMITS	201.7.9.2.9.101 a)
RATED respiration rate	201.7.9.2.9.101 i)
RESIDUAL RISKS associated with the use of phthalates with children, pregnant or nursing women and, if applicable, information on appropriate precautionary measures	201.11.6.4
Specified use of the RGM and ACCESSORY	201.7.9.2.1.101 a)
Statement indicating whether or not the RGM is equipped with automatic barometric pressure compensation	201.7.9.2.1.101 b)
Time from start-up of the RGM to providing ESSENTIAL PERFORMANCE	201.7.9.2.8.101 b)
TOTAL SYSTEM RESPONSE TIME	201.12.1.102

201.C.6 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for the technical description of an RGM are found in Table 201.C.104.

Table 201.C.104 — ACCOMPANYING DOCUMENTS, technical description

Description of disclosure	Subclause
Data sample rate	201.7.9.3.101 b)
Description of the method used to calculate end-tidal GAS READINGS	201.7.9.3.101 c)
Summary of the test method used to determine the RATED respiration rate range and the corresponding effects of end-tidal GAS READING accuracy as a function of respiratory rate	201.7.9.3.101 a)

Annex D
(informative)

Symbols on marking

IEC 60601-1:2005, Annex D applies, except as follows.

Addition:

Table 201.D.101 — Additional symbols on marking

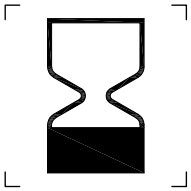
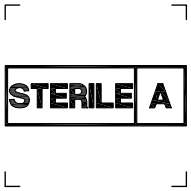
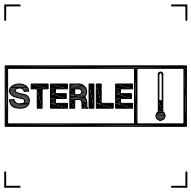
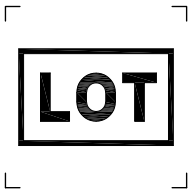
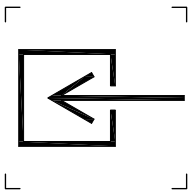
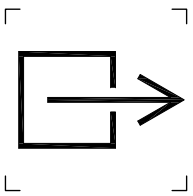
No	Symbol	Reference	Title
1	 (YYYY-MM)	Symbol 5.12 ISO 15223-1:—	Use by date
2		Symbol 5.20 ISO 15223-1:—	Sterile
3		Symbol 5.21 ISO 15223-1:—	Sterilized by aseptic processing techniques
4		Symbol 5.22 ISO 15223-1:—	Sterilized by using ethylene oxide
5		Symbol 5.23 ISO 15223-1:—	Sterilized by irradiation
6		Symbol 5.24 ISO 15223-1:—	Sterilized using steam or dry heat

Table 201.D.101 — *(Continued)*

No	Symbol	Reference	Title
7		Symbol 5.14 ISO 15223-1:—	Batch code
8		Symbol 5.15 ISO 15223-1:—	Catalogue number
9		Symbol 5.16 ISO 15223-1:—	Serial number
10		ISO-7000-2725	Contains, or presence of, natural rubber latex
11		ISO 7000-0794	Input
12		ISO 7000-0795	Output

Additional Annexes:

Annex AA
(informative)

Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of this particular standard and is intended for those who are familiar with the subject of this particular 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 particular standard necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

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

Subclause 201.1.1 — 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.

Preventing unintended awareness under general anaesthesia continues to be an intractable problem. Not infrequently, these events occur when the anaesthetic agent delivery equipment runs empty, or is intentionally turned off when repositioning the PATIENT, and unintentionally not turned back on.

The RGM data and ALARM CONDITIONS could be a valuable adjunct in detecting these events. Unfortunately, this information is not generally available through an electronic interface. However, the development of a smart DISTRIBUTED ALARM SYSTEM could create capabilities to warn the OPERATOR of these situations.

RGM data are also necessary to create a complete and accurate electronic medical record. Therefore, the RGM MANUFACTURER is encouraged to make such data accessible to third parties via an open, standards-based, electronic data interface.

Definition 201.3.206 — MINIMUM ALVEOLAR CONCENTRATION

MAC can vary according to the PATIENT'S age, so it should be possible for the OPERATOR to input the PATIENT'S age into the RGM and for the RGM to use that information to adjust the MAC threshold appropriately. Similarly, the physiological effect of relative anaesthetic agent concentration (vol %) varies with altitude.

Subclause 201.4.3.101 — Additional requirements for ESSENTIAL PERFORMANCE

The committee considered MEASUREMENT ACCURACY of GAS READINGS to be an ESSENTIAL PERFORMANCE requirement; critical clinical decisions can be based upon these readings which, if inaccurate, might result in harm to the PATIENT. The philosophy of the general standard is that ME EQUIPMENT shall remain safe, even in a SINGLE FAULT CONDITION, hence the requirement for the generation of a TECHNICAL ALARM CONDITION when the MEASUREMENT ACCURACY cannot be maintained. Certain conditions such as a leak in the sample tube or its connections might not be detectable and therefore not generate a TECHNICAL ALARM CONDITION. It is acceptable in those conditions to provide appropriate warnings and cautions in the ACCOMPANYING DOCUMENTS.

Subclause 201.4.6 — ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT

Many non-electrical requirements in the general standard are tied to the APPLIED PART. It is important that those requirements apply to the breathing system ACCESSORIES of an RGM. Although it is true that many requirements dealing with APPLIED PARTS are electrical in nature, other requirements do not relate to electricity. That notwithstanding, some RGM ACCESSORIES can have electrical components associated with them. If the breathing system ACCESSORIES of an RGM are not considered APPLIED PARTS, then important requirements of the general standard do not apply, and these requirements affect the safety of an RGM with regard to, *inter alia*, cleaning, compatibility with substances, biocompatibility and excessive temperature.

Subclause 201.4.10.2.101 — Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Most household appliance standards, such as IEC 60335-1, IEC 60065 and IEC 60950-1, have a ±10 % SUPPLY MAINS variation for household equipment. The −15 % to +10 % SUPPLY MAINS variation was considered more appropriate for ME EQUIPMENT intended for the HOME HEALTHCARE ENVIRONMENT given the more critical need for maintaining ESSENTIAL PERFORMANCE. The −15 % low line SUPPLY MAINS variation is based on the −10 % low line considered normal, and the additional −4 % drop allowed for wiring in the electrical installations of buildings[16][19] plus another −1 % for margin.

The −20 % SUPPLY MAINS variation for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM allows operation during "brown-out" conditions and permits the use of inexpensive generators for emergency backup. This is consistent with requirements in existing standards for ventilators intended for the HOME HEALTHCARE ENVIRONMENT for ventilator-dependent PATIENTS.[6]

For DC SUPPLY MAINS, the requirements support operation from lead-acid batteries and automobiles. A typical 12 V lead-acid battery has an open circuit voltage of approximately 12,65 V when fully charged. This voltage drops to approximately 12,06 V when 25 % charged. Furthermore, while cranking the engine, automotive lead-acid batteries are RATED for their ampacity while maintaining 7,2 V. While the engine is running, the battery charging system typically maintains the DC voltage between 12,8 V and 14,8 V.[28][31]

Subclause 201.7.2.3 — Consult ACCOMPANYING DOCUMENTS

An RGM is a RISK CONTROL measure for some types of ME EQUIPMENT (e.g. ventilators). As such, the safety of the PATIENT is dependent on the proper operation of an RGM. Furthermore, there are warnings that are required to be included in the instructions for use. Thus, having the OPERATOR read the instructions for use of an RGM is an essential RISK CONTROL measure. Marking the RGM to indicate this need is the only possible RISK CONTROL measure.

Subclause 201.7.2.101 — Additional requirements for marking on the outside of ME EQUIPMENT or ME SYSTEM parts

An RGM requires various parts or ACCESSORIES for its use. The OPERATOR needs to be able to identify, properly connect and assemble these parts so that the RGM can operate properly. Marking the parts or ACCESSORIES with this information ensures that this information is available to the OPERATOR at all times where it is needed.

Marking the mass is considered important because OPERATORS either move or install the equipment and it is a worker protection issue to know how heavy something is prior to moving it.

Subclause 201.7.2.13.101 — Additional requirements for physiological effects (safety signs and warning statements)

Natural rubber latex is known to cause severe allergic reactions in some PATIENTS and OPERATORS. Although this International Standard could have banned the use of natural rubber latex, doing so would be overly design restrictive as latex is acceptable for most individuals. By marking components that contain this allergen, OPERATORS can appropriately choose ACCESSORIES to avoid this RISK when needed.

Subclause 201.7.9.2.1.101 — Additional general requirements

For safe use of an RGM and its ACCESSORIES, the OPERATOR needs to know the specified INTENDED USE. Since many RGMs and most ACCESSORIES are small, it is not practicable to mark all of this information on each device in a manner that would be understandable by the OPERATOR. The only practicable manner in which to communicate this information to the OPERATOR is in the instructions for use.

Readings from which clinical decisions might be derived need to be corrected for the barometric pressure. If the device is not doing this automatically, the OPERATOR needs to be informed.

Subclause 201.7.9.2.2.101 — Additional requirements for warnings and safety notices

The RISK of respiratory gas transporting micro-organisms that could infect the next PATIENT is not obvious to all OPERATORS. If a DIVERTING RGM has insufficient protection against contamination by micro-organisms and, for clinical or technical reasons the return of the sampled gas to the breathing system is necessary, the OPERATOR has to be made aware of the RISK of cross-infection of the next PATIENT so that he/she can employ other means of RISK CONTROL.

Subclause 201.7.9.2.8.101 — Additional requirements for start-up procedure

Testing of ALARM SYSTEM functions is an accepted RISK CONTROL method for detecting SINGLE FAULT CONDITIONS in the ALARM SYSTEM, e.g. speaker failure. Periodic testing limits the duration of the loss of functionality.

Some RGMs require a significant warm-up or calibration period before they reach their specified MEASUREMENT ACCURACY. The OPERATOR needs to be aware of such delays so that other methods to monitor respiratory gases can be used.

Subclause 201.7.9.2.9.101 — Additional requirements for operating instructions

As the respiration rate increases and the associated inspiratory and expiratory time intervals decrease, there is less time in each breathing cycle for the waveform to reach its plateau value. As such, an RGM with a slower rise time will not be able to reach that plateau value in the shortened expiratory time interval, resulting in a lower end-tidal GAS READING than the GAS LEVEL. For example with a capnometer, this effect can be relatively small (e.g. a couple of mmHg) for a faster responding NON-DIVERTING RGM or more significant (e.g. several mmHg or more) with a slower responding DIVERTING RGM. An RGM is expected to meet its MEASUREMENT ACCURACY over its RATED respiration rate.

It is important that any degradation in MEASUREMENT ACCURACY of the end-tidal GAS READING as a function of respiratory rate and I/E ratio over their RATED ranges be disclosed in the operating instructions.

Most RGMs have a lower display limit where the RGM sets the GAS READINGS to zero when GAS LEVELS are very low. This technique is used to suppress noise in the GAS READINGS and DRIFT at very low GAS LEVELS. The MANUFACTURER of an RGM that measures anaesthetic agents is cautioned that this technique can cause a clinical problem at the end of an anaesthetic case. Anaesthetic agent is stored in the PATIENT'S tissues and is slowly released once the inhaled concentration is lower than tissue concentration. At the conclusion of an anaesthetic, especially one in which the inhaled anaesthetic is supplemented with intravenous medications, the PATIENT might not emerge from anaesthesia until the end-tidal anaesthetic agent concentration is very low – potentially near the RGM lower display limit. This results in a confusing situation for the OPERATOR, where the RGM is displaying zero, but the PATIENT is not emerging from the anaesthetic due to the low, but clinically significant level of exhaled anaesthetic. This standard requires that this threshold level be disclosed. Furthermore, it is recommended that the RGM display differentiate between a state of "no anaesthetic agent detected" and "anaesthetic agent level too low to measure accurately".

Subclause 201.7.9.2.13.101 — Additional requirements for maintenance

Regular calibration, inspection and testing are recognized methods of RISK CONTROL and can be necessary for continued safe operation of an RGM. Consideration should be given to the effectiveness of these RISK CONTROL methods when the RESPONSIBLE ORGANIZATION fails to carry out these actions in a timely fashion.

Subclause 201.7.9.2.14.101 — Additional requirements for ACCESSORIES, supplementary equipment, and used material

The RISK of respiratory gas transporting micro-organisms that could infect the next PATIENT is not obvious to all OPERATORS. For example, the fluids that accumulate in water traps can be contaminated, so proper disposal is necessary to ensure that others are not infected by these fluids.

Subclause 201.7.9.2.15.101 — Additional requirements for environmental protection

Both calibration gases and sampled gases can pose a RISK to the workplace and the global environment. RESPONSIBLE ORGANIZATIONS need to be made aware of those RISKS and given PROCEDURES for the proper handling and disposal of these gases.

Subclause 201.7.9.3.101 — Additional requirements for technical description

Methods of calculating the end-tidal values vary among MANUFACTURERS and can affect the accuracy in clinical use and should be disclosed. This value impacts clinical decision making, particularly if this value serves as input into another algorithm (e.g. closed loop control of ventilation).

Reporting the underlying data acquisition sampling rate of an RGM is important both from a clinical and technical viewpoint. An insufficient data sampling rate (as with an insufficient TOTAL SYSTEM RESPONSE TIME) can cause the displayed waveform peak values to be reduced in amplitude, with the associated decrease in reported end-tidal values. The reduced waveform fidelity results in the apparent dampening or smoothing of waveform features and can obscure or diminish clinically relevant artefacts such as cardiogenic oscillations and features such as curare clefts. As with all acquisition systems, the sampling rate is a key metric for assessing the limitations of such systems, and with all physiological waveforms there are minimum data sampling rates required for data display and feature extraction.

Subclause 201.11.6.5 — Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS

Fluids (including saline, blood and body fluids) are commonly found in the critical care environment. Maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE following reasonably foreseeable encounters with fluids protects OPERATORS and PATIENTS from unacceptable RISKS. The committee considers IPX1 to be sufficient protection in critical care environments where fluids like IV bags and lines are frequently handled and might drip on the RGM. The stricter requirements of IPX2 apply to an RGM intended for use during professional transportation of a PATIENT outside a healthcare facility, where the RGM is more vulnerable (e.g. while being used outside of the ambulance at the scene of an accident in bad weather).

Subclause 201.11.6.6 — Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS

Cleaning and disinfection of the gas pathways through the RGM and its ACCESSORIES is essential to mitigate the RISK of cross infection between PATIENTS. In SINGLE FAULT CONDITION, such as a breach of a breathing system filter, where it can be shown that the RISK of contamination of a gas pathway is acceptable, this might be unnecessary.

Subclause 201.11.8.101.1 — Supply failure TECHNICAL ALARM CONDITION

This International Standard's requirements for MEASUREMENT ACCURACY are based on the assumption that the RGM is only guaranteed to meet its disclosed MEASUREMENT ACCURACY for its RATED range of supply power characteristics (i.e. that which allow it to operate normally). The obvious corollary is that this MEASUREMENT ACCURACY is not guaranteed for supply power characteristics outside that range, which is the basis for requiring the RGM to stop displaying GAS READINGS and to initiate an appropriate ALARM CONDITION if that occurs. Doing so prevents the RGM from displaying potentially inaccurate GAS READINGS which might then lead an OPERATOR to make an incorrect clinical decision.

An RGM is a RISK CONTROL measure for some types of ME EQUIPMENT (e.g. ventilators). As such the safety of the PATIENT is dependent on the proper operation of an RGM. As the RGM approaches the point where it can no longer ensure that the supply power is within the range necessary for normal operation, the OPERATOR needs to be promptly warned of the impending failure. Any further degradation will cause loss of operation of the RGM.

If normal operation is maintained by a switchover to an INTERNAL ELECTRICAL POWER SOURCE, there is much less urgency associated with the pending failure of SUPPLY MAINS. The OPERATOR needs to be informed of the switchover from SUPPLY MAINS, since an INTERNAL ELECTRICAL POWER SOURCE has a finite capacity.

Subclause 201.11.8.101.2 — Settings and data storage following short interruptions or automatic switchover

The selection of settings appropriate for the PATIENT customizes the RGM for that PATIENT. A sudden and unexpected loss of these settings, particularly when the OPERATOR is working to solve an unexpected loss in power, can be an unacceptable RISK for the PATIENT. As is required for ALARM SETTINGS in IEC 60601-1-8:2006, settings are expected to be maintained during short losses of SUPPLY MAINS or automatic switchover.

Subclause 201.11.8.101.3 — Operation following long interruptions

As it might require substantial effort to store settings and PATIENT data for long interruptions of SUPPLY MAINS, the minimum requirement is for the ACCOMPANYING DOCUMENT to describe how the RGM operates following long interruptions.

Subclause 201.11.8.101.4 — RESERVE ELECTRICAL POWER SOURCE

When an RGM is operating from the RESERVE ELECTRICAL POWER SOURCE, its primary electrical supply is not available. An OPERATOR needs to be aware that in a short period of time, operation will cease. A period of 30 min is considered sufficient to safely conclude a procedure or restore SUPPLY MAINS. See also rationale 201.11.8.101.1.

Subclause 201.11.8.101.5 — RESERVE ELECTRICAL POWER SOURCE for transportation outside a healthcare facility

In professional transport outside of a healthcare facility, a longer RESERVE ELECTRICAL POWER SOURCE duration is required since it is more difficult to safely restore the SUPPLY MAINS or conclude a procedure. It is likely that the PATIENT can be taken to an appropriate healthcare facility within the 1 h reserve time. See also rationale 201.11.8.101.4

Subclause 201.12.1.101 — MEASUREMENT ACCURACY

The MEASUREMENT ACCURACY of an RGM is ESSENTIAL PERFORMANCE.

The paragraph immediately following is a reprint of the rationale from ASTM F1452[29], when halothane, enflurane and isoflurane were the only halogenated agents clinically available. Currently two additional halogenated agents, sevoflurane and desflurane, are available. The committee addressed establishing the MEASUREMENT ACCURACY for these new halogenated agents in the same way as was applied by the original committee. Testing for MEASUREMENT ACCURACY is spread over the entire range of measurement capabilities of an RGM and verified using halogenated agent test gases at the low, medium and high values of the clinically utilized GAS LEVELS.

Rationale for MEASUREMENT ACCURACY from ASTM F1452[29].

> The required measurement accuracy for halogenated anaesthetic gases and nitrous oxide was probably the single most extensively discussed subject during committee deliberations. The committee 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 anaesthetic agents and nitrous oxide (that is, clinically permissible inaccuracy of the readout).

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

The resultant values, when an RGM is operating within these specifications, are compared in Table AA.1 below, with the statement of clinical requirements.

Subclause 201.12.1.101.2 — DRIFT of MEASUREMENT ACCURACY

Some possible gas measurement technologies might not be sufficiently stable over time to meet the minimum clinical need. An RGM needs to stay within the specified limits to provide freedom from unacceptable RISK.

Table AA.1 — Actual respiratory gas clinical requirement for resultant performance

GAS LEVEL (%)	Clinical requirement for MEASUREMENT ACCURACY	RGM specified MEASUREMENT ACCURACY (%)
	Halogenated anaesthetic 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

Subclause 201.12.1.101.3 — MEASUREMENT ACCURACY of GAS READINGS for gas mixtures

In clinical use, an RGM is used on a PATIENT and the mixture of gases that the PATIENT is breathing. Depending on the technology used in the RGM, some of the gases in the mixture can cause measurement error. An RGM needs to provide ESSENTIAL PERFORMANCE for all gases or mixtures for which the RGM is intended to be used. The mixtures in Table 201.104 provide an evaluation of MEASUREMENT ACCURACY with gas mixtures seen in clinical practice.

Subclause 201.12.1.102 — TOTAL SYSTEM RESPONSE TIME and rise time

OPERATORS of an RGM need to understand the delays inherent in the RGM to assist them in understanding overall operation and response. Such items as flowrate affect this delay.

The requirement is to measure TOTAL SYSTEM RESPONSE TIME with each breathing system configuration that is specified in the instructions for use. A single value reflecting the TOTAL SYSTEM RESPONSE TIME of the slowest breathing circuit configuration is permitted. MANUFACTURERS are encouraged to separately provide the TOTAL SYSTEM RESPONSE TIME for each type of ACCESSORY (e.g. separately for a DIVERTING RGM utilizing a nasal cannula and an airway adapter).

Subclause 201.12.1.103 — Indication of units of measure for GAS READINGS

MEASUREMENT ACCURACY is of little value if the OPERATOR is unaware of the units of measure. Therefore, it is essential for the OPERATOR be able to determine units of measure easily. If the setting is OPERATOR-configurable, this information needs to be displayed continually, as the previous OPERATOR could have changed the units of measure.

Subclause 201.12.1.104 — Indication of operating mode

While in modes other than normal monitoring modes, the RGM is required to indicate that it is not monitoring a PATIENT**.** There have been circumstances in which an RGM was in a demonstration mode and the OPERATOR believed that it was monitoring the PATIENT. This is why these non-monitoring modes are required to be indicated continuously. An RGM should automatically return to the monitoring mode without requiring OPERATOR action.

Subclause 201.15.3.5.101 — Additional requirements for rough handling

In NORMAL USE, ME EQUIPMENT, including an RGM, will be subjected to mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME 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 [i.e. HOME HEALTHCARE ENVIRONMENT, professional healthcare facility environment and professional transport (wings and wheels)] on various sizes and types of ME EQUIPMENT (i.e. HAND-HELD, PORTABLE and MOBILE). The result of the committee's analysis is shown in Table AA.2 for the various types of shock and vibration which can be experienced.

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 that expected in the professional healthcare facility. The committee chose to combine these two categories, both for simplicity and because many pieces of ME EQUIPMENT are routinely moved from the professional healthcare facility to the HOME HEALTHCARE ENVIRONMENT and vice versa.

Table AA.2 — Qualitative assessment of RGM shock and vibration environment

ME EQUIPMENT category	Location											
	Standard environments						Transport vehicles					
	Home			Healthcare facility			Wheels			Wings/Rotary		
MOBILE	D1	S1	V1	D1	S2	V1	D1	S3	V2	D1	S3	V3
PORTABLE	D1	S2	V0	D1	S2	V1	D1	S3	V2	D1	S3	V3
HAND-HELD	D3	S1	V0	D3	S2	V1	D3	S3	V2	D3	S3	V3
STATIONARY	None			None			Not applicable					

S = shock; V = vibration; D = drop

Rating: 0 = no test; 1 = least severe or 7M1[a] ; 2 = moderate severity or 7M2; 3 = most severe or 7M3

[a] The 7Mx designations are defined in IEC 60721-3-7:2002.

After qualitative assessment, the committee assessed the International Standards in the IEC 60068 series relating to environmental testing, 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 Reviewer Guidance[32] for premarket notification submissions, Mil Std 810, etc.) but found the best fit was with IEC 60721-3-7:2002 and IEC/TR 60721-4-7:2003. These International Standards mapped well to the requirements defined in Table AA.2. The aforementioned International Standards specify three classes of mechanical conditions: 7M1, 7M2 and 7M3. The committee found that the classes 7M2 and 7M3 best represent the conditions seen during PATIENT transport within healthcare facilities and those seen during professional transport of a PATIENT outside healthcare facilities, respectively. The committee agreed that different tests and test levels should be applied to ME EQUIPMENT intended for use in a healthcare facility versus ME EQUIPMENT intended for use during professional transport of a PATIENT outside the healthcare facility.

Verifying that the ME EQUIPMENT is functioning within the MANUFACTURER'S specifications while the vibration (random and sinusoidal) tests are being conducted was not believed necessary. Following thoughtful consideration, the committee decided that such testing would be overly burdensome and that the added cost was not justified given the slight improvement of PATIENT safety. Verifying proper functioning after completion of the tests is believed adequate.

Subclause 201.15.3.5.101.1 — Shock and vibration

An RGM intended for NORMAL USE within a professional healthcare facility will be subjected to these mechanical stresses (e.g. vibration, shock) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used in the professional healthcare facility needs to be robust enough to withstand the vibration and shock testing described by IEC 60721-3-7 level 7M2. IEC 60721-3-7 indicates that this class applies to use at, and during 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.

The committee chose the duration of 10 min for the random vibration test, even though the duration recommended by IEC 60721-3-7 is 30 min, to maintain testing compatibility with ISO 21647:2004. In the first amendment to this particular standard, the committee intends to increase the duration to 30 min.

Subclause 201.15.3.5.101.2 — Shock and vibration for professional transport

In NORMAL USE, ME EQUIPMENT, including an RGM, used for professional transportation of a PATIENT outside a professional 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, ME EQUIPMENT intended to be used for professional transportation of a PATIENT outside a professional healthcare facility needs to 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 during direct transfer between, locations with significant vibrations, or with high-level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments.

There are no established generalized test programmes that exactly reproduce the range of vibration and shock conditions that ME EQUIPMENT can meet when installed in a range of land vehicles and aircraft. Therefore, the dynamic tests specified in this subclause were chosen because ME EQUIPMENT tested to these levels is likely to withstand the normal dynamic disturbances that it is subjected to when used in the range of vehicles and aircraft (including helicopters) likely to be used for the professional transportation of PATIENTS.

The use of ME EQUIPMENT in road ambulances, fixed-wing and rotary-wing aircraft, naval vessels, etc. can require additional tests and verification of safety when used in these different environments.

For the free-fall testing described in IEC 60068-2-31, the committee used the rationale for the various levels to gauge the severity of the test based on Table AA.2 of this rationale. The category of the test level chosen for PORTABLE ME EQUIPMENT was PORTABLE cases. The committee agreed that an RGM should be required to meet a level of drop-testing for the professional transport environment. The committee also agreed that many RGMs are likely to be supplied with a protective or carrying case for use in transport environments. The committee agreed that it would be an adequate test for PORTABLE ME EQUIPMENT to be dropped while in their carrying cases, as this would be most like the real world environment. For MOBILE ME EQUIPMENT, a less severe level was chosen since wheeled ME EQUIPMENT is typically heavier.

The committee chose one fall in each specified attitude for the free-fall test even though IEC 60721-3-7 recommends two falls to maintain testing compatibility with ISO 21647:2004. In the first amendment to this particular standard, the committee intends to increase the number of falls to two.

Subclause 201.15.101 — Mode of operation

PATIENT monitoring requires continuous GAS READINGS, so an RGM is required to operate continuously. There is no reason to permit construction of an RGM that requires, for example, periods of cooling between periods of normal operation.

Subclause 201.101 — Interfering gas and vapour effects

In clinical use, an RGM is used on a PATIENT and the mixture of gases that the PATIENT is breathing. Depending on the technology used in the RGM, some of the gases in the mixture can cause measurement error. An RGM needs to provide ESSENTIAL PERFORMANCE for all gases or mixtures for which the RGM is intended to be used, including known interfering gases. The mixtures in Table 201.105 provide an evaluation of the quantitative effects with known interfering gases seen in clinical practice. The impacts of these gases are required to be disclosed in the instructions for use.

Subclause 201.102 — Gas leakage

In clinical use, leakage from the SENSOR of a NON-DIVERTING RGM can affect the MEASUREMENT ACCURACY and thereby the treatment of the PATIENT. The committee has chosen leakage levels that have been historically demonstrated to permit adequate treatment efficacy.

Subclause 201.103 — Port connector for DIVERTING RGM

In light of the work being done by the joint working group of ISO/TC 210 and IEC 62D, and in light of the reported incidents of misconnection, the use of Luer connectors is no longer acceptable. Misconnections can be adequately prevented by utilizing the small-bore connectors being developed to prevent such misconnections.

Subclause 201.104 — Minimum sampling flowrate

Adequate sample flowrate is essential for accurate GAS READINGS in a DIVERTING RGM. If the sample flowrate falls below the value necessary to ensure MEASUREMENT ACCURACY, the OPERATOR needs to be aware of this HAZARDOUS SITUATION so that it can be corrected. Therefore, to maintain ESSENTIAL PERFORMANCE**,** a TECHNICAL ALARM CONDITION is required to alert the OPERATOR to inadequate sample flowrate.

Subclause 201.105 — Contamination of breathing systems

BASIC SAFETY of the PATIENT requires that a DIVERTING RGM not introduce micro-organisms from one PATIENT into another PATIENT through the breathing system in SINGLE FAULT CONDITION. Since a breathing system filter is not a COMPONENT WITH HIGH INTEGRITY CHARACTERISTICS, it cannot be relied upon to prevent contamination for the EXPECTED SERVICE LIFE of the RGM. When using a breathing system filter, a second means of protection is required to eliminate the possibility of micro-organisms coming through a DIVERTING RGM and back to the breathing system to the PATIENT if the sample gas is returned to the breathing system.

Subclause 202.6.2.1.7 — PATIENT simulation

In order to verify sufficiently the IMMUNITY of a SENSOR in an RGM, a gas sample needs to be measured within the conditions of this subclause while testing occurs. In particular, the RGM needs to be measuring a challenging gas mixture.

Subclause 202.6.2.3.1 — General

The radiated IMMUNITY environment during professional transportation of a PATIENT outside the professional healthcare facility (e.g. land and air ambulances) is harsher than the typical professional in-healthcare facility environment. This is mainly because two-way radio communication systems that intentionally radiate electromagnetic energy are commonly found in this environment. In both of these environments, an RGM meeting the requirements of IEC 60601-1-2:2007 should be adequately protected from unintentional sources of electromagnetic interference. The additional testing needed to qualify an RGM for this environment need only address this additional threat.

Two-way communication devices transmit both voice and PATIENT data. Experience has shown that typical field strengths[34] 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. Based upon the radiated IMMUNITY standard (IEC 61000-4-3), the committee chose a single test point to represent the

typical information modulation band. This single test point is a signal with an 80 % amplitude modulation at 1 kHz. 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 Guidance.[32]

Subclause 208.6.1.2 — ALARM CONDITION priority

This International Standard requires an RGM to generate an ALARM CONDITION when it detects more than one halogenated anaesthetic agent in the respired gas. This helps to 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 anaesthesia. Two ALARM CONDITION monitoring requirements were established. 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 cannot automatically quantify 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 support changing halogenated agents without creating nuisance ALARM SIGNALS.

MAC values are defined to be the values listed by the manufacturer's drug 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. MAC can be used to effectively compare halogenated anaesthetic agents and allow for any future such agents. 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 only deliver one halogenated anaesthetic agent. The committee determined a 3 MAC level was reasonable, which happens to be the default high halogenated anaesthetic agent ALARM LIMIT for most RGMs. MAC can be used to effectively compare halogenated anaesthetic agents and allow for any such agents in the future.

Subclause 208.6.5.1 — General requirements

An inspired gas mixture with less than 18 % oxygen is hypoxic and therefore dangerous. Although there are rare circumstances when such a mixture is needed, allowing an ALARM PRESET to be set below this level is clinically unsafe. An ALARM SYSTEM that permits such a low ALARM PRESET for inspired oxygen can mean that the OPERATOR accidentally loses the notification they expect regarding delivery of a hypoxic gas mixture.

Subclause 208.6.6.2.101 — Additional requirements for an adjustable ALARM LIMIT

The OPERATOR needs to set the ALARM LIMITS appropriately for certain clinical procedures that require specific GAS LEVELS. To avoid accidental adjustment of these ALARM LIMIT settings, deliberate action is required of the OPERATOR.

Although rare, a specific clinical procedure may require an inspired gas mixture with less than 18 % oxygen, which means the OPERATOR needs to be able to set the ALARM LIMITS appropriately in order to avoid having an unmonitored PATIENT. To avoid accidental selection of this otherwise dangerous setting, a second deliberate action is required to set the ALARM LIMIT for low inspired oxygen below 18 %.

Subclause 208.6.8.5.101 — Additional requirements for ALARM SIGNAL deactivation states, indication and access

An interval of 2 min is the longest that AUDIO PAUSED or ALARM PAUSED should last without a deliberate choice by the RESPONSIBLE ORGANIZATION or OPERATOR.

Annex BB
(informative)

Environmental aspects

Those responsible for planning and design of products applicable 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:

a) impact on local environment during NORMAL USE;

b) disposal of contaminated sampled gases and biologic fluids during NORMAL USE;

c) use, cleaning and disposal of consumables during testing and NORMAL USE;

d) 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 the environmental impact caused by those aspects during different stages of the RGM.

Table BB.1 contains a mapping of the life cycle of an RGM to aspects of the environment.

Table BB.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 clause/subclause	Addressed in clause/subclause	Addressed in clause/subclause	Addressed in clause/subclause
1	Resource use	209	209	201.7 209	209
2	Energy consumption	209	209	201.11 209	209
3	Emission to air	209	209	201.7.9.2.15.101 201.9 201.10 201.11 201.15 202 208 209	209
4	Emission to water	209	209	201.11 209	209
5	Waste	209	201.7.2.17.101 209	201.11 201.15 201.7 201.7.2.101 209	201.7 201.7.2.101 209
6	Noise	209	209	201.9 208 209	209
7	Migration of hazardous substances	209	209	201.9 201.11 201.15 201.7 201.7.2.101 209	209
8	Impacts on soil	209	209	209	201.7.2.101 209
9	RISKS to the environment from accidents or misuse	209	209	201.9 201.11 201.15 201.7.2.101 208 209	209

Annex CC
(informative)

Test gas mixtures for calibration

A MANUFACTURER can buy or make test gases for use in the calibration of an RGM according to this International Standard.

The preparation and analysis of traceable calibration gas mixtures using volumetric methods is described in detail in other standards.[1][2][3][15]

The methods of generating calibration gas mixtures using refractometry are detailed in published papers[33][34][38] and are summarized in Table 201.CC.1.

Table 201.CC.1 — Summary of refractometry coefficients

Agent	Refractive power of agents [$(n_a - 1) * 10^6$ at 0 °C, 1 013 mbar, 633 nm]		Virial coefficient [l/mol]	
	a b	c	at 20 °C/25 °C[a b]	at 23 °C[c]
Halothane	1 608,3	1 603,2	−1,279/−1,228	−2,00
Enflurane	1 553,2	1 540,4	−1,625/−1,504	−1,93
Isoflurane	1 550,4	1 563,3	−1,559/−1,473	−1,84
Sevoflurane	1 543,7	1 538,3	−2,169/−2,020	−2,53
Desflurane	1 235,3	1 211,7	−1,231/−1,166	−1,11

[a] According to reference [33].

[b] According to reference [34].

[c] According to reference [38].

Annex DD
(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 given in ISO/TR 16142:2006. 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 given in Annex A of ISO/TR 16142:2006. Other means are possible. Table DD.1 maps the clauses and subclauses of this particular standard with the essential principles of ISO/TR 16142:2006.

Table DD.1 — Correspondence between this International Standard and the essential principles

Essential principle	Corresponding clause/subclause of this International Standard	Comments
1, 2, 3	all	
2	201.4.101, 201.7.2, 201.101.1, 208	
3	201.4, 201.4.102, 201.101.1	
4	201.11.8.101, 201.15.3.5.101, 201.101.1	
5	201.15.3.5.101, 201.101.1	
6	201.4, 201.4.102, 201.4.1032, 201.7.9.2, 201.11, 201.12.1, 201.12.4, 201.101.1, 208	
7.1	201.11, 201.101.1	
7.2	201.11	
7.3	201.11	
7.4	-	Not applicable to an RGM.
7.5	201.11, 201.11.6.4	
7.6	201.11.6.5.101, 201.101.1	
8.1, 8.1.1, 8.1.2	201.11	
8.2	201.7.2.17.101, 201.101.1	
8.3	201.11	
8.4	-	This relevant essential principle is not addressed in this International Standard.
8.5	201.11	
8.6	201.7.2.17.101	
9.1	201.4.10.2.101, 201.7.2, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101, 201.12.4.101, 201.101.1, 201.101.2, 201.102, 208	

Table DD.1 (*continued*)

Essential principle	Corresponding clause/subclause of this International Standard	Comments
9.2	201.15.3.5.101, 201.101.1, 202	
9.3	201.11	
10.1	201.12.1, 201.12.4.101, 201.4.102, 201.101.1	
10.2	201.12.4.101, 201.4.102, 201.102, 206, 208	
10.3	201.7.4.3	
11.1	201.101.1	
11.2.1	201.9, 201.10	
11.2.2	201.10, 201.101.1	
11.3	202	
11.4	201.7.9.2.1.101 c)	
11.5.1, 11.5.2, 11.5.3	-	Not applicable to an RGM.
12.1	201.14	
12.2	201.11.8.101, 208	
12.3	201.11.8.101, 208	
12.4	201.7.2.101, 201.12.4.101, 208	
12.5	201.101.1, 202	
12.6	201.8, 201.101.1	
12.7.1	201.15.3.5.101, 201.101.1	
12.7.2, 12.7.3	201.9	
12.7.4	201.8, 201.15	
12.7.5	201.11, 201.101.1	
12.8.1	-	Not applicable to an RGM.
12.8.2	201.11	
12.8.3	201.7, 206	
13.1	201.7.2, 201.101.2	

Bibliography

[1] ISO 6142:2001, *Gas Analysis — Preparation of calibration gas mixtures — Gravimetric method*

[2] ISO 6143:2001, *Gas Analysis — Comparison methods for determining and checking the composition of calibration gas mixtures*

[3] ISO 6145 (all parts), *Gas Analysis — Preparation of calibration gas mixtures using dynamic volumetric methods*

[4] ISO 7767:1997[3)], *Oxygen monitors for monitoring patient breathing mixtures — Safety requirements*

[5] ISO 9918:1993[4)], *Capnometers for use with humans — Requirements*

[6] ISO 10651-2:2004, *Lung ventilators for medical use — Particular requirements for basic safety and essential performance — Part 2: Home care ventilators for ventilator-dependent patients*

[7] ISO 11196:1995[4)], *Anaesthetic gas monitors*

[8] ISO 14155:2011, *Clinical investigation of medical devices for human subjects — Good clinical practice*

[9] ISO 14159:2002, *Safety of machinery — Hygiene requirements for the design of machinery*

[10] ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

[11] ISO/TR 16142:2006, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[12] ISO 21647:2004 (+Cor 1:2005)[4)], *Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors*

[13] ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

[14] ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

[15] ISO/TS 29041:2008, *Gas mixtures — Gravimetric preparation — Mastering correlations in composition*

[16] IEC 60038:2009, *IEC standard voltages*

[17] IEC 60065:2001, *Audio, video and similar electronic apparatus — Safety requirements*

[18] IEC 60335-1:2010, *Household and similar electrical appliances — Safety — Part 1: General requirements*

[19] IEC 60364 (all parts), *Electrical installations of buildings*

[20] IEC 60601-1-3:2008, *Medical electrical equipment — Part 1-3: General requirements for basic safety and essential performance — Collateral Standard: Radiation protection in diagnostic X-ray equipment*

3) International Standard withdrawn and replaced by ISO 80601-2-55:2011.

[21] IEC 60721-3-7:2002, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

[22] IEC/TR 60721-4-7:2003, *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*

[23] IEC/TR 60878:2003, *Graphical symbols for electrical equipment in medical practice*

[24] IEC 60950-1:2005, *Information technology equipment — Safety — Part 1: General requirements*

[25] IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

[26] EN 864:1997, *Medical electrical equipment — Capnometers for use with humans — Particular requirements*

[27] EN 12598:1999, *Oxygen monitors for patient breathing mixtures — Particular requirements*

[28] EN 13718-1:2008, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances*

[29] ASTM F1452:1992, *Standard Specification for Minimum Performance and Safety Requirements for Anesthetic Gas Monitors*

[30] ASTM F2020-02, *Standard Practice for Design, Construction, and Procurement of Emergency Medical Services Systems (EMSS) Ambulance*s

[31] NFPA 53M[4)], *Fire Hazards in Oxygen-Enriched Atmospheres, 1990 Edition*

[32] US Food and Drug Administration, *Excerpts Related to EMI from Anesthesiology and Respiratory Devices Branch*, November 1993[5)], see Section (i)(7) on page 17

[33] ALLISON, J.M., et al., *Precise determination of refractometric parameters for anesthetic agent vapors,* Applied Optics, **33**(13) pp. 2459-2464, 1994

[34] ALLISON, J.M., et al., *Determination of anesthetic agent concentration by refractometry,* Br. J. Anaesth., **74**, pp. 85-88, 1995

[35] BOIVIN, W. et. al., *Measurement of radiofrequency electromagnetic fields in and around ambulance*s, Biomed. Instrum. Technol., **31**(2), pp. 145-154, 1997

[36] LEROU, J.G., *Nomogram to estimate age-related MAC*, Br. J. Anaesth., **93**(2), pp. 288-291, 2004

[37] NICKALLS, R.W., MAPLESON, W.W., *Age-related iso-MAC charts for isoflurane, sevoflurane and desflurane in man*, Br. J. Anaesth., **91**(2), pp. 170-174, 2003

[38] WALLROTH, C.F., et al., *Refractive indices for volatile anesthetic gases: Equipment and method for calibrating vaporizers and monitors*, Journal of Clinical Monitoring, **11**(3), pp. 168-174, 1995

[39] MIL-STD-810, "Department of Defense Test Method Standard for Environmental Engineering Consideratons and Laboratory Tests"

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

5) Available from FDA at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM081280.pdf.

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6) To be published.

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