INTERNATIONAL STANDARD

ISO 80601-2-55

Second edition
2018-02

Medical electrical equipment —

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

Appareils électromédicaux —

Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

This second edition cancels and replaces the first edition (ISO 80601-2-55:2011), which has been technically revised.

The main changes compared to the previous edition are as follows:

— additional requirements on respiratory gas monitors for use during professional transport of a patient outside a healthcare facility have been deleted because these are now covered by IEC 60601-1-12;

— requirements on marking, warning and safety notices, as well as accompanying documents have been updated;

— 201.11.6.5 and 201.15.3.5 have been revised to distinguish between requirements for stand-alone respiratory gas monitors and requirements for respiratory gas monitors that are incorporated into another medical electrical equipment;

— requirements on port connectors for diverting respiratory gas monitors have been revised;

— a new subclause on functional connection has been added (see 201.106) accompanied by the related rationale and informative annex on data interface requirements;

— Clause 202 has been updated to align with IEC 60601-1-2:2014;

— Clause 208 has been updated to align with IEC 60601-1-8:2006/Amd 1:2012;

— IEC 60601-1-9 has been excluded;

— Annex BB has been deleted;

— requirements on calibration/zeroing have been added.

A list of all the parts of ISO 80601 can be found on the ISO website.

Introduction

In this document, the following print types are used:

— requirements and definitions: roman type.

— compliance checks: *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 document or as noted: SMALL CAPITALS.

In referring to the structure of this document,

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

— "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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in ISO/IEC Directives, Part 2, Clause 7. For the purposes of this document, the auxiliary verb

— "shall" means that compliance with a requirement or a test is mandatory for compliance with document,

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document, and

— "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 rationale related to that item in Annex AA.

Medical electrical equipment —

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

201.1 Scope, object and related standards

IEC 60601-1:2005+Amd 1:2012, Clause 1 applies, except as follows:

201.1.1 *Scope

IEC 60601-1:2005+Amd 1:2012, 1.1 is replaced by:

This document 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 document specifies requirements for

— anaesthetic gas monitoring,

— carbon dioxide monitoring, and

— oxygen monitoring.

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

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

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 document are not covered by specific requirements in this document except in IEC 60601-1:2005+Amd 1:2012, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601-1:2005+Amd 1:2012, 4.2.

201.1.2 Object

IEC 60601-1:2005+Amd 1:2012, 1.2 is replaced by:

The object of this document 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

IEC 60601-1:2005+Amd 1:2012, 1.3 applies with the following addition:

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+Amd 1:2012, Clause 2, as well as those listed in 201.2 of this document and to the following exceptions:

IEC 60601-1-3:2008 and IEC 60601-1-9:2007+Amd 1:2013 do not apply.

201.1.4 Particular standards

IEC 60601-1:2005+Amd 1:2012, 1.4 is replaced by:

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

A requirement of a particular standard takes priority over IEC 60601-1:2005+Amd 1:2012 or the collateral standards.

For brevity, IEC 60601-1:2005+Amd 1:2012 is referred to in this document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to those of the general standard with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits of the collateral standard document number (e.g. 202.4 addresses the content of IEC 60601-1-2, Clause 4 collateral standard, 208.4 addresses the content of IEC 60601-1-8, Clause 4 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 IEC 60601-1:2005+Amd 1:2012 or the applicable collateral standard is replaced completely by the text of this document.

— "Addition" means that the text of this document is additional to the requirements of IEC 60601-1:2005+Amd 1:2012 or the applicable collateral standard.

— "Amendment" means that the clause or subclause of IEC 60601-1:2005+Amd 1:2012 or the applicable collateral standard is amended as indicated by the text of this document.

Subclauses or figures that 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 that 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, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to IEC 60601-1:2005+Amd 1:2012, any applicable collateral standards, and this document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of IEC 60601-1:2005+Amd 1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+Amd 1:2012 or the applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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[1]+Amd 1:2012, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-6:2010[2]+Amd 1:2013, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006[3]+Amd 1:2012, *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 7000:2014, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 14937:2009, *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 15223-1:2017, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 17664:2004[4], *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 80369 (all parts), *Small bore connectors for liquids and gases in healthcare applications*

ISO 80601-2-13:2011+Amd 1:2015 and Amd 2:—[5], *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] A consolidated edition, IEC 60601-1:2012, which includes IEC 60601-1:2005 and its amendment (IEC 60601-1:2005/Amd 1:2012) is available.

[2] A consolidated edition, IEC 60601-1-6:2013, which includes IEC 60601-1-6:2010 and its amendment (IEC 60601-1-6:2010/Amd 1:2013) is available.

[3] A consolidated edition, IEC 60601-1-8:2012, which includes IEC 60601-1-8:2006 and its amendment (IEC 60601-1-8:2006/Amd 1:2012) is available.

[4] Under revision.

[5] To be published. Stage at time of publication ISO 80601-2-13:2011+DAmd 2:2017.

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

IEC 60529:1989[6]+Amd 1:1999 and Amd 2:2013, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1-11:2015, *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*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+Amd 1:2012, IEC 60601-1-2, IEC 60601-1-6:2010+Amd 1:2013, IEC 60601-1-8:2006+Amd 1:2012, IEC 60601-1-11, IEC 60601-1-12 and ISO 80601-2-13:2011+Amd 1:2015 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at https://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

Addition:

NOTE An alphabetical list of defined terms is given in Annex DD.

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

[6] A consolidated edition, IEC 60529:2013, which includes IEC 60529:1989 and its amendments (IEC 60529:1989/Amd 1:1999 and IEC 60529:1989/Amd 2:2013) is available.

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 1 to entry: For the purposes of this document, 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
RESPIRATORY GAS MONITOR
RGM
ME EQUIPMENT intended to measure the GAS LEVEL or PARTIAL PRESSURE of one or more gases in respiratory gas

Note 1 to entry: 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 port.

201.3.211
RISE TIME
RT
time taken for a value to rise from 10 % to 90 % of the indicated reading

[SOURCE: ISO 23747:2015, 3.9, modified — replaced “achieved PEF (peak expiratory flowrate)” by “indicated reading” and “flowrate” by “a value”.]

201.3.212
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

201.3.213
SAMPLING TUBE
conduit for the transfer of gas from the SAMPLING SITE to the SENSOR in a DIVERTING RGM

201.3.214
SENSOR
part of the RGM that is sensitive to the presence of the respiratory gas

201.3.215
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

201.3.216
VOLUME PERCENT
volume of a gas in a mixture, expressed as a percentage of the total volume

201.4 General requirements

IEC 60601-1:2005+Amd 1:2012, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+Amd 1:2012, 4.3 applies, except as follows:

Additional subclause:

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 ALARM CONDITION for the GAS READING	201.12.1.101
or generation of a TECHNICAL ALARM CONDITION	201.11.8.101.1, 208.6.1.2
[a] Methods of evaluating MEASUREMENT ACCURACY as acceptance criteria following specific tests required by this document are found in 202.8.1.	

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

Amendment (add at end of 4.6 prior to the compliance check):

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.

201.5 General requirements for testing of ME EQUIPMENT

IEC 60601-1:2005+Amd 1:2012, 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+Amd 1:2012, Clause 7 applies, except as follows.

201.7.2.3 *Consult ACCOMPANYING DOCUMENTS

IEC 60601-1:2005+Amd 1:2012, 7.2.3 applies, except as follows.

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+Amd 1:2012, Table D.2, Number 10).

If an RGM is incorporated as a module into a housing of another ME EQUIPMENT that already is marked with a safety sign, it does not need to be marked additionally.

Additional subclauses:

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 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. ISO 15223-1:2016, 5.4.5 (see Table 201.D.2.101, symbol 10) may be used. All components containing natural rubber latex shall be disclosed as such in the instructions for use.

Check compliance by 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 ISO 15223-1:2016, 5.1.5, 5.1.6 or 5.1.7 (see Table 201.D.2.101, symbols 7 to 9);

— for packages containing natural rubber latex, the word "LATEX", or ISO 15223-1:2016, 5.4.5 (see Table 201.D.2.101, symbol 10);

— if applicable, the word “STERILE” or one of ISO 15223-1:2016, 5.2.1 to 5.2.5 (see Table 201.D.2.101, symbols 2 to 6);

b) for those parts intended for single use, with the words “SINGLE USE”, “DO NOT REUSE”, “NOT FOR REUSE”, ISO 15223-1:2016, 5.2.6 (see Table 201.D.2.101, symbol 13) or ISO 15223-1:2016, 5.4.2 (see Table 201.D.2.101, symbol 14); for a specific MODEL OR TYPE REFERENCE, the indication of single use shall be consistent.

Packaging of sterile ME EQUIPMENT, parts or ACCESSORIES shall ensure sterile conditions until opened or damaged or until its expiration date is reached.

Consideration should be given to the disposal of packaging waste.

Check compliance by inspection.

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 special storage and/or handling requirements;

b) with a serial number or ISO 15223-1:2016, 5.1.7 or lot identifying number or batch identifying number [or ISO 15223-1:2016, 5.1.5 (see Table 201.D.2.101, symbol 7 or symbol 9)];

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 in ISO 7000:2014, 0794, (see Table 201.D.2.101, symbol 11);

f) for an RGM sampling gas outlet, either with the text “Gas exhaust” or the symbol in ISO 7000:2014, 0795, (see Table 201.D.2.101, symbol 12);

g) for a SAMPLING TUBE, either with the text “Gas sample” or the symbol in ISO 7000:2014, 0794, (see Table 201.D.2.101, symbol 11);

h) for an exhaust tube for a DIVERTING RGM, either with the text “Gas exhaust” or the symbol in ISO 7000:2014, 0795, (see Table 201.D.2.101, symbol 12);

i) for a stand-alone RGM intended to be used in the magnetic resonance (MR) environment,

— IEC 62570:2014, 7.3.1 (with two options: Table 201.D.2.101, symbol 15 or symbol 16) for an “MR Safe” RGM, or

— IEC 62570:2014, 7.3.2 (see Table 201.D.2.101, symbol 17) for an “MR Conditional” RGM, in accordance with IEC 62570.

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. ISO 15223-1:2016, 5.1.4 (see Table 201.D.2.101, symbol 1) may be used.

Check compliance by inspection.

201.7.4.3 Units of measurement

IEC 60601-1:2005+Amd 1:2012, 7.4.3 applies, except as follows:

Amendment:

Add the following lines including footnote b) to Table 1.

GAS READING[b]	% (VOLUME PERCENT)	—
	millimetres of mercury	mmHg
GAS READING of anaesthetic agents	% (VOLUME PERCENT)	—
Flowrate	millilitres per minute	ml/min
[b] The GAS READING of respiratory gases may be expressed as a PARTIAL PRESSURE.		

201.7.9.2 Instructions for use

IEC 60601-1:2005+Amd 1:2012, 7.9.2 applies, except as follows:

Additional subclause:

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, and

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 inspection of the instructions for use.

201.7.9.2.2 Warnings and safety notices

IEC 60601-1:2005, 7.9.2.2, *applies except as follows.*

Additional subclause:

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 inspection of the instructions for use.

If the accuracy of the RGM is not maintained when used with Oxygen 93 there shall be a warning to the effect that the RGM shall not be used with gas supplied from oxygen concentrators.

201.7.9.2.5 ME EQUIPMENT description

IEC 60601-1:2005, 7.9.2.5, applies except as follows.

Additional subclause:

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, and

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

Check compliance by inspection of the instructions for use.

201.7.9.2.8 Start-up PROCEDURE

IEC 60601-1:2005, 7.9.2.8, applies except as follows:

Additional subclause.

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.

c) the conditions under which the ALARM SYSTEM is activated.

Check compliance by inspection of the instructions for use.

201.7.9.2.9 Operating instructions

IEC 60601-1:2005, 7.9.2.9, applies except as follows.

Additional subclause:

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 and the fixed limit for high inspired nitrous oxide ALARM CONDITION;

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

n) the temperature range where the operating conditions are met.

Check compliance by inspection of the instructions for use.

201.7.9.2.13 Maintenance

IEC 60601-1:2005, 7.9.2.13, applies except as follows:

Additional subclause:

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 inspection of the instructions for use.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

IEC 60601-1:2005+Amd 1:2012, 7.9.2.14, applies except as follows:

Additional subclause:

201.7.9.2.14.101 *Additional requirements for ACCESSORIES, supplementary equipment and 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) advice on the proper disposal of accumulated fluids.

EXAMPLE Fluids in reusable water traps.

Check compliance by inspection of the instructions for use.

201.7.9.2.15 Environmental protection

IEC 60601-1:2005+Amd 1:2012, 7.9.2.15, applies except as follows:

Additional subclause:

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 inspection of the instructions for use.

201.7.9.3 Technical description

IEC 60601-1:2005+Amd 1:2012, 7.9.3, applies except as follows:

Additional subclause:

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 201.7.9.2.9.101 i) and j);

b) the data sample rate;

c) a description of the method used to calculate end-tidal gas readings.

Check compliance by inspection of the technical description.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

IEC 60601-1:2005+Amd 1:2012, Clause 8 applies.

201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+Amd 1:2012, Clause 9 applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

IEC 60601-1:2005+Amd 1:2012, Clause 10 applies.

201.11 Protection against excessive temperatures and other HAZARDS

IEC 60601-1:2005+Amd 1:2012, Clause 11 applies, except as follows:

201.11.6.4 Leakage

Amendment (add after existing text):

The MANUFACTURER shall address in the design documentation 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 design documentation. 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 design documentation 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 a stand-alone 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.

If an RGM is incorporated as a module into a housing of another ME EQUIPMENT (e.g. an anaesthesia system), the requirements for ingress protection of that other ME EQUIPMENT shall apply. For a stand-alone RGM the ingress protection defined in this document shall apply.

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 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 document 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 design documentation 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 SYSTEM

Amendment (add note before compliance test):

NOTE Additional requirements are found in IEC 60601-1:2005+Amd 1:2012, 11.6.6 and IEC 60601-1-11:2015, Clause 8.

201.11.8 Interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT

Additional subclauses:

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 TECHNICAL ALARM CONDITION of at least MEDIUM PRIORITY;

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 it is no longer within the levels specified by the MANUFACTURER.

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

Check compliance by 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 the SUPPLY MAINS is restored after 30 s.

Check compliance by inspecting the ACCOMPANYING DOCUMENTS.

201.11.8.101.4 *RESERVE ELECTRICAL POWER SOURCE (except for transport outside a healthcare facility)

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 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+Amd 1:2012, 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+Amd 1:2012, 7.1.2.

Check compliance by applying the tests of IEC 60601-1:2005+Amd 1:2012, 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, or levels specified by the MANUFACTURER if better. 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 PERCENT)

Gas	MEASUREMENT ACCURACY
Halogenated agent	±(0,2 % + 15 % of GAS LEVEL)
CO_2	±(0,43 % + 8 % of GAS LEVEL)
Nitrous oxide	±(2,0 % + 8 % of GAS LEVEL)
O_2	±(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 × 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 BB.

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, or levels specified by the MANUFACTURER if better, within the temperature range specified by the MANUFACTURER.

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, or the levels specified by the MANUFACTURER if better, 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.

NOTE Some SENSOR principles do not have a measurement DRIFT over time. For those SENSORS, the measurement DRIFT need not be disclosed.

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

GAS LEVELS in % (VOLUME PERCENT)

Nitrogen	Nitrous oxide[a]	Halothane[a]	Enflurane[a]	Isoflurane[a]	Sevo-flurane[a]	Des-flurane[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								2,5
Balance								5,0[c,d]
Balance								10,0
Balance							15,0	
Balance							40,0	
Balance							60,0[c,d]	
Balance							100,0	

[a] Included if the RGM is intended for use with this halogenated agent.

[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 as the end concentration for TOTAL SYSTEM RESPONSE TIME testing (if applicable). For TOTAL SYSTEM RESPONSE TIME testing, a lower accuracy of the test gas mixture is acceptable.

NOTE For all TOTAL RESPONSE TIME tests, the initial concentration is intended to be 0 % of that gas except for oxygen which is intended to be 21 %. For gas SENSOR systems with automatic agent identification features (e.g. for halothane, enflurane, isoflurane, sevoflurane and desflurane), increasing the initial concentration up to 10 % of the end value for verification is allowed.

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 at constant ambient conditions. 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. Test gas mixtures should be disposed of properly.

Verify that the MEASUREMENT ACCURACY requirements of Table 201.102 are met at each sample point for each test GAS LEVEL, or that they are within the level specified by the MANUFACTURER.

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, or the levels specified by the MANUFACTURER if better, 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. Test gas mixtures should be disposed of properly.

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

Table 201.104 — Mixtures for combined GAS MEASUREMENT ACCURACY testing

GAS LEVELS in % (VOLUME PERCENT)

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.

201.12.1.101.4 Calibration/Zeroing

201.12.1.101.4.1 General

For calibration/zeroing of an RGM the following requirements shall apply:

a) *Calibration/zeroing of an RGM in NORMAL USE shall be indicated on the gas measurement display (this is also required if the measurement data is mirrored on another display, e.g. a PATIENT monitor).

NOTE 1 This can be achieved e.g. by displaying it in the measured derived numerical values or in the real-time curves or via a LOW PRIORITY ALARM SIGNAL.

b) During the generation of ALARM SIGNALS as required by this document, an RGM shall not automatically calibrate/zero unless there are only TECHNICAL ALARM CONDITIONS generated by the RGM (e.g. related to measurement inaccuracy or RGM failure) which may be corrected by calibrating/zeroing.

c) Derived numerical values shall be invalidated within 30 s of the start of calibration/zeroing.

d) If a calibration/zeroing of an RGM in NORMAL USE can take more than 30 s but less than 60 s, there shall be a countdown displayed for at least 120 s, showing the time left to the start of the calibration/zeroing (this is also required if the measurement data is mirrored on another display, e.g. a PATIENT monitor).

NOTE 2 This can be achieved, e.g. by displaying it in the measured derived numerical values or in the real-time curves.

e) If a calibration/zeroing of an RGM in NORMAL USe can take longer than 60 s, there shall be a countdown displayed for at least 120 s, showing the time left to the start of the calibration/zeroing (this is also required if the measurement data is mirrored on another display, e.g. a PATIENT monitor) and it shall be possible for the OPERATOR to postpone the calibration/zeroing of an RGM by at least 5 min.

f) If a calibration/zeroing of an RGM in NORMAL USE can take longer than 60 s, it shall be possible for the operator to cancel the calibration/zeroing if it is already progressing.

201.12.1.101.4.2 Suppression of automatic calibration/zeroing

Unless a calibration/zeroing is required to generate GAS READINGS, an automatic calibration/zeroing of an RGM shall be suppressed during and for at least 5 min after any of the following situations:

a) *if the apnoea alarm is activated;

b) *if no breathing activity of the PATIENT is detected for more than 30 s after breathing phases have been detected.

*If the inspiratory oxygen concentration reading is above 80 % (VOLUME PERCENT) for more than 30 s calibration/zeroing may be suppressed for at least 5 min increments for RGMs that measure oxygen concentration.

For this scenario, the calibration/zeroing suppression may be disabled by the OPERATOR, e.g. in the device configuration.

Any suppression of an automatic calibration/zeroing shall be limited to no more than 20 min.

201.12.1.102 *TOTAL SYSTEM RESPONSE TIME and RISE TIME

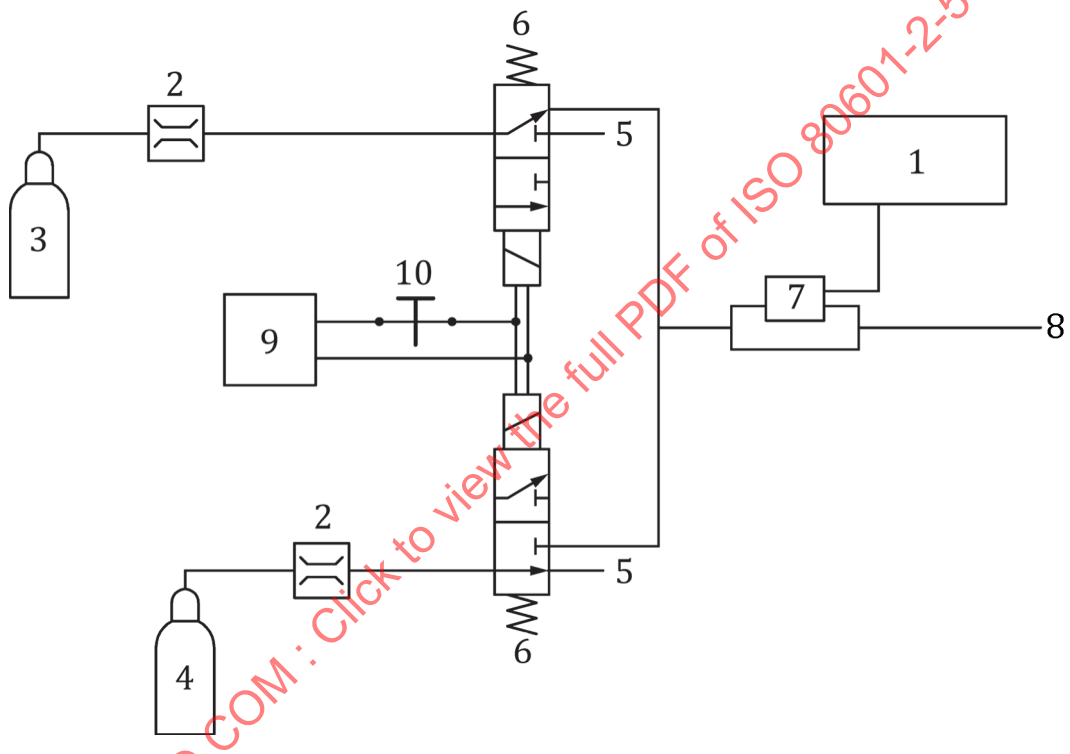
The TOTAL SYSTEM RESPONSE TIME shall be disclosed in the instructions for use. For a DIVERTING RGM with adjustable flow rates, the TOTAL SYSTEM RESPONSE TIME and the 10 % to 90 % RISE TIME, both over the RATED gas diversion flow rates, shall be disclosed in the instructions for use. The TOTAL SYSTEM 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. Test gas mixtures should be disposed of properly.

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 maximum 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 with adjustable flowrates, repeat at every specified gas diversion flowrate. Repeat for each breathing system configuration indicated in the instructions for use.*



Key

1	RGM under test	6	two 3-way valves (non-mixing), power supply controlled
2	flowmeter	7	SENSOR/SAMPLING SITE
3	calibrated test gas	8	tube (preventing backflow)
4	compressed air or calibrated test gas	9	power supply
5	open to room	10	manual pushbutton or electrically controlled switch

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

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

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 the 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. For a stand-alone RGM, after 1 min without OPERATOR interaction, other modes except standby should return automatically to normal operating mode.

NOTE Integrated RGMS are excluded. For example anaesthetic workstations can take longer than 1 min for a fully automated self-test.

Check compliance by functional testing.

201.13 HAZARDOUS SITUATIONS and fault conditions

IEC 60601-1:2005+Amd 1:2012, Clause 13 applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

IEC 60601-1:2005+Amd 1:2012, Clause 14 applies.

201.15 Construction of ME EQUIPMENT

IEC 60601-1:2005+Amd 1:2012, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5 Rough handling test

IEC 60601-1:2005+Amd 1:2012, Clause 15 applies, except as follows:

Additional subclauses:

201.15.3.5.101 Additional requirements for shock and vibration

201.15.3.5.101.1 General

If an RGM is incorporated as a module into another ME EQUIPMENT (e.g. an anaesthesia system), the requirements for shock and vibration of that ME EQUIPMENT shall apply.

A stand-alone RGM shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, pushing, impact, dropping and rough handling.

A stand-alone RGM intended for use during professional transportation of a PATIENT outside a healthcare facility shall comply with IEC 60601 1-12:2014, Clause 10.

A stand-alone RGM intended for use in the HOME HEALTHCARE ENVIRONMENT shall comply with IEC 60601 1-11:2015, Clause 10.

201.15.3.5.101.2 Shock and vibration for stand-alone RGM (robustness)

After the following tests, a stand-alone RGM intended to be used inside a healthcare facility shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

STATIONARY RGMs are exempt from the requirements of this subclause.

Compliance is checked by performing the following tests:

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

NOTE 1 This represents IEC/TR 60721-4-7:2003[19], Class 7M2.

1) test type: Type 1,

— *peak acceleration: 150 m/s² (15 g);*

— *duration: 11 ms;*

— *pulse shape: half-sine;*

— *number of shocks: 3 shocks per direction per axis (18 total); or*

2) test type: Type 2,

— *peak acceleration: 300 m/s² (30 g);*

— *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+Amd 1:2012, 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 following conditions:

NOTE 3 This represents IEC/TR 60721-4-7:2003, Classes 7M1 and 7M2[19].

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);

c) Confirm that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained following the tests.

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+Amd 1:2012, Clause 16 applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005+Amd 1:2012, 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.

Where an RGM is integral to another device (such as a lung ventilator) and any specific interfering gas cannot be present at the SAMPLING SITE, this may be stated in lieu of disclosure of quantitative effects.

Check compliance by inspecting the instructions for use.

Table 201.105 — Test GAS LEVELS of interfering gases and vapours

GAS LEVELS in % (VOLUME PERCENT)

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 with an intended SAMPLING SITE within the breathing system 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 connectors for DIVERTING RGMs

The exhaust port of a DIVERTING RGMs shall not be compatible with any of the small-bore connectors in the ISO 80369 series.

Check compliance by inspection and functional testing.

201.104 *Sampling flowrate

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

Check compliance by 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 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 inspection and by inspecting the design documentation.

201.106 FUNCTIONAL CONNECTION

201.106.1 General

BASIC SAFETY and ESSENTIAL PERFORMANCE shall be maintained if connections to the SIGNAL INPUT/OUTPUT PART of an RGM are disrupted or if the equipment connected to those parts fails.

Check compliance by functional testing.

201.106.2 *Connection to an electronic health record

An RGM should be equipped with a SIGNAL INPUT/OUTPUT PART that permits data transmission from the RGM to, for example, an electronic health record.

201.106.3 *Connection to a DISTRIBUTED ALARM SYSTEM

An RGM should be equipped with a SIGNAL INPUT/OUTPUT PART that permits connection to a DISTRIBUTED ALARM SYSTEM.

201.106.4 Connection for remote control

An RGM may be equipped with a SIGNAL INPUT/OUTPUT PART for connection for external control of an RGM.

201.106.5 *Connection to external medical device data interface

201.106.5.1General

An RGM should be equipped with a SIGNAL INPUT/OUTPUT PART that provides for the transmission of data between the RGM and other ME EQUIPMENT, medical devices or information/communication technology. The SIGNAL INPUT/OUTPUT PART data may be used for, but is not limited to, external decision support applications, control or data logging systems.

NOTE 1 The SIGNAL INPUT/OUTPUT PART may reside in another ME EQUIPMENT, medical device, or middleware residing locally or remotely.

NOTE 2 Annex CC provides information on data interface requirements.

201.106.5.2*Data transmitted or received

If a SIGNAL INPUT/OUTPUT PART is provided, the data transmitted or received should include:

a) Parameters and units of measurement (see Table CC.101);

b) RGM identification (see Table CC.102);

c) usage monitoring (see Table CC.103);

d) RGM settings, the RGM should permit the querying of all settings (see Table CC.104);

e) RGM configuration; the RGM should permit the querying of the configuration (see Table CC.105). The configuration refers to connected hardware that cannot be changed using the SIGNAL INPUT/OUTPUT PART;

f) RGM specifications; the RGM should permit the querying of all specifications (see Table CC.106). Settings refer to software settings that can be changed via the SIGNAL INPUT/OUTPUT PART;

g) RGM service monitoring indicators; an RGM should permit the querying of all service monitoring indicators (see Table CC.107);

h) if an ALARM SYSTEM is provided

   — the ALARM LIMITS;

   — the presence of any ALARM CONDITIONS;

   NOTE Examples of ALARM CONDITIONS include the SENSOR is not connected to the monitor, the SENSOR is not detected, detection of an artefact, no signal detected, low quality of signal, display error, device inoperative,

low battery, defective SENSOR or cable, unrecognized SENSOR, incompatible cable, interference, line frequency, ambient light interference, inadequate display.

— the occurrence of any ALARM SIGNAL inactivation.

The data transmission should be capable of being provided with an IT-NETWORK.

202 Electromagnetic disturbances — Requirements and tests

This clause only applies to stand-alone RGMs.

IEC 60601-1-2:2014 applies except as follows:

202.8.1 General

Amendment:

During and after non-transient electromagnetic (EM) phenomena (i.e. radiated RF EM fields, proximity fields from RADIO FREQUENCY (RF) wireless communications equipment, RATED power frequency magnetic fields, conducted disturbances induced by RF fields, and voltage dips) the ME EQUIPMENT shall meet BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE Examples of readily identifiable interferences are excessive noise on waveforms, and rapidly fluctuating numeric values, ALARM CONDITIONS, etc.

During transient EM phenomena (i.e. electrostatic discharge, electrical fast transients/bursts, surges, electrical transient conduction along supply lines and voltage interruptions) ME EQUIPMENT may show temporary degradation of MEASUREMENT ACCURACY or disruption of operation.

Within a maximum of 30 s (or shorter if the RISK MANAGEMENT FILE of the MANUFACTURER indicates otherwise) after transient and non-transient EM phenomena ME EQUIPMENT shall resume normal operation without loss of any OPERATOR settings or stored data and shall meet the MEASUREMENT ACCURACY limits.

Check compliance by testing and inspection of the RISK MANAGEMENT FILE.

206 Usability

IEC 60601-1-6:2010+Amd 1:2013 applies except as follows.

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

a) observing the GAS READING;

EXAMPLES FiO_2, CO_2, anaesthetic agent concentration.

b) setting ALARM LIMITS;

c) deactivating ALARM SIGNALS;

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

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

f) starting the RGM from power-off;

g) 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+Amd 1:2012 applies except as follows:

208.6.1.2 *Determination of ALARM CONDITIONS and assignment of priority

Amendment (add before the compliance test):

NOTE For the purposes of this document, 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.

For each respiratory gas that an RGM is designed to monitor, the RGM shall generate a LOW or MEDIUM PRIORITY TECHNICAL ALARM CONDITION if the RGM fails to measure the parameters specified.

The RGM shall generate a LOW PRIORITY TECHNICAL ALARM CONDITION if the RGM detects conditions that lead to a reduced MEASUREMENT ACCURACY.

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);

— 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 document.

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	

Table 201.106 *(continued)*

Row number	Gas reading	ALARM CONDITION priority for low GAS READING	ALARM CONDITION priority for high GAS READING
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 priorities. 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 or higher.

[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 PERCENT
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 document, 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.

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 (volume concentration in %) varies with altitude.

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.

208.6.6.2 Adjustable ALARM LIMIT

IEC 60601-1-8:2006+Amd 1:2012, 6.6.2 applies except as follows:

Additional subclause:

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 inspection and functional testing.

208.6.8.5 Indication and access

IEC 60601-1-8:2006+Amd 1:2012, 6.8.5 applies except as follows:

Additional subclause:

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.

211 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the HOME HEALTHCARE ENVIRONMENT

For RGMs intended for use in the HOME HEALTHCARE ENVIRONMENT, IEC 60601-1-11:2015 applies.

212 General requirements, tests and guidance for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS intended for use in the emergency medical services environment

For RGMs intended for use during professional transport outside healthcare facilities, IEC 60601-1-12:2014 applies.

The annexes of the general standard 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, its parts, and ACCESSORIES are found in Table 201.C.101.

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

Description of marking	Subclause
Follow "instructions for use" safety sign	201.7.2.3
Any special storage and/or handling requirements	201.7.2.101 a)
Serial number or lot identifying number or batch identifying number	201.7.2.101 b)
Proper disposal	201.7.2.101 c)
For an OPERATOR-interchangeable component that is flow-direction-sensitive, an arrow showing direction of gas flow	201.7.2.101 d)
RGM sampling gas inlet	201.7.2.101 e)
RGM sampling gas outlet	201.7.2.101 f)
SAMPLING TUBE	201.7.2.101 g)
Exhaust tube for a DIVERTING RGM	201.7.2.101 h)
For packages containing natural rubber latex, so indicated	201.7.2.17.101 a)
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)
If applicable for packaging, indicate sterile contents	201.7.2.17.101 a)
For packaging containing parts intended for single use, so indicated	201.7.2.17.101 b)
For parts or ACCESSORIES that contain phthalates, so indicated on part or packaging	201.11.6.4
If applicable, date after which it should not be used	201.7.2.101
For an ACCESSORY for single PATIENT use, so indicated on the ACCESSORY or package	201.7.2.4.101
If containing natural rubber latex, so indicated	201.7.2.13.101
If applicable, for a stand-alone RGM to be used in the MR environment, the appropriate symbol	201.7.2.101 i)

201.C.2 ACCOMPANYING DOCUMENTS, general

Additional requirements for general information to be included in the ACCOMPANYING DOCUMENTS of an RGM or its parts are found in Table 201.C.102.

Table 201.C.102 — General

Description of disclosure	Subclause
Operation of the RGM after the SUPPLY MAINS has been interrupted after 30 s	201.11.8.101.3

201.C.3 ACCOMPANYING DOCUMENTS, instructions for use

Additional requirements for information to be included in the instructions for use of an RGM or its parts are found in Table 201.C.103.

Table 201.C.103 — Instructions for use

Description of disclosure	Subclause
Level for respiratory GAS READING where display will stop	201.11.8.101.1 b)
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)
For an RGM without automatic compensation, the quantitative effect of barometric pressure on the GAS READING	201.7.9.2.1.101 c)
PROCEDURES for calibration before or during use	201.7.9.2.13.101 a)
Methods and frequency of routine inspection and testing	201.7.9.2.13.101 b)
Information, as regards toxicity and/or effect on tissues, about materials with which the PATIENT or any other person can come into contact	201.7.9.2.14.101 a)
Advice on the proper disposal of accumulated fluids	201.7.9.2.14.101 b)
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)
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)
If applicable, description of 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)
Method of verifying all OPERATOR-adjustable ALARM SYSTEM functions	201.7.9.2.8.101 a)
Time from start-up of the RGM to providing ESSENTIAL PERFORMANCE	201.7.9.2.8.101 b)
Range of adjustment of the ALARM LIMITS and the fixed limit for high inspired nitrous oxide ALARM CONDITION	201.7.9.2.9.101 a)

Table 201.C.103 *(continued)*

Description of disclosure	Subclause
Maximum specified interval between any necessary OPERATOR interventions to the water-handling system	201.7.9.2.9.101 b)
Detection threshold for halogenated anaesthetic gas(es) in a gas mixture	201.7.9.2.9.101 c)
If MAC GAS READINGS are provided, the MAC values or algorithms used	201.7.9.2.9.101 d)
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 sampled gas flowrates and their tolerances	201.7.9.2.9.101 f)
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)
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)
RATED respiration rate	201.7.9.2.9.101 i)
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)
Known adverse effects on stated performance	201.7.9.2.9.101 k)
For single use component information on characteristics and technical factors known to the MANUFACTURER that could pose a RISK if re-used	201.7.9.2.9.101 l)
Highest GAS LEVEL for a single halogenated anaesthetic gas in a gas mixture that is concealed when the anaesthetic concentration falls	201.7.9.2.9.101 m)
Temperature range where the operating conditions are met	201.7.9.2.9.101 n)
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
Processing and/or reprocessing instructions for the RGM and its ACCESSORIES	201.11.6.6
GAS READING range	201.12.1.101.1
MEASUREMENT ACCURACY	201.12.1.101.1
Minimum sample flowrate at which the DIVERTING RGM will meet MEASUREMENT ACCURACY specifications	201.12.1.101.1
For a DIVERTING RGM, the RISE TIME	201.12.1.102
Total system response time	201.12.1.102
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

Table 201.C.103 *(continued)*

Description of disclosure	Subclause
Warning to the effect that the RGM shall not be used with gas supplied from oxygen concentrators, if applicable	201.7.9.2.2.101
For an RGM that is equipped with A RESERVE ELECTRICAL POWER SOURCE, the conditions under which it shall operate normally for at least 30 min	201.11.8.101.4
If containing natural rubber latex, so indicated	201.7.2.13.101
Mode of operation (e.g. CONTINUOUS OPERATION)	201.15.101
Quantitative effects (if any) on GAS READINGS caused by interfering gases	201.101
The conditions under which the ALARM SYSTEM is activated	201.7.9.2.8101 c)

201.C.4 ACCOMPANYING DOCUMENTS, technical description

Additional requirements for information to be included in the technical description of an RGM or its parts are found in Table 201.C.104.

Table 201.C.104 — Technical description

Description of disclosure	Subclause
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)
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)

Annex D
(informative)
Symbols on marking

IEC 60601-1:2005+Amd 1:2012, Annex D *applies, except as follows:*

Addition:

Table 201.D.2.101 — Additional symbols on marking

No	Symbol	Reference	Title
1		ISO 7000:2014, 2607 ISO 15223-1:2016, 5.1.4	Use-by date
2		ISO 7000:2014, 2499 ISO 15223-1:2016, 5.2.1	Sterile
3		ISO 7000:2014, 2500 ISO 15223-1:2016, 5.2.2	Sterilized using aseptic PROCESSING techniques
4		ISO 7000:2014, 2501 ISO 15223-1:2016, 5.2.3	Sterilized using ethylene oxide
5		ISO 7000:2014, 2502 ISO 15223-1:2016, 5.2.4	Sterilized using irradiation

Table 201.D.2.101 *(continued)*

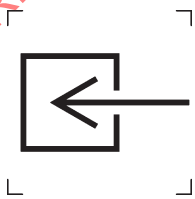
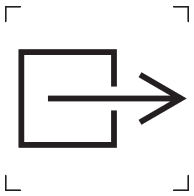
No	Symbol	Reference	Title
6		ISO 7000:2014, 2503 ISO 15223-1:2016, 5.2.5	Sterilized using steam or dry heat
7		ISO 7000:2014, 2492 ISO 15223-1:2016, 5.1.5	Batch code
8		ISO 7000:2014, 2493 ISO 15223-1:2016, 5.1.6	Catalogue number
9		ISO 7000:2014, 2498 ISO 15223-1:2016, 5.1.7	Serial number
10		ISO-7000:2014, 2725 ISO 15223-1:2016, 5.4.5	Contains, or presence of natural rubber latex
11		ISO 7000:2014, 0794	Input

Table 201.D.2.101 *(continued)*

No	Symbol	Reference	Title
12		ISO 7000:2014, 0795	Output
13		ISO-7000:2014, 2608 ISO 15223-1:2016, 5.2.6	Do not re-sterilize
14		ISO-7000:2014, 1051 ISO 15223-1:2016, 5.4.2	Do not re-use
15		option one IEC 62570:2014, 7.3.1	MR Safe
16		option two IEC 62570:2014, 7.3.1	MR Safe
17		IEC 62570:2014, 7.3.2	MR Conditional
EN 15986:2011 provides additional information for phthalate symbols.			

Annex AA
(informative)
Particular guidance and rationale

AA.1 General guidance

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationales 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 document necessitated by those developments.

AA.2 Rationale for particular clauses and subclauses

The numbering of the following rationales corresponds to the numbering of the subclauses in this document. The numbering is, therefore, not consecutive.

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 document 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.

201.4.3.101Additional 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 SAMPLING 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.

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 cleaning, compatibility with substances, biocompatibility and excessive temperature.

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.

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 document 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 necessary.

201.7.2.101Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT 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 when it is needed.

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.

201.7.9.2.2.101 Additional requirements for warnings and safety notices

The RISK of respiratory gas transporting microorganisms that could infect the next PATIENT is not obvious to all OPERATORS. If a DIVERTING RGM has insufficient protection against contamination by microorganisms 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.

In this subclause, a requirement has been added for the provision of a warning statement to the effect that the RGM shall not be used with gas supplied from oxygen concentrators if the accuracy of the RGM under use with Oxygen 93 cannot be maintained. This is of particular concern in rebreathing systems due to the accumulation of argon as a byproduct of oxygen concentrators.

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.

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. An RGM with a slower RISE TIME will not be able to reach that plateau value in the shortened expiratory time interval, resulting in an end-tidal GAS READING lower 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 document 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".

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.

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

The RISK of respiratory gas transporting microorganisms 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.

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.

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 therefore 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. A low sampling rate (as with a long 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.

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 onto 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).

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.

201.11.8.101.1 Supply failure TECHNICAL ALARM CONDITION

The requirements for MEASUREMENT ACCURACY in this document 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 power supply 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 power supply 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.

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+Amd 1:2012, settings are expected to be maintained during short losses of SUPPLY MAINS or automatic switchover.

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.

201.11.8.101.4 RESERVE ELECTRICAL POWER SOURCE (except for transport outside a healthcare facility)

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.

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.

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[25], 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[25].

> 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.

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

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.

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.

201.12.1.101.4.1 Calibration/Zeroing

A flat CO_2 curve may be interpreted by an OPERATOR as an incident with a PATIENT. Especially after an intubation or re-connection of a PATIENT this may lead to wrong therapy decisions. Thus it is essential to indicate when a flat CO_2 curve is based on a temporarily situation initiated by an RGM itself. Such a temporarily situation of an RGM may be caused when the RGM automatically calibrates or zeroes. But there may also be other device-specific situations where an RGM may be switched automatically to a state that disconnects the sample gas of the PATIENT from the PATIENT sampling port. Such states may also include e.g. switching the pneumatics of an RGM to ambient air or any other gas to check the correctness of measured values or to measure gas concentrations at a different location within a ventilator or a breathing system.

For all those situations where an RGM is not measuring the PATIENT's gas concentrations, an immediate information for the OPERATOR is required.

201.12.1.101.4.2 Suppression of an automatic calibration/zeroing

Rationale to list items a) and b): This circumstance can e.g. indicate an intubation or disconnection of the PATIENT, whereas GAS READINGS are immediately required afterwards to check the correctness of the pneumatic connection to the PATIENT. Additionally this circumstance can indicate breathing suppression of the PATIENT itself.

Rationale to the second paragraph: A high oxygen concentration can indicate a period of preoxygenation prior to intubation of the PATIENT in which case GAS READINGS are required immediately. Additionally a high oxygen concentration can indicate an emergency situation where GAS READINGS are constantly required.

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).

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 to 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.

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.

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.

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.

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.

201.103 Port connectors for DIVERTING RGMs

The Joint Working Group considered both the inlet and the exhaust ports of DIVERTING RGMs and decided to specify the exhaust port connector only as it was thought this was the greater area of RISK where the RGM could provide gas to a PATIENT and if wrongly connected could cause HARM. Although the exhaust port connector is not a specified connector it was felt important to make sure it did not interconnect with any of the small-bore connectors specified in the ISO 80369 series which includes Luer connectors (ISO 80369-7).

It was agreed that the inlet port connector should remain unspecified as it was agreed that this posed little RISK of HARM to the PATIENT especially as it is envisaged that the connection at the inlet of the RGM sample tubing would, in all probability, be changing to the R1 small-bore connector specified in ISO 80369-2 when this standard is published. It is also presumed that MANUFACTURERS that use a Luer connector at the inlet port will assess the RISK of HARM to the PATIENT should the sample tubing be misconnected to, for instance, an IV cannula.

201.104 Sampling flowrate

An 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 an inadequate sample flowrate.

201.105 Contamination of breathing systems

BASIC SAFETY of the PATIENT requires that a DIVERTING RGM does not introduce microorganisms 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 microorganisms coming through a DIVERTING RGM and back to the PATIENT if the sample gas is returned to the breathing system.

201.106.2 Connection to electronic health record

Electronic documentation of PATIENT care interventions is rapidly becoming the standard of care. The primary motivations are to improve the quality of care for an individual PATIENT through accurate and complete documentation and to improve the completeness and accuracy of aggregate data to facilitate continuous quality improvement.

201.106.3 Connection to a DISTRIBUTED ALARM SYSTEM

A DISTRIBUTED ALARM SYSTEM facilitates delivery of ALARM SIGNALS to other rooms where the OPERATOR might be located, thereby permitting a timely response and intervention to support PATIENT care.

201.106.5 Connection to external medical device data interface

The transmission of RGM data to other ME EQUIPMENT or ME SYSTEMS for purposes including decision support, control and data logging is problematic due the use of proprietary interfaces and protocols. It is the intent of this document, as a safety and performance standard, to define a minimum set of measured parameters, equipment identification parameters and equipment settings that should be available for transmission if the RGM is connected to an external medical device data interface. The standardization of a minimum set of parameters and settings allows greater interoperability between the RGM and external systems, thus enabling new applications and paradigms that can increase PATIENT safety and improve PATIENT care such as part of a PATIENT-controlled analgesia system.

It is not intended to define a specific device information model for device communication. The ISO/IEEE 11073 family of standards defines such models and includes requirements for specific devices; however, no models for an RGM exist at this time. Another approach divides the healthcare space into domains. One such domain, the IHE Patient Care Device (PCD) domain, through the use of existing standards such as HL7 and clinical language vocabularies such as the Logical Observation Identifiers Names and Codes (LOINC)[37] [38] [39], is described as providing a framework for integrating medical devices into the healthcare enterprise. This framework in combination with device-specific frameworks has defined transactions for the exchange of device observations sets with clinical information systems.

201.106.5.2 Data transmitted or received

An RGM in clinical use provides parameters, identification data, and settings through the SIGNAL INPUT/OUTPUT PART. However, that data has been transmitted primarily using proprietary interfaces and protocols. To help foster interoperability of RGMs increased standardization of this interface is desirable. This document has sought to logically categorize the data that may be transmitted or received as parameters, identification information, settings, configurations, specifications, service monitoring data and alarm data. In addition to these categories and types of data, MANUFACTURERS are encouraged to leverage the SIGNAL INPUT/OUTPUT PART to allow the RGM greater capabilities, including the use of intelligent algorithms that may reside in the RGM and which may adjust their algorithms or display settings based upon information received externally.

With the proliferation of RGMs with varying performance and features, it is becoming increasingly important for clinical care to determine the RGM's suitability for a particular clinical application. At the moment, this is solely determined by caregivers based on their knowledge of the equipment and requirements of the application. Given that the requirements for an application such as closed loop control (whether it be autonomous or with a clinician providing the titration) depends on device specifics such as averaging time, accuracy of the SENSOR, time response and delays, the determination of applicability of the device can be challenging for the average caregiver. However, if the RGM provides this information through the SIGNAL INPUT/OUTPUT PART, the determination of applicability can be made by querying the equipment settings, configuration and specifications.

208.6.1.2 Determination of ALARM CONDITIONS and assignment of priority

This document 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 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.