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
ISO 80601-2-55:2018(E)

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Published in Switzerland

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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*

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[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.