INTERNATIONAL STANDARD

ISO 80601-2-55

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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.

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

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

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

ISO 80601-2-55 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment,* Subcommittee SC 1, *Breathing attachments and anaesthetic machines* and IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC 62D, *Electromedical equipment*.

This first edition cancels and replaces ISO 21647:2004 and ISO 21647:2004/Cor.1:2005. This edition constitutes a minor technical revision and alignment with the third edition of IEC 60601-1.

ISO 80601 consists of the following parts, under the general title *Medical electrical equipment*:

— *Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*

— *Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

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

— *Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

— *Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment*

IEC 80601-2-30: *Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers,* IEC 80601-2-35: *Particular requirements for basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use,* IEC 80601-2-58: *Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery,* IEC 80601-2-59: *Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening* and IEC 80601-2-60: *Particular requirements for basic safety and essential performance of dental equipment* are published by IEC.

Introduction

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

— Requirements and definitions: roman type.

— *Test specifications: italic type*.

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

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

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

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

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

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

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

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

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

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

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

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

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

Medical electrical equipment —

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

1 Scope

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

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

This International Standard specifies requirements for

— anaesthetic gas monitoring,

— carbon dioxide monitoring, and

— oxygen monitoring.

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

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

Environmental aspects are addressed in Annex BB.

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

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

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

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

Replacement:

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

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

201.1.3 Collateral standards

Addition:

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

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Subclause 1.4 of the general standard is replaced by:

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

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

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

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

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

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

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

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

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

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

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

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

201.2 Normative references

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

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

Replacement:

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

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

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

Addition:

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

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

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

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

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

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

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

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

1) To be published.

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

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

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

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

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

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

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

201.3 Terms and definitions

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

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

Addition:

201.3.201
DIVERTING RGM
SIDESTREAM MONITOR
RGM that transports a portion of respiratory gases from the SAMPLING SITE through a SAMPLING TUBE to the SENSOR, which is remote from the SAMPLING SITE

201.3.202
DRIFT
change in the GAS READING of an RGM, for a given GAS LEVEL over a stated period of time, under reference conditions that remain constant

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

201.3.204
GAS READING
measured GAS LEVEL as displayed by the RGM

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

201.3.206
*** MINIMUM ALVEOLAR CONCENTRATION**
MAC
alveolar concentration of an inhaled anaesthetic agent that, in the absence of other anaesthetic agents and at equilibrium, prevents 50 % of subjects from moving in response to a standard surgical stimulus

NOTE For the purposes of this International Standard, MAC is calculated from the end-tidal GAS LEVEL.

201.3.207
NON-DIVERTING RGM
MAINSTREAM MONITOR
RGM that uses a SENSOR at the SAMPLING SITE

201.3.208
PARTIAL PRESSURE
pressure that each gas in a gas mixture would exert if it alone occupied the volume of the mixture at the same temperature

201.3.209
RESERVE ELECTRICAL POWER SOURCE
part of the ME EQUIPMENT that temporarily supplies power to the electrical system in the event of an interruption of the primary electrical supply

201.3.210
RGM
RESPIRATORY GAS MONITOR
ME EQUIPMENT intended to measure the GAS LEVEL or PARTIAL PRESSURE of one or more gases in respiratory gas

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

201.3.211
SAMPLING SITE
location of the SENSOR for a NON-DIVERTING RGM or location at which respiratory gases are diverted for measurement to a remote SENSOR for a DIVERTING RGM

201.3.212
SAMPLING TUBE
conduit for the transfer of gas from the SAMPLING SITE to the SENSOR in a DIVERTING RGM

201.3.213
SENSOR
part of the RGM that is sensitive to the presence of the respiratory gas

201.3.214
TOTAL SYSTEM RESPONSE TIME
time from a step function change in GAS LEVEL at the SAMPLING SITE to the achievement of 90 % of the final GAS READING of the RGM

201.3.215
VOLUME FRACTION
volume of a gas in a mixture, expressed as a percentage of the total volume

201.4 General requirements

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

201.4.3 ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 * Additional requirements for ESSENTIAL PERFORMANCE

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

Table 201.101 — Distributed ESSENTIAL PERFORMANCE requirements

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

201.4.3.102 Additional requirements for acceptance criteria

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

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

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

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

Addition:

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

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

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

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

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

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

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

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

201.5 General requirements for testing ME EQUIPMENT

IEC 60601-1:2005, Clause 5 applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1:2005, Clause 6 applies.

201.7 ME EQUIPMENT identification, marking and documents

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

201.7.2.3 * Consult ACCOMPANYING DOCUMENTS

Replacement:

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

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

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

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

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

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

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

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

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

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

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

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

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

Check compliance by means of inspection.