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*

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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*

[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.

