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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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.