SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-55:2016

01-december-2016

Medicinska električna oprema - 2-55. del: Posebne zahteve za osnovno varnost in bistvene lastnosti monitorjev dihalnih plinov (ISO/DIS 80601-2-55:2016)

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO/DIS 80601-2-55:2016)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO/DIS 80601-2-55:2016)

Appareils électromédicaux -- Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO/DIS 80601-2-55:2016)

Ta slovenski standard je istoveten z: **prEN ISO 80601-2-55**

ICS:

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment

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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

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

This draft is submitted to a parallel vote in ISO and in IEC.

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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 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.

The committee responsible for this document is 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 of ISO 80601-2-55 cancels and replaces the first edition of ISO 80601-2-55:2011. This edition of ISO 80601-2-55 constitutes a technical revision of ISO 80601-2-55:2011 and includes the following technical modifications:

— amendments following the publication of IEC 60601-1-12 (Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment) that resulted in the deletion of additional requirements on respiratory gas monitors for use during professional transport of a patient outside a healthcare facility because these are now covered by IEC 60601-1-12;

— amendment of requirements on marking, warning and safety notices as well as accompanying documents, in part due to the publication of the amendment 1:2012 to IEC 60601-1:2005;

— revision of 201.11.6.5 – ingress of water or particulate matter into equipment – and 201.15.3.5 - shock and vibration – in order to distinguish between requirements on stand-alone respiratory gas monitors and requirements on respiratory gas monitors that are incorporated into another medical electrical equipment;

— inclusion of ISO 80369-2 - Connectors for breathing systems and driving gases applications – as the normative reference for the port connector for diverting respiratory gas monitors;

— addition of a new subclause 201.106 on functional connection accompanied by the related rationale and informative annex on data interface requirements;

— revision of Clause 202 on electromagnetic disturbances based on the new edition of IEC 60601-1-2:2014;

— revision of Clause 208 on alarms by taking into consideration the amendment 1:2012 to IEC 60601-1-8:2006;

— exclusion of IEC 60601-1-9 - Collateral Standard: Requirements for environmentally conscious design;

— deletion of the informative Annex BB on environmental aspects

— addition of requirements on calibration/zeoring.

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 for medical use*

— *Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment*

— *Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment*

— *Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment*

— *Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients*

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

— *Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers*

— *Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

— *Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery*

— *Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening*

209 — *Part 2-60: Particular requirements for basic safety and essential performance of dental equipment*

210 — *Part 2-71: Particular requirements for the basic safety and essential performance of functional Near-*
211 *Infrared Spectroscopy (NIRS) equipment*

212 The ISO and IEC 80601 family of standards are also parts of the IEC 60601 family of standards.

213 **European foreword**

214 The following referenced documents are indispensable for the application of this document. For undated
215 references, the latest edition of the referenced document (including any amendments) applies. For dated
216 references, only the edition cited applies. However, for any use of this standard within the meaning of
217 Annex ZA, the user should always check that any referenced document has not been superseded and that its
218 relevant contents can still be considered the generally acknowledged state-of-art.

219 When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative
220 reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC
221 standard, as listed below.

222 NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in
223 whole or in part) to which they apply.

224 **Table 1 — Correlation between normative references and dated EN and ISO standards**

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO
ISO 7000:2014	-	ISO 7000:2014
ISO 7010:2011	EN ISO 7010:2012	ISO 7010:2011
ISO 14937:2009	EN ISO 14937:2009	ISO 14937:2009
ISO 15223-1:2012	EN ISO 15223-1:2012	ISO 15223-1:2012
ISO 17664:2004	EN ISO 17664:2004	ISO 17664:2004
ISO 80601-2-13:2011+AMD1:2015	EN ISO 80601-2-13:2012[a]	ISO 80601-2-13:2011
ISO 80369-2:-[b]	ISO 80369-2:-[b]	ISO 80369-2:-[b]
IEC 60601-1:2005+AMD1:2012	EN 60601-1:2006 + Cor.:2010+ A1:2013	IEC 60601-1:2005+AMD1:2012
IEC 60601-1-2:2014	EN 60601-1-2:2015	IEC 60601-1-2:2014
IEC 60601-1-6:2010+AMD1:2013	EN 60601-1-6:2010 + A1:2015	IEC 60601-1-6:2010+AMD1:2013
IEC 60601-1-8:2006+AMD1:2012	EN 60601-1-8:2007 + Cor.:2010 + A1:2013	IEC 60601-1-8:2006+AMD1:2012
IEC 60601-1-11:2015	EN 60601-1-11:2015	IEC 60601-1-11:2015
IEC 60601-1-12:2014	EN 60601-1-12:2015	IEC 60601-1-12:2014
IEC 60068-2-27:2008	EN 60068-2-27:2009	IEC 60068-2-27:2008
IEC 60068-2-64:2008	EN 60068-2-64:2008	IEC 60068-2-64:2008
IEC 60529:1989+AMD1:1999 +AMD2:2013	EN 60529:1991+A1:2000 +A2:2013	IEC 60529:2001

[a] AMD1:2015 to ISO 80601-2-13 has not yet been adopted at European level.

[b] To be published.

Introduction

In this document, 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 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 Annex H of the ISO/IEC Directives, Part 2. 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.

The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations might 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 them for conducting new or revised tests. It is the recommendation of the committee that the content of this document not be adopted for mandatory implementation nationally earlier than three years from the date of publication for equipment newly designed and not earlier than five 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

201.1 Scope, object, and related standards

IEC 60601-1:2005+AMD1:2012, Clause 1 applies, except as follows:

201.1.1 * Scope

IEC 60601-1:2005+AMD1:2012, 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+AMD1:2012, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in IEC 60601–1:2005+AMD1:2012, 4.2.

201.1.2 Object

IEC 60601-1:2005+AMD1:2012, 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+AMD1:2012, 1.3 applies with the following addition:

This document refers to those applicable collateral standards that are listed in IEC 60601-1:2005+AMD1:2012, 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+AMD1:2013 do not apply.

201.1.4 Particular standards

IEC 60601-1:2005+AMD1:2012, 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+AMD1:2012 or the collateral standards.

For brevity, IEC 60601-1:2005+AMD1:2012 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+AMD1:2012 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+AMD1:2012 or the applicable collateral standard.

- "Amendment" means that the clause or subclause of IEC 60601-1:2005+AMD1:2012 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+AMD1:2012, 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+AMD1:2012 or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005+AMD1:2012 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.

NOTE Informative references are listed in the bibliography beginning on page 60.

IEC 60601-1:2005+AMD1:2012[1)], *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)], *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*
+Amendment 1:2013

IEC 60601-1-8:2006[3)], *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*
+Amendment 1:2012

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

ISO 80601-2-13:2011, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*
+Amendment 1:2015

ISO 80369-2:-[4)] *Small-bore connectors for liquids and gases in healthcare applications — Part 2: Connectors for breathing systems and driving gas applications*

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

1) There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

2) There exists a consolidated edition 3.1(2013) including IEC 60601-1-6:2010 and its Amendment 1:2013.

3) There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and its Amendment 1:2012.

4) To be published.