ELEKTRILISED MEDITSIINISEADMED. OSA 2-55: ERINÕUDED HINGAMISGAASIDE MONITORI ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018 + ISO 80601-2-55:2018/Amd 1:2023)

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-55:2018 +A1:2023 sisaldab Euroopa standardi EN ISO 80601-2-55:2018 ja selle muudatuse A1:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-55:2018+A1:2023 consists of the English text of the European standard EN ISO 80601-2-55:2018 and its amendment A1:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.02.2018, muudatus A1 13.12.2023.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 28.02.2018, for A1 13.12.2023.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] [A1].	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags [A1] [A1].
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-55 + A1

February 2018, December 2023

ICS 11.040.10

Supersedes EN ISO 80601-2-55:2011

English Version

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018 + ISO 80601-2-55:2018/Amd 1:2023)

Appareils électromédicaux - Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO 80601-2-55:2018 + ISO 80601-2-55:2018/Amd 1:2023)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO 80601-2-55:2018 + ISO 80601-2-55:2018/Amd 1:2023)

This European Standard was approved by CEN on 18 January 2018. Amendment A1 was approved by CEN on 6 June 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendment the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard and its Amendment A1 exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 80601-2-55:2018 E
+ EN ISO 80601-2-55:2018/A1:2023 E

European foreword

This document (EN ISO 80601-2-55:2018) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2018, and conflicting national standards shall be withdrawn at the latest by August 2021.

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

This document supersedes EN ISO 80601-2-55:2011.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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

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

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

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

Normative references as listed in 201.2	Equivalent dated International 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 15223-1:2016, corrected version 2017	EN ISO 15223-1:2016	ISO 15223-1:2016, corrected version 2017
ISO 17664:2004	EN ISO 17664:2004	ISO 17664:2004
ISO 80601-2-13:2011 + Amd 1:2015 and Amd 2:—[a]	EN ISO 80601-2-13:2012[a] + Amd 1: — and Amd 2:—[a]	ISO 80601-2-13:2011 + Amd 1:2015 and Amd 2:—[a]
ISO 80369-1: 2010[b]	EN ISO 80369-1:2010[b]	ISO 80369-1:2010[b]
ISO 80369-2[a]	EN ISO 80369-2:-[a]	ISO 80369-2[a]
ISO 80369-3	EN ISO 80369-3:2016	ISO 80369-3:2016
IEC 80369-5	EN ISO 80369-5:2016	IEC 80369-5:2016
ISO 80369-6	EN ISO 80369-6:2016	ISO 80369-6:2016
ISO 80369-7	EN ISO 80369-7:2017	ISO 80369-7:2017
ISO 80369-20	EN ISO 80369-20:2015	ISO 80369-20:2015
IEC 60601-1:2005 + Amd 1:2012	EN 60601-1:2006 + Cor:2010 and + Amd 1:2013	IEC 60601-1:2005 + Amd 1:2012
IEC 60601-1-2:2014	EN 60601-1-2:2015	IEC 60601-1-2:2014
IEC 60601-1-6:2010 + Amd 1:2013	EN 60601-1-6:2010 + Amd 1:2015	IEC 60601-1-6:2010 + Amd 1:2013
IEC 60601-1-8:2006 + Amd 1:2012	EN 60601-1-8:2007 + Cor:2010 and Amd 1:2013	IEC 60601-1-8:2006 + Amd 1:2012
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 + Amd 1:1999 and Amd 2:2013	EN 60529:1991 + Amd 1:2000 and Amd 2:2013	IEC 60529:2001

[a] To be published.

[b] Under revision.

Endorsement notice

The text of ISO 80601-2-55:2018 has been approved by CEN as EN ISO 80601-2-55:2018 without any modification.

A1 Amendment A1 European foreword

This document (EN ISO 80601-2-55:2018/A1:2023) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This Amendment to the European Standard EN ISO 80601-2-55:2018 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

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

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-55:2018/Amd 1:2023 has been approved by CEN as EN ISO 80601-2-55:2018/A1:2023 without any modification. A1

Contents

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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.

Amendment A1 foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 or www.iec.ch/members_experts/refdocs).

ISO and IEC draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO and IEC take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO and IEC had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents and https://patents.iec.ch. ISO and IEC shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of 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 www.iso.org/iso/foreword.html. In the IEC, see www.iec.ch/understanding-standards.

This document was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 1, *Breathing attachments and anaesthetic machines,* in collaboration with Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*, and with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO/IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

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 this 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

〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, Clause 1 applies, except as follows:

201.1.1 *Scope

〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, 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 〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, 7.2.13 and 8.4.1.

NOTE 2 Additional information can be found in 〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, 4.2.

201.1.2 Object

〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, 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

〈A1〉 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 〈A1〉, 1.3 applies with the following addition:

This document refers to those applicable collateral standards that are listed in [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1], 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

[A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1], 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 [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] or the collateral standards.

For brevity, [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] 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 [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] 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 [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] or the applicable collateral standard.

— "Amendment" means that the clause or subclause of [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] 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 [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1], 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 [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] or the applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of [A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1] 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.

[A1] IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 [A1], Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2014+Amd 1:2020, *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+Amd 1:2013+Amd 2:2020, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, *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[1], *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:—[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*

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

IEC 60529:1989[3]+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+Amd 1:2020, *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*

[1] Under revision.

[2] To be published. Stage at time of publication ISO 80601-2-13:2011+DAmd 2:2017.

[3] 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.

IEC 62570:2014, *Standard practice for marking medical devices and other items for safety in the magnetic resonance environment*

201.3 Terms and definitions

〈A1〉 For the purpose of this document, the terms and definitions given in IEC 60601-1:2005+Amd 1:2012+Amd 2:2020, IEC 60601-1-2, IEC 60601-1-6:2010+Amd 1:2013+Amd 2:2020, IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020, IEC 60601-1-11, IEC 60601-1-12 and ISO 80601-2-13:2011+Amd 1:2015 and the following apply. 〈A1〉

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

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

