



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN ISO 80601-2-55:2018+A1:2023. It is identical to ISO 80601-2-55:2018, incorporating amendment 1:2023. It supersedes BS EN ISO 80601-2-55:2018, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to ISO text carry the number of the ISO amendment. For example, text altered by ISO amendment 1 is indicated by A1 A1.

The UK participation in its preparation was entrusted to Technical Committee CH/121/1, Breathing attachments and anaesthetic machines.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at www.bsigroup.com/standardsandregulation.

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UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of www.gov.uk.

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Amendments/corrigenda issued since publication

Date	Text affected
31 December 2023	Implementation of ISO amendment 1:2023 with CEN endorsement A1:2023. National foreword updated.

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)**

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)

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

This European Standard was approved by CEN on 18 January 2018.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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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.

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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.

European foreword to amendment A1

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.

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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.

Annex ZA (informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

**Table ZA.1 — Correspondence between this European Standard
and Annex I of Directive 93/42/EEC [OJ L 169]**

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.3	201.11.6.4	Only the first sentence relating to design is partially addressed as follows: - only normal use is addressed; - only leaking or leaching of substances is addressed.
7.6	201.11.6.5	only addressed with regard to - ingress of water or particulate matter and only addressed for normal use.

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
8.1	201.11.6.6, 201.105	Only addressed as far as contamination resulting from reverse flow through the sampling tube and return flow. Easy handling and manufacturing are not addressed.
8.7	201.7.2.17.101	
9.1	201.7.2.101 d), e), f), g), h), 201.103	Only addressed by marking <ul style="list-style-type: none"> – of the gas sampling gas inlet and outlet including the related tubes – of flow-direction-sensitive components that are operator-interchangeable
9.2	201.101, 202, 206	Covered for the effects of interfering gases and vapours, electromagnetic disturbances and usability.
10.1	201.12.1, 201.101	
10.2	201.12.1.103, 201.12.1.104, 206	Covered for the indication of units of measures for gas readings, or indication of the operating mode and for usability.
10.3	201.7.4.3	
12.2	201.11.8.101	
12.3	201.11.8.101	
12.4	208	
12.5	202	Covered with respect to electromagnetic disturbances
12.7.4	201.103	Covered for the risk of misconnecting the exhaust port of a diverting RGM
12.8.2	201.104	Only the first sentence of

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
		ER 12.8.2 is covered
12.9	201.7, 201.12.1, 206	
13.2	201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	<p>Covered with regard to</p> <ul style="list-style-type: none"> – marking of the equipment with the safety sign “Follow instructions for use” – marking of the equipment, parts or accessories with the symbol for presence of latex, if applicable, and with the symbol for serial or lot number, for gas inlet or outlet, with the appropriate symbol indicating the possible use in the magnetic resonance environment, and with the symbol for the use-by-date – marking of the protective packaging of equipment, parts or accessories with the symbol for serial, type or batch number, and if applicable, for presence of latex, for sterile conditions, and for single use <p>Except for the requirement on marking with the safety sign “Follow instructions for use” all other requirements on marking with symbols are included as alternatives to corresponding requirements on marking using text elements</p>
13.3 b)	201.7.2.17.101 a) first dash	Covered for marking of the packages of the equipment, parts or accessories with a description of the content

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
13.3 c)	201.7.2.17.101, a) 4th dash	Covered for marking of the packages of the equipment, parts or accessories with text or symbol indicating sterile conditions, if applicable
13.3 d)	201.7.2.17.101, 201.7.2.101	Is only covered if the batch number is preceded by the word LOT
13.3 e)	201.7.2.101, last paragraph	
13.3 f)	201.7.2.4.101, 201.7.2.17.101 b)	Distinction between “single use” and “single-patient use” taken into account
13.3 i)	201.7.2.101 a)	
13.4	201.7.9.2.1.101 a), 201.7.2.17.101, 201.7.2.101	
13.5	201.7.2.17.101 a), 201.7.2.101 b)	Is only covered if the batch number is preceded by the word LOT
13.6 d)	201.7.9.2.8.101 a), 201.7.9.2.13.101	Covered for instructions for procedures for calibration before and during use including methods and frequency of routine inspection and testing. Covered for verifying alarms.
13.6 f)	201.7.9.2.9.101 g)	Covered for indication if the equipment is suitable for use in a magnetic resonance imaging environment
13.6 h)	201.7.9.2.9.101 l)	Covered with regard to information on characteristics and technical factors known to the manufacturer that could pose a risk if equipment, parts or accessories, that intended for single use, were re-used

Essential requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
13.6 n)	201.7.9.2.15.101	covered for the disposal of calibration gas and sampled gas
13.6 p)	201.12.1.101.1	

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC, the following Table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than essential requirements of Directive 93/42/EEC along with the corresponding clauses of this document. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

Table ZA.2 — Relevant Essential Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Essential health and safety requirements of Directive 2006/42/EC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
1.2.2	201.12.1, 201.12.1.104, 206	Only the parts of EHSR 1.2.2 relevant to the RGM are addressed
1.5.4	201.7.2.101 d), 201.7.2.101 e), 201.7.2.101 f), 201.7.2.101 g), 201.7.2.101 h), i), 201.103, 201.105	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

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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 **A1** IEC 60601-1-2:2014+Amd 1:2020 **A1**;
- Clause 208 has been updated to align with **A1** IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020 **A1**;
- 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+Amd 2:2020 ^{A1}, Clause 1 applies, except as follows:

201.1.1 *Scope

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 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 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 ^{A1}, 4.2.

201.1.2 Object

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

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 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

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

For brevity, 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 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 IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 A1 or the applicable collateral standard.
- “Amendment” means that the clause or subclause of 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 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 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

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:

■^{A1} IEC 60601-1-2:2014+Amd 1:2020 ■^{A1}, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic disturbances — Requirements and tests*

■^{A1} IEC 60601-1-6:2010+Amd 1:2013+Amd 2:2020 ■^{A1}, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

■^{A1} IEC 60601-1-8:2006+Amd 1:2012+Amd 2:2020 ■^{A1}, *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 17664:2004¹, *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*

¹ Under revision.

² 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 60529:1989³+Amd 1:1999 and Amd 2:2013, *Degrees of protection provided by enclosures (IP code)*

Ⓐ IEC 60601-1-11:2015+Amd 1:2020 Ⓐ, *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*

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

201.3 Terms and definitions

Ⓐ 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. Ⓐ

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

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.

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

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

RESPIRATORY GAS MONITOR

RGM

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

Note 1 to entry: 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 port.

201.3.211

RISE TIME

RT

time taken for a value to rise from 10 % to 90 % of the indicated reading

[SOURCE: ISO 23747:2015, 3.9, modified — replaced “achieved PEF (peak expiratory flowrate)” by “indicated reading” and “flowrate” by “a value”.]

201.3.212

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

201.3.213

SAMPLING TUBE

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

201.3.214

SENSOR

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

201.3.215

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

201.3.216

VOLUME PERCENT

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

201.4 General requirements

IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 ^{A1}, Clause 4 applies, except as follows:

201.4.3 ESSENTIAL PERFORMANCE

IEC 60601-1:2005+Amd 1:2012+Amd 2:2020 ^{A1}, 4.3 applies, except as follows:

Additional subclause:

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 ALARM CONDITION for the GAS READING	201.12.1.101
or generation of a TECHNICAL ALARM CONDITION	201.11.8.101.1, 208.6.1.2
^a Methods of evaluating MEASUREMENT ACCURACY as acceptance criteria following specific tests required by this document are found in 202.8.1.	

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

Amendment (add at end of 4.6 prior to the compliance check):

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.