

Equipos electromédicos. Parte 2-55: Requisitos particulares para la seguridad básica y el funcionamiento esencial de los monitores de gas respiratorio (ISO 80601-2-55:2018) (Ratificada por la Asociación Española de Normalización en abril de 2018.)

UNE-EN ISO 80601-2-55:2018

Equipos electromédicos. Parte 2-55: Requisitos particulares para la seguridad básica y el funcionamiento esencial de los monitores de gas respiratorio (ISO 80601-2-55:2018) (Ratificada por la Asociación Española de Normalización en abril de 2018.)

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018) (Endorsed by Asociación Española de Normalización in April of 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) (Entérinée par l'Asociación Española de Normalización en avril 2018.)

En cumplimiento del punto 11.2.5.4 de las Reglas Internas de CEN/CENELEC Parte 2, se ha otorgado el rango de documento normativo español UNE al documento normativo europeo EN ISO 80601-2-55:2018 (Fecha de disponibilidad 2018-02-28)

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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.

This European Standard exists 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, 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
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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.

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.

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 – 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, for 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