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)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-55:2018 sisaldab Euroopa standardi EN ISO 80601-2-55:2018 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-55:2018 consists of the English text of the European standard EN ISO 80601-2-55:2018.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 28.02.2018.	Date of Availability of the European standard is 28.02.2018.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

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EUROPEAN STANDARD

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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.

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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.

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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

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	Covered with regard to – 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 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
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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