Elektrilised meditsiiniseadmed. Osa 2-55: Erinõuded hingamisgaaside monitori esmasele ohutusele ja olulistele toimimisnäitajatele (ISO 80601-2-55:2011)

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-55:2011 sisaldab Euroopa standardi EN ISO 80601-2-55:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-55:2011 consists of the English text of the European standard EN ISO 80601-2-55:2011.
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 15.12.2011.	Date of Availability of the European standard is 15.12.2011.
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.

ICS 11.040.10

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 80601-2-55

December 2011

ICS 11.040.10

Supersedes EN ISO 21647:2009

English Version

Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)

Appareils électromédicaux - Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires (ISO 80601-2-55:2011)

Medizinische elektrische Geräte - Teil 2-55: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Überwachungsgeräten für Atemgase (ISO 80601-2-55:2011)

This European Standard was approved by CEN on 2 December 2011.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 80601-2-55:2011: E

Foreword

This document (EN ISO 80601-2-55:2011) 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 June 2012, and conflicting national standards shall be withdrawn at the latest by December 2014.

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

This document supersedes EN ISO 21647:2009.

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.

For relationship with EU Directive, 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-55:2011 has been approved by CEN as a EN ISO 80601-2-55:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This International Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means to conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive).

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11.6.4 to 201.11.6.6	7.2	Only the parts of ER 7.2 relating to safety in use for the patient are addressed
201.11.6.4, 201.11.6.8	7.3	Only the part of the first sentence relating to design is addressed
201.11.6.4	7.5	
201.11.6.5, 201.101	7.6	
201.11.6.6, 201.11.6.7 , 201.105	8.1	The part of ER 8.1 relating to easy handling is not addressed
201.11.6.7	8.4	Validated processes for sterilization are required via the normative references to ISO 11134, ISO 11135, ISO 11137
201.7.2.17.101	8.7	
201.7.2.101, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.12.1.102, 201.102, 201.103, 208	9.1	
201.9, 201.101, 202, 206	9.2	The 4th indent of ER 9.2 is not addressed

Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.11	9.3	
201.12.1, 201.101	10.1	
201.7, 201.12.1.103, 201.12.1.104, 206, 208	10.2	
201.7.4.3	10.3	
201.10	11.1.1	
202	11.3.1	
201.14	12.1	
201.14	12.1 a)	
201.11.8.101, 208	12.2	
201.11.8.101, 208	12.3	
208	12.4	
202	12.5	
201.8	12.6	
201.9	12.7.1	
201.9	12.7.2	
201.9	12.7.3	
201.8, 201.15, 201.103	12.7.4	
201.11	12.7.5	
201.104	12.8.2	Only the first sentence of ER 12.8.2 is covered
201.7, 201.12.1, 206	12.9	
201.7, 201.7.2.4.101, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.1	
201.7, 201.7.2.3, 201.7.2.13.101, 201.7.2.17.101, 201.7.2.101	13.2	
201.7.9.1	13.3 a)	
201.7, 201.7.2.17.101, 201.7.2.101	13.3 b)	
201.7, 201.7.2.17.101	13.3 c)	
201.7.2.17.101, 201.7.2.101	13.3 d)	Is only covered if the batch number is preceded by the word LOT
201.7.2.101	13.3 e)	
201.7.2.4.101, 201.7.2.17.101 b)	13.3 f)	Distinction between “single use“ and “single-patient use” taken into account
201.7.2.101 a)	13.3 i)	
201.7, 201.7.2	13.3 j)	

Table ZA.1 (*continued*)

Clause(s)/subclause(s) of this European Standard	Essential requirements (ERs) of EU Directive 93/42/EEC	Qualifying remarks/Notes
201.7, 201.7.9.2.2.101	13.3 k)	
201.7, 201.7.2.17 a)	13.3 m)	Presumption of conformity is only provided if symbols 5.21 to 5.24 are utilized
201.7.9.2.1.101 a), 201.7.2.17.101, 201.7.2.101	13.4	
201.7.2.17.101 a), 201.7.2.101 b)	13.5	Is only covered if the batch number is preceded by the word LOT
201.7, 201.7.9.1, 201.7.9.2.1.101, 201.7.9.2.2.101	13.6 a)	
201.7, 201.7.9.2.1.101, 201.7.9.2.2.101, 201.7.9.2.9.101 c), 201.7.9.2.9.101 d)	13.6 b)	
201.7, 201.7.9.2.2.101, 201.7.9.2.5.101, 201.7.9.2.9.101 e)	13.6 c)	
201.7, 201.7.9.2.13.101	13.6 d)	
201.7, 201.7.9.2.9.101 g), , 201.7.9.2.9.101 k)	13.6 f)	
201.7.9.2.14.101 b)	13.6 g)	
201.7, 201.7.9.2.9.101 l) , 201.7.9.2.14.101 b)	13.6 h)	
201.7	13.6 i)	
201.7.9.2.1.101 c)	13.6 j)	
201.7	13.6 k)	
201.7	13.6 l)	
201.7, 201.7.9.2.14.101 c), 201.7.9.2.15.101	13.6 n)	
201.12.1.101.1	13.6 p)	
201.7.9.2.9.101 m)	13.6 q)	

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 International Standard. 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)

Clause(s)/subclause(s) of this European Standard	Essential health and safety requirements (ERs) of EU Directive 2006/42/EC	Qualifying remarks/Notes
201.7, 201.12.1	1.1.4	Only the first sentence of EHSR 1.1.4 is addressed
201.12.1, 201.12.1.104, 206, 208.6.5.1, 208.6.6.2.101	1.2.2	Only the parts of EHST 1.2.2 relevant to the RGM are addressed
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), 201.103, 201.105	1.5.4	
201.7	1.6.2	
201.8	1.6.3	
201.7, 201.7.2.101 i)	3.6.2	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

Contents

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Introduction

In this International Standard, 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 PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this International Standard, the term

— "clause" means one of the 17 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— "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 International Standard are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular standard are by number only.

In this International Standard, 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 International Standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— "shall" means that compliance with a requirement or a test is mandatory for compliance with this standard;

— "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— "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 a 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 may 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 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 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

1 Scope

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

This International Standard 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 International Standard specifies requirements for

— anaesthetic gas monitoring,

— carbon dioxide monitoring, and

— oxygen monitoring.

NOTE 1 An RGM can be either standalone ME EQUIPMENT or integrated into other equipment, e.g. an anaesthetic workstation or a ventilator.

This International Standard is not applicable to an RGM intended for use with flammable anaesthetic agents.

Environmental aspects are addressed in Annex BB.

NOTE 2 Additional aspects of environmental impact are addressed in ISO 14971 and IEC 60601-1-9.

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 standard are not covered by specific requirements in this particular standard, except in 7.2.13 and 8.4.1 of the general standard (IEC 60601-1).

NOTE 3 See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard 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

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-3 does not apply.

201.1.4 Particular standards

Subclause 1.4 of the general standard is replaced by:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this particular standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2:2007 collateral standard, 206.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-6:2010 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 the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which 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 which 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 60601-1-2:2007, 203 for IEC 60601-1-3:2008, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding section, clause or subclause in this particular standard, the section, clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

The following referenced documents are indispensable for the application 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.

IEC 60601-1:2005, Clause 2 applies, except as follows:

Replacement:

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility — Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-8:2006, *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 7000:2004, *Graphical symbols for use on equipment — Index and synopsis*

ISO 7010:2011, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

ISO 14937, *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:—[1)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*
Amendment 1:2008

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

ISO 80369-1:2010, *Small-bore connectors for liquids and gases in healthcare applications — Part 1: General requirements*

ISO/IEC 80601-2-13:2011 [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) To be published.

2) Cancels and replaces ISO 8835-2:2007, ISO 8835-3:2007, ISO 8835-4:2004, ISO 8835-5:2004 and IEC 60601-2-13:2003.

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment type specimens*

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

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*
Corrigendum 1:2003
Corrigendum 2:2007
Corrigendum 3:2009

IEC 60601-1-9:2007, *Medical electrical equipment — Part 1-9: General requirements for basic safety and essential performance — Collateral Standard: Requirements for environmentally conscious design*

IEC 60601-1-10:2007, *Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

IEC 60601-1-11:2010, *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*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006, IEC 60601-1-11:2010 and ISO/IEC 80601-2-13:2011 apply, except as follows:

NOTE An alphabetized index of defined terms is found beginning on page 50.

Addition:

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

