



# SLOVENSKI STANDARD

## SIST EN ISO 80601-2-55:2013

01-november-2013

Nadomešča:  
SIST EN ISO 21647:2009

---

**Medicinska električna oprema - 2-55. del: Posebne zahteve za osnovno varnost in bistvene lastnosti monitorjev dihalnih plinov (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)

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

**Ta slovenski standard je istoveten z: EN ISO 80601-2-55:2011**

**ICS:**

11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
-----------	--	--

**SIST EN ISO 80601-2-55:2013** en

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>

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**

<b>Contents</b>	<b>Page</b>
<b>Foreword</b> .....	<b>3</b>
<b>Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC</b> .....	<b>4</b>

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)  
<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>

## 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.

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c4/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c4/sist-en-iso-80601-2-55-2013>

### 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 4 <sup>th</sup> 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)	

## EN ISO 80601-2-55:2011 (E)

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 EHRS 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	

SIST EN ISO 80601-2-55:2013

<https://standards.itech.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-cccc70d744c/sist-en-iso-80601-2-55-2013>

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

**iTeh STANDARD PREVIEW**  
**(standards.iteh.ai)**

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>

INTERNATIONAL  
STANDARD

ISO  
80601-2-55

First edition  
2011-12-15

---

---

**Medical electrical equipment —**  
**Part 2-55:**  
**Particular requirements for the basic**  
**safety and essential performance of**  
**respiratory gas monitors**

iTeh STANDARD PREVIEW

*Appareils électromédicaux —*

*(Partie 2-55: Exigences particulières relatives à la sécurité de base et aux performances essentielles des moniteurs de gaz respiratoires*

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>

---

---

Reference number  
ISO 80601-2-55:2011(E)



## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>



### **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2011

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
Case postale 56 • CH-1211 Geneva 20  
Tel. + 41 22 749 01 11  
Fax + 41 22 749 09 47  
E-mail [copyright@iso.org](mailto:copyright@iso.org)  
Web [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

Page

Foreword .....	vi
Introduction.....	vii
<b>1 Scope .....</b>	<b>1</b>
<b>201.1 Scope, object and related standards.....</b>	<b>1</b>
201.1. 1 * Scope .....	1
201.1. 2 Object.....	2
201.1. 3 Collateral standards .....	2
201.1. 4 Particular standards .....	2
<b>201.2 Normative references .....</b>	<b>3</b>
<b>201.3 Terms and definitions .....</b>	<b>4</b>
<b>201.4 General requirements .....</b>	<b>6</b>
201.4. 3 ESSENTIAL PERFORMANCE .....	6
201.4. 3.101 * Additional requirements for ESSENTIAL PERFORMANCE .....	6
201.4. 3.102 Additional requirements for acceptance criteria .....	6
201.4. 6 * ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT .....	6
201.4.10.2.101 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS .....	6
<b>201.5 General requirements for testing ME EQUIPMENT .....</b>	<b>7</b>
<b>201.6 Classification of ME EQUIPMENT and ME SYSTEMS.....</b>	<b>7</b>
<b>201.7 ME EQUIPMENT identification, marking and documents .....</b>	<b>7</b>
201.7. 2.3 * Consult ACCOMPANYING DOCUMENTS.....	7
201.7. 2.101 * Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts .....	7
201.7. 2.4.101 Additional requirements for ACCESSORIES .....	8
201.7. 2.13.101 * Additional requirements for physiological effects (safety signs and warning statements) .....	8
201.7. 2.17.101 Additional requirements for protective packaging .....	8
201.7. 4.3 Unit of measure .....	8
201.7. 9.1 General requirements .....	9
201.7. 9.2.1.101 * Additional general requirements .....	9
201.7. 9.2.2.101 * Additional requirements for warnings and safety notices .....	9
201.7. 9.2.5.101 Additional requirements for ME EQUIPMENT description .....	10
201.7. 9.2.8.101 * Additional requirements for start-up procedure.....	10
201.7. 9.2.9.101* Additional requirements for operating instructions .....	10
201.7. 9.2.13.101 * Additional requirements for maintenance.....	11
201.7. 9.2.14.101 * Additional requirements for ACCESSORIES, supplementary equipment, used material .....	11
201.7. 9.2.15.101* Additional requirements for environmental protection .....	11
201.7. 9.3.101 * Additional requirements for technical description.....	12
<b>201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....</b>	<b>12</b>
<b>201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....</b>	<b>12</b>
<b>201.10 Protection against unwanted and excessive radiation HAZARDS .....</b>	<b>12</b>
<b>201.11 Protection against excessive temperatures and other HAZARDS .....</b>	<b>12</b>
201.11. 6.4 Leakage .....	12
201.11. 6.5 * Ingress of water or particulate matter into ME EQUIPMENT or ME SYSTEMS .....	13
201.11. 6.6 * Cleaning and disinfection of ME EQUIPMENT or ME SYSTEMS .....	13
201.11. 6.7 Sterilization of ME EQUIPMENT or ME SYSTEMS .....	13

## ISO 80601-2-55:2011(E)

201.11. 6.8	Compatibility with substances used with ME EQUIPMENT.....	13
201.11. 8.101	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT.....	14
201.11. 8.101.1	* Supply failure TECHNICAL ALARM CONDITION.....	14
201.11. 8.101.2	* Settings and data storage following short interruptions or automatic switchover .....	14
201.11. 8.101.3	* Operation following long interruptions.....	14
201.11. 8.101.4	* RESERVE ELECTRICAL POWER SOURCE .....	14
201.11. 8.101.5	* RESERVE ELECTRICAL POWER SOURCE for transport outside a healthcare facility .....	15
201.12	Accuracy of controls and instruments and protection against hazardous outputs.....	15
201.12. 1	Accuracy of controls and instruments .....	15
201.12. 1.101	* Measurement accuracy.....	15
201.12. 1.101.1	General .....	15
201.12. 1.101.2	* DRIFT of MEASUREMENT ACCURACY .....	16
201.12. 1.101.3	* MEASUREMENT ACCURACY of GAS READINGS for gas mixtures .....	17
201.12. 1.102	* TOTAL SYSTEM RESPONSE TIME and rise time .....	17
201.12. 1.103	* Indication of units of measure for GAS READINGS .....	18
201.12. 1.104	* Indication of operating mode.....	19
201.13	HAZARDOUS SITUATIONS and fault conditions .....	19
201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	19
201.15	Construction of ME EQUIPMENT.....	19
201.15. 3.5.101	* Additional requirements for rough handling.....	19
201.15. 3.5.101.1	* Shock and vibration .....	19
201.15. 3.5.101.2	* Shock and vibration for professional transportation .....	20
201.15. 101	* Mode of operation .....	21
201.16	ME SYSTEMS .....	21
201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS.....	21
201.101	* Interfering gas and vapour effects.....	22
201.102	* Gas leakage.....	22
201.103	* Port connector for DIVERTING RGM.....	22
201.104	* Minimum sampling flowrate .....	23
201.105	* Contamination of breathing systems .....	23
201.105. 1	Sampling tube .....	23
201.105. 2	Exhaust tube .....	23
202	Electromagnetic compatibility — Requirements and tests .....	23
202.6.2.1.7	* PATIENT simulation.....	23
202.6.2.1.10	Compliance criteria .....	23
202.6.2.3.1	* Requirements.....	24
206	Usability .....	24
206.6.2.2.2	Primary operating functions.....	24
208	General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.....	24
208.6.1.2	* ALARM CONDITION priority.....	24
208.6.5.1	* General requirements.....	26
208.6.6.2.101	* Additional requirements for adjustable ALARM LIMIT .....	26
208.6.8.5.101	* Additional requirements for ALARM SIGNAL deactivation states, indication and access 26	
209	Requirements for environmentally conscious design.....	26

210	Requirements for the development of physiologic closed-loop controllers .....	26
211	Requirements for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS used in the home healthcare environment.....	27
<b>Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS.....</b>		<b>28</b>
<b>201.C.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts .....</b>		<b>28</b>
<b>201.C.4 ACCOMPANYING DOCUMENTS, general .....</b>		<b>28</b>
<b>201.C.5 ACCOMPANYING DOCUMENTS, instructions for use .....</b>		<b>29</b>
<b>201.C.6 ACCOMPANYING DOCUMENTS, technical description .....</b>		<b>30</b>
<b>Annex D (informative) Symbols on marking .....</b>		<b>31</b>
<b>Annex AA (informative) Particular guidance and rationale .....</b>		<b>33</b>
<b>Annex BB (informative) Environmental aspects.....</b>		<b>43</b>
<b>Annex CC (informative) Test gas mixtures for calibration .....</b>		<b>45</b>
<b>Annex DD (informative) Reference to the essential principles .....</b>		<b>46</b>
<b>Bibliography.....</b>		<b>48</b>

## iTeh STANDARD PREVIEW (standards.iteh.ai)

[SIST EN ISO 80601-2-55:2013](https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013)

<https://standards.iteh.ai/catalog/standards/sist/d0b78081-dc9f-4cd1-b4c7-ceed70d744c/sist-en-iso-80601-2-55-2013>