SLOVENSKI STANDARD
kSIST FprEN ISO 80601-2-13:2012

01-julij-2012

Elektromedicinska oprema - 2-13: del: Posebne zahteve za osnovno varnost in bistvene lastnosti delovnega mesta za anestezijo (ISO 80601-2-13:2011)

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie (ISO 80601-2-13:2011)

Ta slovenski standard je istoveten z: **FprEN ISO 80601-2-13**

ICS:

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

kSIST FprEN ISO 80601-2-13:2012 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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FINAL DRAFT
FprEN ISO 80601-2-13

May 2012

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English Version

Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation (ISO 80601-2-13:2011)

Appareils électromédicaux - Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie (ISO 80601-2-13:2011)

Medizinische elektrische Geräte - Teil 2-13: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Anästhesie-Arbeitsplätzen (ISO 80601-2-13:2011)

This draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 215.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. FprEN ISO 80601-2-13:2012: E

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Foreword

The text of ISO 80601-2-13:2011 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as FprEN ISO 80601-2-13:2012 by Technical Committee CEN/TC 215 “Respiratory and anaesthetic equipment” the secretariat of which is held by BSI.

This document is currently submitted to the Unique Acceptance Procedure.

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.

Endorsement notice

The text of ISO 80601-2-13:2011 has been approved by CEN as a FprEN ISO 80601-2-13:2012 without any modification.

Annex ZA
(informative)

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

This European 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 EN	Corresponding essential requirements of Directive 3/42/EEC	Qualifying remarks/ynotes
201.11.6.8; 201.102.3; 201.104.7	7.2	only the risks to patients during NORMAL USE are addressed
201.11.6.3; 201.11.6.8	7.3	
201.7.2.105, 201.7.9.2.14	7.5, 2nd and 3rd paragraph	
201.101.4.1.2; 201.11.6.3	7.6	IP classification according IEC 60529 is governed by EN 60601-1:2006
201.11.101; 201.104.7	8.1	Easy handling and contamination by the patients are not addressed.
201.11.101	8.6	
201.16.9.2.1; 201.16.101; 201.101.3; 201.101.4.1 201.101.4.2; 201.101.9; 201.102.5; 201.102.9; 201.103.4 to 201.103.7; 201.104.4; 201.104.5, 201.104.6; 201.105.4; 201.105.6	9.1	
201.9.4; 201.9.4.2.4.3; 201.105.7, 202; 209	9.2 (First and second indents)	Clause 202 refers to EN 60601-1-2:2007, Clause 209 refers to EN 60601-1-9:2008
201.11; 201.102.4	9.3	
201.12.4.104.1; 201.101.6.1; 201.104.2.2	10.1	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 3/42/EEC	Qualifying remarks/ynotes
201.7.4.2;	10.2	
201.7.4.3	10.3	
201.14	12.1	EN 62304:2006, 1.4
201.14, 201.14.101	12.1 a)	EN 62304:2006, 1.4
201.11.8.102; 201.11.8.103	12.2	
201.11.8.102	12.3	
201.12.4.104.2; 201.12.4.105; 201.12.4.106; 208	12.4	Clause 208 refers to EN 60601-1-8:2006
202	12.5	Clause 202 refers to EN 60601-1-2:2007
201.9	12.7.1	
201.9, 201.9.2.103	12.7.2	
201.9, 201.11.8.102	12.7.3	
201.15, 201.16, 201.101.4.2.1	12.7.4	Covered by compliance with EN 60601-1:2006, 15.4.1 and 16.9
201.11	12.7.5	EN 60601-1:2006, Clause 11
201.101.4.1.3; 201.101.6.2; 201.101.6.3; 201.102.2.1; 201.102.2.2; 201.102.10.4; 201.104.2.1; 201.104.5; 201.105.2.1; 201.105.2.2;	12.8.1	
201.12.4.104.2; 201.12.4.106; 201.12.4.107.1; 201.12.4.107.2; 201.12.4.107.3; 201.12.4.109; 201.101.2; 201.101.4.3; 201.102.10: 201.102.10.4; 201.104.5; 201.105.5; 201.105.8; 208	12.8.2	
201.101.6.1; 201.104.2.1;	12.9	
201.7, 201.7.2.104; 201.7.9.1; 201.102.1.1.1	13.1	
201.7, 201.7.2.3; 201.7.2.101; 201.7.2.103; 201.7.2.107; 201.7.4.2	13.2	
201.7.9.1	13.3 a)	
201.7.2.101	13.3 e)	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 3/42/EEC	Qualifying remarks/ynotes
201.7, 201.7.2.101	13.3 f)	The indication that the device is for single use must be consistent across the Community is not addressed in a requirement.
201.7, 201.7.9.3.102	13.3 i)	
201.7, 201.7.2 201.7.2.102, 201.7.2.103, 201.7.2.104 201.7.2.107 201.7.4.2 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.1.1.4 201.102.5.2 201.102.5.3 201.102.5.4 201.102.5.7 201.103.1.1 201.104.1.1 201.104.2.1 201.104.6 201.105.6	13.3 j)	
201.7, 201.7.2.3 201.104.1.1	13.3 k)	
201.7.2.101	13.3.l)	
201.7.2.102; 201.102.5.2; 201.102.5.4; 201.102.5.5; 201.102.5.6; 201.103.5; 201.103.6; 201.104.4	13.5	
201.7	13.6 a)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7	13.6 b)	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7.9.2.1 201.7.9.2.14 201.11.8 201.11.8.101 201.11.8.103 201.12.4.102 201.12.4.103.3 201.12.4.106 201.12.4.107.2 201.12.4.108 201.101.1.1 201.101.1.2 201.102.1.2 201.102.7	13.6 c)	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 3/42/EEC	Qualifying remarks/ynotes
201.102.8.2 201.102.9.2 201.102.9.3 201.102.10.3 201.103.1.2 201.104.1.2 201.104.2.1 201.104.6 201.105.1 201.105.2.2 201.105.5		
201.7, 201.102.10.1 201.103.3.1.5 208.5.2.2	13.6 d)	maintenance and frequency covered by compliance with EN 60601-1:2006, 7.9.2.13
201.7.9.2.14	13.6 f)	
201.7 201.7.9.2.14	13.6 h), first paragraph only	Covered by compliance with EN 60601-1:2006, 7.9.2
201.7 201.7.9.2.1 201.7.9.2.8	13.6 i)	Covered by compliance with EN 60601-1:2006, 7.9
201.7.9.2.2 201.7.9.2.14	13.6 k)	
201.12.4.103 ; 201.12.4.104.1, 201.12.4.109; 201.101.6.1; 201.104.2.2;	13.6 p)	
201.7.9.2.1	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.102 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 European Standard. Table ZA.102, 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.102 — 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 EN	EHSR of Directive 2006/42/EC	Qualifying remarks/notes
201.9.2.102	1.1.4	
201.9.2.103	1.1.8	
201.7.4.2 201.9.2 201.9.2.104 201.101.6.1 201.102.1.1.2 201.102.1.1.3 201.102.9.2 201.104.1.1 201.104.2.1 206 208	1.2.2	
201.101.3 201.101.4.1.1 201.101.4.1.2 201.101.9 201.102.5 201.102.8.1 201.102.9.1 201.103.4, 201.103.5; 201.103.6 201.103.7 201.104.4 201.105.4 201.105.6	1.5.4	
201.9.2.101	1.6.2	
201.8	1.6.3	
201.7 201.7.2.106	3.6.2	Covered by compliance with EN 60601-1:2006, 7.2

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

INTERNATIONAL STANDARD

ISO 80601-2-13

First edition
2011-08-01

Medical electrical equipment —

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

Appareils électromédicaux —

Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 80601-2-13 was prepared by a joint working group of 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, *Electromedical equipment*. The draft was circulated for voting to the national bodies of both ISO and IEC.

This first edition of ISO 80601-2-13 cancels and replaces the following:

— ISO 8835-2:2007, *Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems*

— ISO 8835-3:2007, *Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems*

— ISO 8835-4:2004, *Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices*

— ISO 8835-5:2004, *Inhalational anaesthesia systems — Part 5: Anaesthetic ventilators*

— IEC 60601-2-13:2003, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems*

This edition constitutes a major technical revision of the material that was contained in the previous standards by consolidating it into a single document, removing duplications and inconsistencies as well as harmonization with the third edition of IEC 60601-1.