Elektrilised meditsiiniseadmed. Osa 2-13: Erinõuded anesteesia tööjaama esmasele ohutusele ja olulistele toimimisnäitajatele (ISO 80601-2-13:32011)

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 80601-2-13:2012 sisaldab Euroopa standardi EN ISO 80601-2-13:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 80601-2-13:2012 consists of the English text of the European standard EN ISO 80601-2-13:2012.
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 12.12.2012.	Date of Availability of the European standard is 12.12.2012.
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 80601-2-13

December 2012

ICS 11.040.10

Supersedes EN ISO 8835-2:2009, EN ISO 8835-3:2009, EN ISO 8835-4:2009, EN ISO 8835-5:2009, EN 60601-2-13:2006

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 European Standard was approved by CEN on 18 November 2012.

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, 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 80601-2-13:2012: E

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 EN ISO 80601-2-13:2012 by 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 2013, and conflicting national standards shall be withdrawn at the latest by December 2015.

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 8835-2:2009, EN ISO 8835-3:2009, EN ISO 8835-4:2009, EN ISO 8835-5:2009, EN 60601-2-13:2006.

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 organisations 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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 80601-2-13:2011 has been approved by CEN as a EN 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 93/42/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 93/42/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 93/42/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	13.6 c)	

Clause(s)/subclause(s) of this EN	Corresponding essential requirements of Directive 93/42/EEC	Qualifying remarks/ynotes
201.102.7 201.102.8.2 201.102.9.2 201.102.9.3 201.102.10.3 201.103.1.2 201.104.1.2 201.104.2.1 201.104.6 201.105.1 201.105.2.2 201.105.5		
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 European 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: in 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 standard, the term

— “clause” means one of the seventeen 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 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 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 not be adopted for mandatory implementation nationally 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.

This International Standard considers both an ANAESTHETIC WORKSTATION supplied complete and its individual components. It has been structured to allow RESPONSIBLE ORGANIZATIONS to configure an ANAESTHETIC WORKSTATION from individual components in conformance with professional guidelines and to meet the needs of their clinical practice. In order to achieve this aim, this International Standard identifies particular

requirements pertinent to specific ANAESTHETIC WORKSTATION components, and to their associated MONITORING EQUIPMENT, ALARM SYSTEM(S) and PROTECTION DEVICE(S), and defines the interfaces.

Figure 201.101 is a graphical representation of the structure of this International Standard and is provided for informational purposes only.

<table>
<tr><td colspan="3">ANAESTHETIC WORKSTATION</td></tr>
<tr><td>General requirements
Clauses 201.1 – 201.17, 201.106, 201.107, 202-211</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Mandatory elements;
see also Table AA.1</td></tr>
<tr><td>ANAESTHETIC GAS DELIVERY SYSTEM
Clause 201.101</td></tr>
<tr><td>ANAESTHETIC BREATHING SYSTEM
Clause 201.102</td></tr>
<tr><td>ANAESTHETIC GAS SCAVENGING SYSTEM
Clause 201.103</td><td rowspan="3">MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES</td><td rowspan="3">Optionally present;
see also Table AA.1</td></tr>
<tr><td>ANAESTHETIC VAPOUR DELIVERY SYSTEM
Clause 201.104</td></tr>
<tr><td>ANAESTHETIC VENTILATOR
Clause 201.105</td></tr>
</table>

Figure 201.101 — Configuration of an ANAESTHETIC WORKSTATION and corresponding organization of this International Standard

Medical electrical equipment —

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

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 is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an ANAESTHETIC WORKSTATION for administering inhalational anaesthesia whilst continuously attended by a professional OPERATOR.

This International Standard specifies particular requirements for a complete ANAESTHETIC WORKSTATION and the following ANAESTHETIC WORKSTATION components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant ANAESTHETIC WORKSTATION components, to form an ANAESTHETIC WORKSTATION to a given specification:

— ANAESTHETIC GAS DELIVERY SYSTEM;

— ANAESTHETIC BREATHING SYSTEM;

— ANAESTHETIC GAS SCAVENGING SYSTEM;

— ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— ANAESTHETIC VENTILATOR;

— MONITORING EQUIPMENT;

— ALARM SYSTEM;

— PROTECTION DEVICE.

NOTE 1 MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES are summarized in Table AA.1.

An ANAESTHETIC WORKSTATION supplied complete and its individual components are considered as ME EQUIPMENT or ME SYSTEMS with regard to the general standard.

NOTE 2 The applicability of this International Standard is indicated in Table AA.2.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to an ANAESTHETIC WORKSTATION where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ANAESTHETIC WORKSTATION.

If a clause or subclause is specifically intended to be applicable to ANAESTHETIC WORKSTATION components 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 an ANAESTHETIC WORKSTATION and its individual components, as relevant.

HAZARDS inherent in the intended physiological function of an ANAESTHETIC WORKSTATION and its individual components within the scope of this International Standard are not covered by specific requirements in this International Standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE 3 See also 4.2 of the general standard.

This International Standard is not applicable to any ANAESTHETIC WORKSTATION intended for use with flammable anaesthetic agents, as determined by Annex BB.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for an ANAESTHETIC WORKSTATION and its individual components designed for use in the ANAESTHETIC WORKSTATION (as defined in 201.3.211) and its ACCESSORIES.

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 60601-1-3:2008 and IEC 60601-1-11:2010 do not apply.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards, 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 60601-1:2005 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 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 collateral standard, 206.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-6 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, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 to 3.139, additional definitions in this standard are numbered beginning from 201.3.201. 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, 206 for IEC 60601-1-6, 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 clause or subclause in this particular standard, the 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:

Replace references to ISO 2878, ISO 15223, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-8 by the following:

ISO 2878:2005, *Rubber — Antistatic and conductive products — Determination of electrical resistance*

ISO 15223-1:—[1)], *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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 407:2004, *Small medical gas cylinders — Pin-index yoke-type valve connections* [alternative normative reference to ISO 5145]

ISO 594-2:1998[2)] , *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

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1) To be published.

2) To be revised by ISO 80369-7, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*, which is under preparation.

ISO 5145:2004, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning* [alternative normative reference to ISO 407]

ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2:2006, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases*

ISO 5360:2006, *Anaesthetic vaporizers — Agent-specific filling systems*

ISO 5362:2006, *Anaesthetic reservoir bags*

ISO 5367:2000, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

ISO 8836, *Suction catheters for use in the respiratory tract*

ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 9170-2, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems*

ISO 10079-1, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements* [alternative normative reference to ISO 10079-3]

ISO 10079-3, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source* [alternative normative reference to ISO 10079-1]

ISO 10524-1:2006, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 80601-2-55:—[3)], *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors*

IEC 60079-11, *Explosive atmospheres — Part 11: Equipment protection by intrinsic safety "i"*

IEC 60079-20-1, *Explosive atmospheres — Part 20-1: Material characteristics for gas and vapour classification — Test methods and data*

IEC 60601-1:2005, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

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*

3) To be published.

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*

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 62304:2006, *Medical device software — Software life cycle processes*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006 and the following apply.

NOTE An index of defined terms is found at the end of this document.

Addition:

201.3.201
ACTIVE ANAESTHETIC GAS SCAVENGING SYSTEM
ANAESTHETIC GAS SCAVENGING SYSTEM in which gas flow in the DISPOSAL SYSTEM results from a POWER DEVICE

NOTE Adapted from ISO 4135:2001, definition 7.1.2.

201.3.202
AIRWAY PRESSURE
pressure at the PATIENT CONNECTION PORT

201.3.203
ANAESTHETIC BREATHING SYSTEM
inspiratory and expiratory pathways through which ANAESTHETIC GAS flows at respiratory pressure between the FRESH-GAS INLET, the PATIENT CONNECTION PORT and an EXHAUST VALVE or EXHAUST PORT

NOTE Adapted from ISO 4135:2001, definitions 3.1.6 and 4.1.1.

201.3.204
ANAESTHETIC GAS
gases and, if present, vapour of a volatile anaesthetic agent, used in anaesthesia

NOTE In parts of an ANAESTHETIC BREATHING SYSTEM, ANAESTHETIC GAS includes gases exhaled by the PATIENT.

201.3.205
ANAESTHETIC GAS DELIVERY SYSTEM
ANAESTHETIC WORKSTATION component that receives separate supplies of MEDICAL GAS(ES) and delivers mixed gases in concentrations or individual flow rates adjustable by the OPERATOR

NOTE An ANAESTHETIC GAS DELIVERY SYSTEM can include a means of flow rate adjustment control, FLOWMETERS or a gas mixer and ANAESTHETIC GAS DELIVERY SYSTEM PIPING but does not include vaporizers.

201.3.206
ANAESTHETIC GAS DELIVERY SYSTEM PIPING
all piping, including unions, from the UNIDIRECTIONAL VALVES in the pipeline inlets and from the outlets of the PRESSURE REGULATOR(S) to the means of flow rate adjustment control, as well as the piping connecting the