



SLOVENSKI STANDARD
oSIST prEN ISO 80601-2-69:2013
01-januar-2013

Elektromedicinska oprema - 2-69. del: Posebne zahteve za osnovno varnost in bistvene lastnosti naprav za koncentriranje kisika (ISO/DIS 80601-2-69:2012)

Medical Electrical Equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO/DIS 80601-2-69:2012)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO/DIS 80601-2-69:2012)

Appareils électromédicaux - Partie 2-63 : exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO/DIS 80601-2-69:2012)

Ta slovenski standard je istoveten z: prEN ISO 80601-2-69 rev

ICS:

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

oSIST prEN ISO 80601-2-69:2013 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

DRAFT
prEN ISO 80601-2-69 rev

October 2012

ICS 11.040.10

Will supersede EN ISO 8359:2009

English Version

Medical Electrical Equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO/DIS 80601-2-69:2012)

Appareils électromédicaux - Partie 2-63 : exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène (ISO/DIS 80601-2-69:2012)

Medizinische elektrische Geräte - Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale für Sauerstoff-Konzentratoren (ISO/DIS 80601-2-69:2012)

This draft European Standard is submitted to CEN members for parallel enquiry. 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.

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.

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

Contents	Page
Foreword.....	3

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 80601-2-69:2014

<https://standards.iteh.ai/catalog/standards/sist/52dcf26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014>

Foreword

This document (prEN ISO 80601-2-69:2012) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 8359:2009.

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(s).

Endorsement notice

The text of ISO/DIS 80601-2-69:2012 has been approved by CEN as a prEN ISO 80601-2-69:2012 without any modification.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 80601-2-69:2014

<https://standards.iteh.ai/catalog/standards/sist/52dcf26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014>



DRAFT INTERNATIONAL STANDARD ISO/DIS 80601-2-69

ISO/TC 121/SC 3

Secretariat: **ANSI**Voting begins on
2012-10-25Voting terminates on
2013-03-25

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Medical Electrical Equipment —

Part 2-69:

Particular requirements for basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

[Revision of second edition (ISO 8359:1996)]

ICS 11.040.10

ITEH STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 80601-2-69:2014

<https://standards.iteh.ai/catalog/standards/sist/80601-2-69/2014/iso-80601-2-69-2014>

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENT AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

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.

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 80601-2-69:2014

<https://standards.iteh.ai/catalog/standards/sist/52dcf26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014>

Copyright notice

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to 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
Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

1	Contents		Page
2	201.1	Scope, object and related standards	1
3	201.1.1	Scope	1
4	201.1.2	Object.....	2
5	201.1.3	Collateral standards.....	2
6	201.1.4	Particular standards.....	2
7	201.2	Normative references	3
8	201.3	Terms and definitions	4
9	201.4	General requirements.....	5
10	201.4.3	ESSENTIAL PERFORMANCE	5
11	201.4.3.101	Additional requirements for ESSENTIAL PERFORMANCE	5
12	201.4.6	ME EQUIPMENT or ME SYSTEM parts that contact the PATIENT.....	5
13	201.5	General requirements for testing of ME EQUIPMENT.....	6
14	201.5.101	Additional requirements for general requirements for testing of ME EQUIPMENT	6
16	201.5.101.1	Gas flowrate and leakage specifications	6
17	201.5.101.2	OXYGEN CONCENTRATOR testing errors	6
18	201.6	Classification of ME EQUIPMENT and ME SYSTEMS.....	6
19	201.7	ME EQUIPMENT identification, marking and documents	6
20	201.7.1.2	Legibility of markings	6
21	201.7.2.4.101	Additional requirements for ACCESSORIES	6
22	201.7.2.13.101	Additional requirements for physiological effects.....	7
23	201.7.2.101	Additional requirements for marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts.....	7
25	201.8	Protection against electrical HAZARDS from ME EQUIPMENT.....	12
26	201.8.11.3.4.101	Additional requirements for APPLIANCE COUPLERS	12
27	201.9	Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS.....	12
28	201.9.6.2.1.101	Additional requirements for audible acoustic energy	12
29	201.10	Protection against unwanted and excessive radiation HAZARDS.....	13
30	201.11	Protection against excessive temperatures and other HAZARDS.....	13
31	201.11.1	Maximum temperature during NORMAL USE	13
32	201.11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT.....	14
33	201.11.2.101	Additional requirements for fire prevention.....	14
34	201.11.6.4	Leakage	14
35	201.11.6.6	Cleaning and disinfection of ME EQUIPMENT or ME SYSTEM.....	14
36	201.11.6.7	Sterilization of ME EQUIPMENT or ME SYSTEM	15
37	201.11.8.101	Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT	15
39	201.11.8.101.1	TECHNICAL ALARM CONDITION for power supply failure.....	15
40	201.11.8.101.2	INTERNAL ELECTRICAL POWER SOURCE	16
41	201.12	Accuracy of controls and instruments and protection against hazardous outputs	16
43	201.12.1	Accuracy of controls and instruments.....	16
44	201.12.1.101	Accuracy of continuous flowrate	17

45	201.12.1.102	Accuracy of triggered flowrate	17
46	201.12.1.103	Accuracy of concentration.....	17
47	201.12.1.104	Outlet pressure	19
48	201.12.4	Protection against hazardous output.....	20
49	201.12.4.4.101	Additional requirements for incorrect output.....	20
50	201.12.4.4.101.1	Flowrate control.....	20
51	201.12.4.4.101.2	Indication of start-up period	20
52	201.12.4.102	Low oxygen concentration ALARM CONDITION	20
53	201.12.4.103	Delivered gas filter.....	20
54	201.13	HAZARDOUS SITUATIONS and fault conditions.....	21
55	201.13.2.101	Additional specific SINGLE FAULT CONDITIONS.....	21
56	201.14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS).....	21
57	201.15	Construction of ME EQUIPMENT	21
58	201.16	ME SYSTEMS	21
59	201.16.1.101	Additional general requirements for ME SYSTEMS	21
60	201.17	Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	21
61	201.17.101	Additional requirements for electromagnetic compatibility of	
62		ME EQUIPMENT and ME SYSTEMS	21
63	201.101	Outlet connector.....	22
64	201.102	Requirements for parts and ACCESSORIES.....	22
65	201.102.1	General.....	22
66	201.102.2	Labelling	22
67	201.102.3	Fire RISK reduction in ACCESSORIES.....	22
68	201.103	SIGNAL INPUT/OUTPUT PART	23
69	201.103.1	General.....	23
70	201.103.2	Connection to a DISTRIBUTED ALARM SYSTEM.....	23
71	201.103.3	Connection for remote control	23
72	201.104	Indication of duration of operation	23
73	201.105	Integrated CONSERVING EQUIPMENT.....	23
74	202.6.2.1.10	Compliance criteria	24
75	211.4.2.2	Environmental operating conditions.....	25
76	ANNEX C (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and	
77		ME SYSTEMS.....	26
78	Annex D (informative)	Symbols on marking.....	30
79	Annex AA (informative)	Particular guidance and rationale	31
80	Annex BB (informative)	Reference to the Essential Principles.....	38
81	Bibliography	40
82	Alphabetical index of defined terms used in this particular standard.....		41
83	Annex ZA (informative)	Relationship between this Document and the Essential Requirements	
84		of EU Directive 93/42/EEC	43
85			

86 **Foreword**

87 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
 88 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO
 89 technical committees. Each member body interested in a subject for which a technical committee has been
 90 established has the right to be represented on that committee. International organizations, governmental and
 91 non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the
 92 International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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

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

97 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
 98 rights. ISO shall not be held responsible for identifying any or all such patent rights.

99 ISO/IEC 80601-2-69 was prepared by a joint working group of Technical Committee ISO/TC 121, *Anaesthetic*
 100 *and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment* and Technical
 101 Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electrical equipment*.

102 This first edition of ISO 80601-2-69 cancels and replaces the first edition of ISO 8359:1996. This edition of
 103 ISO 80601-2-69 constitutes a major technical revision of ISO 8359:1996 and includes an alignment with third
 104 edition of IEC 60601-1 and IEC 60601-1-11.

105 The most significant changes are the following modifications:

- 106 – extending the scope to include not only the OXYGEN CONCENTRATOR but also its ACCESSORIES,
 107 where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL
 108 PERFORMANCE of the OXYGEN CONCENTRATOR;
- 109 – identification of ESSENTIAL PERFORMANCE for an OXYGEN CONCENTRATOR and its ACCESSORIES;
- 110 – and the following additions:
 - 111 — tests for oxygen delivery performance;
 - 112 — new symbols;
 - 113 — new requirement for a means to prevent the propagation of fire into the OXYGEN CONCENTRATOR
 114 and its ACCESSORIES;
 - 115 — tests for cleaning and disinfection procedures; and
 - 116 — consideration of contamination of the breathing gas delivered to the PATIENT from the gas
 117 pathways.

118 In this standard, the following print types are used:

- 119 – Requirements and definitions: roman type.
- 120 – *Test specifications: italic type.*
- 121 – Informative material appearing outside of tables, such as notes, examples and references: in smaller type.
 122 Normative text of tables is also in a smaller type.
- 123 – TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED:
 124 SMALL CAPITALS TYPE.

125 In referring to the structure of this standard, the term

- 126 – "clause" means one of the seventeen numbered divisions within the table of contents, inclusive of
127 all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- 128 – "subclause" means a numbered subdivision of a clause (e.g. 201.7.1, 201.7.2 and 201.7.2.1 are
129 all subclauses of Clause 201.7).
- 130 References to clauses within this standard are preceded by the term "Clause" followed by the clause number.
131 References to subclauses within this particular standard are by number only.
- 132 In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of
133 the conditions is true.
- 134 The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part
135 2. For the purposes of this standard, the auxiliary verb:
- 136 – "shall" means that compliance with a requirement or a test is mandatory for compliance with this
137 standard;
- 138 – "should" means that compliance with a requirement or a test is recommended but is not
139 mandatory for compliance with this standard;
- 140 – "may" is used to describe a permissible way to achieve compliance with a requirement or test.
- 141 An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that
142 there is guidance or rationale related to that item in Annex A.
- 143 The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers
144 and testing organizations may need a transitional period following publication of a new, amended or revised
145 ISO or IEC publication in which to make products in accordance with the new requirements and to equip
146 themselves for conducting new or revised tests. It is the recommendation of the committee that the content of
147 this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of
148 publication for equipment newly designed and not earlier than 5 years from the date of publication for
149 equipment already in production.

[SIST EN ISO 80601-2-69:2014](https://standards.iteh.ai/catalog/standards/sist/52def26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014)

<https://standards.iteh.ai/catalog/standards/sist/52def26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014>

150 Introduction

151 Oxygen supplementation can be part of management of PATIENTS with chronic, acute-on-chronic and
152 acute respiratory disorders. The amount of supplemental oxygen depends on the individual PATIENT'S
153 needs under various conditions. The managing healthcare team typically prescribes the endpoint of
154 treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can
155 be controlled by the flow rate.

156 The goal of long term oxygen therapy is to keep the oxygen saturation above 90 % in PATIENTS that require
157 supplemental oxygen. The flow rate should be adjusted for rest, exertion, and sleep to meet the individual
158 PATIENT'S needs under these various conditions. Ideally, the resting flowrate can be adjusted by monitoring
159 pulse oximetry to $SpO_2 > 90 \%$.

160 Supplemental oxygen is supplied by three types of sources: OXYGEN CONCENTRATORS, compressed
161 gas cylinders, and liquid oxygen reservoirs. This standard covers the particular requirements for
162 BASIC SAFETY and ESSENTIAL PERFORMANCE of OXYGEN CONCENTRATORS. OXYGEN CONCENTRATORS
163 produce oxygen enriched air from room air for delivery to a PATIENT requiring oxygen therapy. The
164 most common OXYGEN CONCENTRATOR uses molecular sieve beds to filter and concentrate oxygen
165 molecules from the ambient air, generating oxygen concentrations of 82 to 95%. The main
166 component of this type of OXYGEN CONCENTRATOR is the molecular sieve, which adsorbs nitrogen from
167 air to produce a product gas which is a mixture of up to 95% oxygen and 5 % of other gases. The
168 periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption process.

169

STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 80601-2-69:2014](https://standards.iteh.ai/catalog/standards/sist/52def26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014)

<https://standards.iteh.ai/catalog/standards/sist/52def26f-5fc2-4d97-a3ce-12874efb8f20/sist-en-iso-80601-2-69-2014>

170 **Medical Electrical Equipment — Part 2-69: Particular**
 171 **requirements for basic safety and essential performance of**
 172 **oxygen concentrator equipment**

173 **201.1 Scope, object and related standards**

174 *IEC 60601-1:2005+Amendment 1:2012, Clause 1 applies, except as follows:*

175 **201.1.1 Scope**

176 *IEC 60601-1:2005+Amendment 1:2012, 1.1 is replaced by:*

177 This **particular** standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an OXYGEN
 178 CONCENTRATOR in combination with its ACCESSORIES, hereafter referred to as ME EQUIPMENT, intended
 179 to increase the oxygen concentration in the gas intended to be delivered to a single PATIENT. Such
 180 OXYGEN CONCENTRATORS are typically intended for use in the HOME HEALTHCARE ENVIRONMENT,
 181 including TRANSIT-OPERABLE use by a single PATIENT in various environments including any private
 182 and public transportation and commercial aircraft.

183 NOTE 1 An OXYGEN CONCENTRATOR can also be used in professional healthcare facilities.

184 This **particular** standard is applicable to a TRANSIT-OPERABLE or non-TRANSIT-OPERABLE OXYGEN
 185 CONCENTRATOR. This **particular** standard is applicable to an OXYGEN CONCENTRATOR integrated into or
 186 used with other ME EQUIPMENT or ME SYSTEMS.

187 EXAMPLE 1 An OXYGEN CONCENTRATOR with integrated oxygen CONSERVING EQUIPMENT or humidifier.

188 EXAMPLE 2 An OXYGEN CONCENTRATOR used with a flowmeter stand.

189 This **particular** standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to
 190 be connected to an OXYGEN CONCENTRATOR, where the characteristics of those ACCESSORIES can
 191 affect the BASIC SAFETY or ESSENTIAL PERFORMANCE of the OXYGEN CONCENTRATOR.

192 This **particular** standard does not specify the requirements for OXYGEN CONCENTRATORS for use with a
 193 MEDICAL GAS PIPELINE SYSTEM which are given in ISO 10083.

194 If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to
 195 ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case,
 196 the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

197 HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the
 198 scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and
 199 8.4.1 of the general standard.

200 NOTE 2 See also 4.2 of the General Standard.

201 This **particular** standard is a particular standard in the IEC 60601-1 series of standards.

202 **201.1.2 Object**

203 *IEC 60601-1:2005, 1.2 is replaced by:*

204 The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL
205 PERFORMANCE requirements for an OXYGEN CONCENTRATOR [as defined in 201.3.203] and its
206 ACCESSORIES.

207 NOTE ACCESSORIES are included because the combination of the OXYGEN CONCENTRATOR and the
208 ACCESSORIES needs to be adequately safe. ACCESSORIES can have a significant impact on the BASIC SAFETY or
209 ESSENTIAL PERFORMANCE of an OXYGEN CONCENTRATOR.

210 **201.1.3 Collateral standards**

211 *IEC 60601-1:2005+Amendment 1:2012, 1.3 applies with the following addition:*

212 This particular standard refers to those applicable collateral standards that are listed in IEC 60601-
213 1:2005+Amendment 1:2012, Clause 2 of the general standard and 201.2 of this particular standard.

214 IEC 60601-1-3:2008 does not apply.

215 **201.1.4 Particular standards**

216 *IEC 60601-1:2005+Amendment 1:2012, 1.4 is replaced by:*

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

220 A requirement of a particular standard takes priority over the general standard or the collateral
221 standards.

222 For brevity, IEC 60601-1:2005+Amendment 1:2012 is referred to in this particular standard as the
223 general standard. Collateral standards are referred to by their document number.

224 The numbering of clauses and subclauses of this particular standard corresponds to those of the
225 general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of
226 the general standard) or applicable collateral standard with the prefix "2xx" where xx is the final digits
227 of the collateral standard document number (e.g. 202.4 in this particular standard addresses the
228 content of Clause 4 of the IEC 60601-1-2 collateral standard, 208.4 in this particular standard
229 addresses the content of Clause 4 of the IEC 60601-1-8 collateral standard, etc.). The changes to the
230 text of the general standard are specified by the use of the following words:

231 "Replacement" means that the clause or subclause of the general standard or applicable collateral
232 standard is replaced completely by the text of this particular standard.

233 "Addition" means that the text of this particular standard is additional to the requirements of the
234 general standard or applicable collateral standard.

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

237 Subclauses or figures that are additional to those of the general standard are numbered starting from
238 201.101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.