ELEKTRILISED MEDITSIINISEADMED. OSA 2-43: ERINÕUDED INVASIIVPROTSEDUURIDE RÖNTGENSEADMETE ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X ray equipment for interventional procedures (IEC 60601-2-43:2010 + IEC 60601-2-43:2010/A1:2017 + IEC 60601-2-43:2010/A2:2019)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-2-43:2010 +A1+A2:2020 sisaldab Euroopa standardi EN 60601-2-43:2010 ingliskeelset teksti ja selle muudatuste A1:2018 ja A2:2020 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-2-43:2010 +A1+A2:2020 consists of the English text of the European standard EN 60601-2-43:2010 and its amendments A1:2018 and A2:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 11.06.2010, muudatused A1 18.05.2018 ja A2 03.04.2020.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 11.06.2010, for A1 18.05.2018 and A2 03.04.2020.
Parandusega AC lisatud või muudetud teksti algus ja lõpp on tekstis ära märgitud märgenditega ⟦AC⟩ ⟨AC⟧. Sellesse standardisse on muudatus A1 sisse viidud ja tehtud muudatused tähistatud topeltpüst-kriipsuga lehe välisveerisel. Sellesse standardisse on muudatus A2 sisse viidud ja tehtud muudatused tähistatud kolmekordse püstkriipsuga lehe välisveerisel. Selles standardis on rahvusvahelise standardi ühismuudatused tähistatud püstkriipsuga teksti välimisel veerisel. Standard on kättesaadav Eesti Standardi-keskusest.	The start and finish of text introduced or altered by amendment AC is indicated in the text by symbols ⟦AC⟩ ⟨AC⟧. The amendment A1 has been incorporated into this standard and changes have been marked by a double vertical line on the outer row of the page. The amendment A2 has been incorporated into this standard and changes have been marked by a triple vertical line on the outer row of the page. Common modifications has been incorporated into this international standard and changes have been marked by a vertical line on the outer row of the page. 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 11.040.50; 37.040.25

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-43 + A1 + A2

June 2010, May 2018, April 2020

ICS 11.040.50; 37.040.25

Supersedes EN 60601-2-43:2000, EN 60601-2-54:2009
〈AC〉 *deleted* 〈AC〉 + EN 60601-2-43:2010/A1 +

English Version

Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010 + IEC 60601-2-43:2010/A1:2017 + IEC 60601-2-43:2010/A2:2019)

Appareils électromédicaux - Partie 2-43: Exigences particulières pour la sécurité de base et les performances essentielles des appareils à rayonnement X lors d'interventions
(IEC 60601-2-43:2010 + IEC 60601-2-43:2010/A1:2017 + IEC 60601-2-43:2010/A2:2019)

Medizinische elektrische Geräte - Teil 2-43: Besondere Festlegungen für die Sicherheit und wesentlichen Leistungsmerkmale von Röntgeneinrichtungen für interventionelle Verfahren
(IEC 60601-2-43:2010 + IEC 60601-2-43:2010/A1:2017 + IEC 60601-2-43:2010/A2:2019)

This European Standard was approved by CENELEC on 2010-06-01. Amendment A1 was approved by CENELEC on 2017-07-05. Amendment A2 was approved by CENELEC on 2019-11-20. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendments 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 CENELEC member.

This European Standard and its Amendment A1 and A2 exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 60601-2-43:2010 E + EN 60601-2-43:2010/A1:2018 E
+ EN 60601-2-43:2010/A2:2020 E

Foreword

The text of document 62B/779/FDIS, future edition 2 of IEC 60601-2-43, prepared by SC 62B, Diagnostic imaging equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-43 on 2010-06-01.

This European Standard supersedes EN 60601-2-43:2000 ▌〈AC〉 *deleted text* 〈AC〉▐.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on EN 60601-1:2006 and relevant collaterals. EN 60601-2-43:2010 is extended to become a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

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

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2011-03-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2013-06-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 60601-2-43:2010 was approved by CENELEC as a European Standard without any modification.

Amendment A1 European foreword

The text of document 62B/1012/CDV, future edition 2 of IEC 60601-2-43:2010/A1, prepared by SC 62B "Diagnostic imaging equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-43:2010/A1:2018.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2018-11-18
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2021-05-18

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

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010/A1:2017 was approved by CENELEC as a European Standard without any modification.

Amendment A2 European foreword

The text of document 62B/1137/FDIS, future IEC 60601-2-43/A2, prepared by SC 62B "Diagnostic imaging equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-43:2010/A2:2020.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-10-03
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-04-03

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s), see informative Annex ZZ, included in EN 60601-2-43:2010.

Endorsement notice

The text of the International Standard IEC 60601-2-43:2010/A2:2019 was approved by CENELEC as a European Standard without any modification.

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-43 has been prepared by IEC subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision.

This particular standard has been revised to provide a complete set of safety requirements for X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, based on the third edition of IEC 60601-1 and relevant collaterals. The present edition is extended to become a system standard for X-RAY EQUIPMENT designed for the use during interventional procedures using X-ray imaging, whether of prolonged or normal duration.

The text of this standard is based on the following documents:

FDIS	Report on voting
62B/779/FDIS	62B/792/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this 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. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 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 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 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.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

AMENDMENT 1 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

CDV	Report on voting
62B/1012/CDV	62B/1037/RVC

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

AMENDMENT 2 FOREWORD

This amendment has been prepared by subcommittee 62B: Diagnostic imaging equipment, of IEC technical committee 62: Electrical equipment in medical practice.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62B/1137/FDIS	62B/1146/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES may subject PATIENTS and OPERATORS to higher levels of RADIATION than those which normally prevail during diagnostic X-ray imaging procedures. One consequence for the PATIENT may be the occurrence of deterministic injury when procedures involve the delivery of substantial amounts of RADIATION to localized areas. Another consequence can be an increased RISK of stochastic effects, such as cancer. These health concerns apply also to the OPERATOR. In addition, for this particular type of equipment, there is a need for availability of critical functions with minimal periods of loss.

Interventional procedures of the type envisaged are well established in clinical fields such as:

– invasive cardiology;
– interventional RADIOLOGY;
– interventional neuroradiology.

These procedures also include many newly developing and emerging applications in a wide range of medical and surgical specialities.

NOTE Attention is drawn to the existence of legislation in some countries concerning RADIOLOGICAL PROTECTION, which may not align with the provisions of this standard.

INTRODUCTION to Amendment 1

The purpose of this first amendment to IEC 60601-2-43:2010 is to introduce changes as follows:

– refer to IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 and its applicable collateral standards;

– refer to IEC 60601-2-54:2009 and IEC 60601-2-54:2009/AMD1:2015 and consequent subclause adaptations;

– include a requirement to have a maximum time of 10 min to recover all functions after a recoverable failure in 201.4.101;

– include several aspects from IEC 61910-1:2014 and remove the reference to IEC PAS 61910-1:2007 in 201.4.102;

– include an alternative way of testing in 201.11.6.5.103;

– include a clarification for tableside controls in 201.12.4.106.

In addition, a number of technical errors have been corrected.

INTRODUCTION to Amendment 2

The purpose of this second amendment to IEC 60601-2-43:2010 is to introduce changes as follows:

– scope clarification with regards to MOBILE X-ray equipment and applicability of IEC 60601-2-54 subclauses;

– reference to IEC 60601-2-54:2009/AMD2:2018 for common subclauses;

– alignment of 201.7.9.1 with IEC 60601-2-54:2009/AMD2:2018 – 201.7.9.1 is no longer modified;

– inclusion of adapted requirements or recommendations from IEC 60601-2-54:2009/AMD2:2018 for

- management of radioscopy image storage in 203.6.1.101,
- display of last image hold (LIH RADIOGRAM) in 203.6.7.101, and
- graphical indication of the boundaries of the X-RAY FIELD in 203.8.102.2;

– inclusion of a recommendation for protection of gantry enclosures in 201.11.6.5.103;

– inclusion of a requirement for X-RADIATION pulse repetition frequency during radioscopy in 203.6.3.103;

– inclusion of a recommendation for a DOSE MAP in 203.6.4.5 with additional definitions in 201.3;

– inclusion of a requirement for display unit of dose area product in 203.6.4.5;

– addition of a number of technical clarifications.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of both FIXED and MOBILE X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, hereafter referred to as INTERVENTIONAL X-RAY EQUIPMENT. Its scope excludes, in particular:

– equipment for RADIOTHERAPY;
– equipment for COMPUTED TOMOGRAPHY;
– ACCESSORIES intended to be introduced into the PATIENT;
– mammographic X-RAY EQUIPMENT;
– dental X-RAY EQUIPMENT.

NOTE 1 Examples of RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, for which the use of INTERVENTIONAL X-RAY EQUIPMENT complying with this standard is recommended, are given in Annex AA.

NOTE 2 Specific requirements for magnetic navigation devices, and for the use of INTERVENTIONAL X-RAY EQUIPMENT in an operating room environment were not considered in this particular standard; therefore no specific requirements have been developed for these devices or uses. In any case, such devices or uses remain under the general clause requirements.

NOTE 3 INTERVENTIONAL X-RAY EQUIPMENT, when used for cone-beam CT mode, is covered by this standard and not by IEC 60601-2-44 [2][2]. No additional requirements for operation in cone-beam CT mode were identified for this standard (see also Note 4 in 203.6.4.5).

INTERVENTIONAL X-RAY EQUIPMENT declared by the MANUFACTURER to be suitable for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, which does not include a PATIENT SUPPORT as part of the system, is exempt from the PATIENT SUPPORT provisions of this standard.

If a clause or subclause is specifically intended to be applicable to INTERVENTIONAL X-RAY 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 INTERVENTIONAL X-RAY EQUIPMENT and to ME SYSTEMS, as relevant.

NOTE 4 See also 4.2 of the general standard.

The subclauses of this standard supersede IEC 60601-2-54 subclauses. IEC 60601-2-54 applies only with regards to the cited subclauses; non-cited subclauses of IEC 60601-2-54 do not apply.

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1) The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2) Figures in square brackets refer to the Bibliography.

201.1.2 Object

Replacement:

The object of this particular standard is:

– to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the design and manufacture of X-RAY EQUIPMENT for RADIOSCOPICALLY GUIDED INTERVENTIONAL PROCEDURES, as defined in 201.3.203.

– to specify information which is to be provided with such INTERVENTIONAL X-RAY EQUIPMENT for the assistance of the RESPONSIBLE ORGANIZATION and OPERATOR in managing the RADIATION RISK and equipment failure RISK arising from these procedures which could affect PATIENTS or staff.

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 60601-1-2 and IEC 60601-1-3 apply as modified in Clause 202 and Clause 203 respectively. IEC 60601-1-8[3)], IEC 60601-1-9[4)], IEC 60601-1-10[5)], IEC 60601-1-11[6)] and IEC 60601-1-12[7)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

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3) IEC 60601-1-8, 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

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

5) IEC 60601-1-10, 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

6) IEC 60601-1-11, 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

7) IEC 60601-1-12, Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

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, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 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 through 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, figures or tables 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, 203 for IEC 60601-1-3, 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

Clause 2 of the general standard applies, except as follows:

NOTE Informative references are listed in the Bibliography beginning on page 64.

Amendment:

IEC 60529:1989, Degrees *of protection provided by enclosures* (IP Code)
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-3:2008, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment*
IEC 60601-1-3:2008/AMD1:2013