EESTI STANDARD EVS-EN 60601-1:2006+A1+A12+A2:2021

Sisaldab värvilisi lehekülgi
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ELEKTRILISED MEDITSIINISEADMED. OSA 1: ÜLDISED NÕUDED ESMASELE OHUTUSELE JA OLULISTELE TOIMIMISNÄITAJATELE

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + IEC 60601-1:2005/A1:2012 + IEC 60601-1:2005/A2:2020)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1:2006+A1+A12 +A2:2021 sisaldab Euroopa standardi EN 60601-1:2006 ja selle muudatuste A1:2013, A12:2014 ja A2:2021 ning paranduste AC:2010 ja AC:2016 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1:2006+A1 +A12+A2:2021 consists of the English text of the European standard EN 60601-1:2006 and its amendments A1:2013, A12:2014 and A2:2021, and its corrigenda AC:2010 and AC:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 20.10.2006, muudatused A1 04.10.2013, A12 03.10.2014 ja A2 08.10.2021.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 20.10.2006, for A1 04.10.2013, A12 03.10.2014 and A2 08.10.2021.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦A1⟩ ⟨A1⟧. Muudatusega A12 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦A12⟩ ⟨A12⟧. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦A2⟩ ⟨A2⟧. Parandusega AC:2010 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦AC⟩ ⟨AC⟧. Parandusega AC:2016 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega ⟦AC2⟩ ⟨AC2⟧. Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags ⟦A1⟩ ⟨A1⟧. The start and finish of text introduced or altered by amendment A12 is indicated in the text by tags ⟦A12⟩ ⟨A12⟧. The start and finish of text introduced or altered by amendment A2 is indicated in the text by tags ⟦A2⟩ ⟨A2⟧. The start and finish of text introduced or altered by corrigendum AC:2010 is indicated in the text by tags ⟦AC⟩ ⟨AC⟧. The start and finish of text introduced or altered by corrigendum AC:2016 is indicated in the text by tags ⟦AC2⟩ ⟨AC2⟧. The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1 + A1 + A12 + A2

October 2006, October 2013, October 2014 + October 2021

ICS 11.040

Supersedes EN 60601-1:1990 + amendments

English Version

Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + IEC 60601-1:2005/A1:2012 + IEC 60601-1:2005/A2:2020)

Appareils électromédicaux - Partie 1: Exigences générales pour la sécurité de base et les performances essentielles (CEI 60601-1:2005 + CEI 60601-1:2005/A1:2012 + IEC 60601-1:2005/A2:2020)

Medizinische elektrische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale (IEC 60601-1:2005 + IEC 60601-1:2005/A1:2012 + IEC 60601-1:2005/A2:2020)

This European Standard was approved by CENELEC on 2006-09-12. Amendment A1 was approved by CENELEC on 2013-09-24. Amendment A12 was approved by CENELEC on 2014-09-26. Amendment A2 was approved by CENELEC on 2020-09-24. 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 Amendments A1, A12 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 60601-1:2006 E + EN 60601-1:2006/A1:2013 E
+ EN 60601-1:2006/A12:2014 E + EN 60601-1:2006/A2:2021 E

Foreword

The text of document 62A/505A//FDIS, future edition 3 of IEC 60601-1, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1 on 2006-09-12.

The following date was 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)	2007-07-01
	▌AC〉 (dow)	2012-06-01 〈AC▐

▌A1〉 This European Standard supersedes EN 60601-1:1990 and its amendments, EN 60601-1-1:2001 and EN 60601-1-4:1996 + A1:1999 〈A1▐. ▌AC〉 *deleted text* 〈AC▐

This EN 60601-1:2006 has been significantly restructured compared to EN 60601-1:1990. Requirements in the electrical section have been further aligned with those for information technology equipment covered by EN 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Clause A.3.

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 Directives 90/385/EEC and 93/42/EEC. See Annex ZZ.

In this standard the following print types are used:

- requirements and definitions: in roman type;
- *test specifications: in 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN 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 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 G 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 A.

Annexes ZA and ZZ have been added by CENELEC.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60073	NOTE	Harmonized as EN 60073:2002 (not modified).
IEC 60086-1	NOTE	Harmonized as EN 60086-1:2001 (not modified).
IEC 60127-6	NOTE	Harmonized as EN 60127-6:1994 (not modified).
IEC 60309-1	NOTE	Harmonized as EN 60309-1:1999 (not modified).
IEC 60317-43	NOTE	Harmonized as EN 60317-43:1997 (not modified).
IEC 60601-1-1	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-2-49	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).
IEC 60695-1-1	NOTE	Harmonized as EN 60695-1-1:2000 (not modified).
IEC 60721 series	NOTE	Harmonized in EN 60721 series (not modified).
IEC 60990	NOTE	Harmonized as EN 60990:1999 (not modified).
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11:2004 (not modified).
IEC 61010-1	NOTE	Harmonized as EN 61010-1:2001 (not modified).
IEC 61140	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 62079	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62304	NOTE	Harmonized as EN 62304:2006 (not modified).
ISO 407	NOTE	Harmonized as EN ISO 13407:2004 (not modified).
ISO 8041	NOTE	Harmonized as EN ISO 8041:2005 (not modified).
ISO 13485	NOTE	Harmonized as EN ISO 13485:2003 (not modified).

Endorsement notice

The text of the International Standard IEC 60601-1:2005 was approved by CENELEC as a European Standard without any modification.

⟨A1⟩ Amendment A1 foreword

The text of document 62A/805/FDIS, future IEC 60601-1:2005/A1, prepared by SC 62A, "Common aspects of electrical equipment used in medical practice", of IEC TC 62, "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1:2006/A1:2013.

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) 2014-06-24
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-24

In the foreword of EN 60601-1:2006, ***replace*** *the first sentence of the third paragraph by:*

This European Standard supersedes EN 60601-1:1990 and its amendments, EN 60601-1-1:2001 and EN 60601-1-4:1996 + A1:1999.

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.

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 ⟨A12⟩ Annex ZZA ⟨A12⟩, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification.

Replace *the Bibliography of EN 60601-1:2006 by:*

IEC 60073	NOTE	Harmonized as EN 60073.
IEC 60086-1	NOTE	Harmonized as EN 60086-1.
IEC 60127-6	NOTE	Harmonized as EN 60127-6.
IEC 60309-1	NOTE	Harmonized as EN 60309-1.
IEC 60332-1-2	NOTE	Harmonized as EN 60332-1-2.
IEC 60332-2-2	NOTE	Harmonized as EN 60332-2-2.
IEC 60317-43	NOTE	Harmonized as EN 60317-43.
IEC 60601-1-1:2000	NOTE	Harmonized as EN 60601-1-1:2001 (not modified).
IEC 60601-1-4:1996	NOTE	Harmonized as EN 60601-1-4:1996 + A1:1999 (not modified).
IEC 60601-1-11	NOTE	Harmonized as EN 60601-1-11.
IEC 60601-2-22	NOTE	Harmonized as EN 60601-2-22.
IEC 60601-2-49:2001	NOTE	Harmonized as EN 60601-2-49:2001 (not modified).

IEC 60695-1-10	NOTE	Harmonized as EN 60695-1-10.
IEC 60721 series	NOTE	Harmonized in EN 60721 series.
IEC 60990	NOTE	Harmonized as EN 60990.
IEC 61000-4-11	NOTE	Harmonized as EN 61000-4-11.
IEC 61010 series	NOTE	Harmonized in EN 61010 series.
IEC 61010-1:2010	NOTE	Harmonized as EN 61010-1:2010 (not modified).
IEC 61140:2001	NOTE	Harmonized as EN 61140:2002 (not modified).
IEC 61558-1	NOTE	Harmonized as EN 61558-1.
IEC 61558-2-4	NOTE	Harmonized as EN 61558-2-4.
IEC 61558-2-23	NOTE	Harmonized as EN 61558-2-23.
IEC 62079:2001	NOTE	Harmonized as EN 62079:2001 (not modified).
IEC 62353	NOTE	Harmonized as EN 62353.
IEC 62471:2006	NOTE	Harmonized as EN 62471:2008 (modified).
IEC 80001-1:2010	NOTE	Harmonized as EN 80001-1:2011 (not modified).
ISO 407	NOTE	Harmonized as EN ISO 407.
ISO 7396-1	NOTE	Harmonized as EN ISO 7396-1.
ISO 8041	NOTE	Harmonized as EN ISO 8041.
ISO 13485	NOTE	Harmonized as EN ISO 13485.
ISO 15001	NOTE	Harmonized as EN ISO 15001.

A12 Amendment A12 Foreword

This document (EN 60601-1:2006/A12:2014) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

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)	2015-03-26
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2015-03-26

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.

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 Annexes ZZA and ZZB, which are an integral part of this document. 〈A12

A2 Amendment A2 European foreword

The text of document 62A/1389/FDIS, future IEC 60601-1/A2, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-1:2006/A2:2021.

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) 2022-04-08
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2024-10-08

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.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 60601-1:2005/A2:2020 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-2-57	NOTE	Harmonized as EN 60601-2-57
IEC 62366-1:2015	NOTE	Harmonized as EN 62366-1:2015 (not modified)
ISO 2409	NOTE	Harmonized as EN ISO 2409
ISO 4624	NOTE	Harmonized as EN ISO 4624
ISO 10524-1:2018	NOTE	Harmonized as EN ISO 10524-1:2019 (not modified)
ISO 13732-1:2006	NOTE	Harmonized as EN ISO 13732-1:2008 (not modified)

A2

IEC 60601-1

Edition 3.2 2020-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

IEC 60601-1:2005-12+AMD1:2012-07+AMD2:2020-08 CSV(en)

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The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

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The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC 60601-1

Edition 3.2 2020-08
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

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 60601-1 has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

〈A1〉 This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a risk management process has been added. For an expanded description of this revision, see Annex A.3. 〈A1〉

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

FDIS	Report on voting
62A/505A/FDIS	62A/512/RVD

Full information on the voting for the approval of this 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: in roman type.
- *Test specifications: in 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 USED THROUGHOUT THIS STANDARD THAT HAVE BEEN DEFINED IN CLAUSE 3 AND ALSO GIVEN IN THE INDEX: IN 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 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 G 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 A.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result 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.

The contents of the corrigenda of December 2006 and 2007 and the Interpretation sheets of April 2008, January 2009 and May 2013 have been included in this copy.

〈A1〉 NOTE The attention of 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 IEC or ISO 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 be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication. 〈A1〉

AMENDMENT A1 FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, 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
62A/805/FDIS	62A/820/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 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.

The contents of the corrigendum of July 2014 have been included in this copy.

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.

AMENDMENT A2 FOREWORD

This amendment has been prepared by subcommittee 62A: Common aspects of electrical equipment used in medical practice, 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
62A/1389/FDIS	62A/1404/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 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.

NOTE The attention of the users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO 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 be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

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

In 1976, IEC subcommittee 62A published the first edition of IEC/TR 60513, *Basic aspects of the safety philosophy for electrical equipment used in medical practice*. The first edition of IEC/TR 60513 provided the basis for developing:

– the first edition of IEC 60601-1 (the parent safety standard for MEDICAL ELECTRICAL EQUIPMENT);

– the IEC 60601-1-xx series of collateral standards for MEDICAL ELECTRICAL EQUIPMENT;

– the IEC 60601-2-xx series of particular standards for particular types of MEDICAL ELECTRICAL EQUIPMENT; and

– the IEC 60601-3-xx series of performance standards for particular types of MEDICAL ELECTRICAL EQUIPMENT.

Aware of the need and the urgency for a standard covering electrical equipment used in medical practice, the majority of National Committees voted in 1977 in favour of the first edition of IEC 60601-1, based on a draft that at the time represented a first approach to the problem. The extent of the scope, the complexity of the equipment concerned, and the specific nature of some of the protective measures and the corresponding tests for verifying them, required years of effort in order to prepare this first standard, which can now be said to have served as a universal reference since its publication.

However, the frequent application of the first edition revealed room for improvement. These improvements were all the more desirable in view of the considerable success that this standard has enjoyed since its publication.

The careful work of revision subsequently undertaken and continued over a number of years resulted in the publication of the second edition in 1988. This edition incorporated all the improvements that could be reasonably expected up to that time. Further developments remained under constant study. The second edition was amended in 1991 and then again in 1995.

The original IEC approach was to prepare separate BASIC SAFETY and performance standards for MEDICAL ELECTRICAL EQUIPMENT. This was a natural extension of the historical approach taken at the national and international level with other electrical equipment standards (e.g. those for domestic equipment), where BASIC SAFETY is regulated through mandatory standards but other performance specifications are regulated by market pressure. In this context, it has been said that, “The ability of an electric kettle to boil water is not critical to its safe use!”

It is now recognized that this is not the situation with many items of MEDICAL ELECTRICAL EQUIPMENT, and RESPONSIBLE ORGANIZATIONS have to depend on standards to ensure ESSENTIAL PERFORMANCE as well as BASIC SAFETY. Such areas include the accuracy with which the equipment controls the delivery of energy or therapeutic substances to the PATIENT, or processes and displays physiological data that will affect PATIENT management.

This recognition means that separating BASIC SAFETY and performance is somewhat inappropriate in addressing the HAZARDS that result from inadequate design of MEDICAL ELECTRICAL EQUIPMENT. Many particular standards in the IEC 60601-2-xx series address a range of ESSENTIAL PERFORMANCE requirements that cannot be directly evaluated by the RESPONSIBLE ORGANIZATION without applying such standards. (However, the current IEC 60601 series includes fewer requirements for ESSENTIAL PERFORMANCE than for BASIC SAFETY).

In anticipation of a third edition of IEC 60601-1, IEC subcommittee 62A prepared a second edition of IEC/TR 60513 [12][1)] in 1994. It was intended that the second edition of IEC/TR 60513 would provide guidance for developing this edition of IEC 60601-1, and for the further development of the IEC 60601-1-xx and IEC 60601-2-xx series.

1) Figures in square brackets refer to the Bibliography.

In order to achieve consistency in international standards, address present expectations in the health care community and align with developments in IEC 60601-2-xx, the second edition of IEC/TR 60513 includes two major new principles:

– the first change is that the concept of "SAFETY" has been broadened from the BASIC SAFETY considerations in the first and second editions of IEC 60601-1 to include ESSENTIAL PERFORMANCE matters, (e.g. the accuracy of physiological monitoring equipment). Application of this principle leads to the change of the title of this publication from "Medical electrical equipment, Part 1: General requirements for safety" in the second edition, to "Medical electrical equipment, Part 1: General requirements for basic safety and essential performance";

– the second change is that, in specifying minimum safety requirements, provision is made for assessing the adequacy of the design PROCESS when this is the only practical method of assessing the safety of certain technologies such as programmable electronic systems. Application of this principle is one of the factors leading to introduction of a general requirement to carry out a RISK MANAGEMENT PROCESS. In parallel with the development of the third edition of IEC 60601-1, a joint project with ISO/TC 210 resulted in the publication of a general standard for RISK MANAGEMENT of medical devices. ▌A1⟩ Compliance with this edition of IEC 60601-1 requires that the manufacturer have in place a risk management process complying with parts of ISO 14971 (see 4.2). ⟨A1▐

This standard contains requirements concerning BASIC SAFETY and ESSENTIAL PERFORMANCE that are generally applicable to MEDICAL ELECTRICAL EQUIPMENT. For certain types of MEDICAL ELECTRICAL EQUIPMENT, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

▌A1⟩ Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005. ⟨A1▐

▌A2⟩ Throughout this document, there are many references to, and requirements incorporated from IEC 60950-1. Some of these requirements are derived from IEC 60950-1. For example, the requirements for spaces filled by insulating compound in 8.9.3. In other cases, the requirements are incorporated by a normative reference to IEC 60950-1:2005. For example, the requirements for solid insulation forming a MEANS OF OPERATOR PROTECTION in 8.5.1.3. The requirements incorporated by reference are primarily found in Clause 8 of this document, including many of the tables used to determine the requirements for MEANS OF PROTECTION, primarily MEANS OF OPERATOR PROTECTION and INSULATION CO-ORDINATION. The requirements incorporated by reference are addressed in Amendment 2. The derived requirements will be addressed during the development of the fourth edition of this document. ⟨A2▐

〈A1〉 INTRODUCTION TO AMENDMENT 1

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those listed in 62A/593/DC and 62A/602/INF;
– the way in which RISK MANAGEMENT[2] has been introduced into IEC 60601-1:2005; and
– the way the concept of ESSENTIAL PERFORMANCE[3] is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues. 〈A1〉

[2] EE NOTE 1 Print type of the term has been changed into small capitals.

[3] EE NOTE 2 Print type of the term has been changed into small capitals.

▌A2⟩ INTRODUCTION TO AMENDMENT 2

The third edition of IEC 60601-1 was published in 2005 and amended in 2012. Since the publication of IEC 60601-1:2005/AMD1:2012, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees and questions submitted to IEC/SC 62A/Working Group (WG) 14. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in Amendment 2 and should not wait until the fourth edition of IEC 60601-1, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 2 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 109 items were presented to the National Committees present. A total of 78 items received the required 2/3 majority of the National Committees present and voting and were included in the "short list" for consideration in preparing Amendment 2. All remaining issues have been placed on a "long list" for consideration in the fourth edition of IEC 60601-1.

The "short list" of issues was documented in the design specification for Amendment 2. The responsible expert groups were directed to consider each issue assigned to it in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to the 2005 edition of IEC 60601-1, the style in force at the time of publication of IEC 60601-1 has been applied to this amendment. The style specified in ISO/IEC Directives, Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes. For example, notes to definitions are designated as "NOTE" rather than "Note to entry" in Clause 3.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference. ⟨A2▌

MEDICAL ELECTRICAL EQUIPMENT –

Part 1: General requirements for basic safety and essential performance

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

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

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

NOTE [A1] 1 [/A1] See also 4.2.

[A1] *deleted text* [/A1]

[A1] The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];
– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or
– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS. [/A1]

1.2 Object

The object of this standard is to specify general requirements and to serve as the basis for particular standards.

1.3 * Collateral standards

In the IEC 60601 series, collateral standards specify general requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE applicable to:

– a subgroup of ME EQUIPMENT (e.g. radiological equipment);
– a specific characteristic of all ME EQUIPMENT not fully addressed in this standard.

[A2] Applicable collateral standards shall apply together with this standard. [/A2]

NOTE 1 When evaluating compliance with IEC 60601-1, it is permissible to independently assess compliance with the collateral standards.

NOTE 2 When declaring compliance with IEC 60601-1, the declarer should specifically list the collateral standards that have been applied. This allows the reader of the declaration to understand which collateral standards were part of the evaluation.

[A1] NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published. [/A1]

[A2] *deleted text* [A2]

1.4 * Particular standards

[A2] In the IEC 60601 series, particular standards specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for the particular ME EQUIPMENT and ME SYSTEMS. Particular standards may modify, replace or delete requirements contained in this standard and applicable collateral standards as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration. [A2]

[A1] NOTE Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "http://webstore.iec.ch" and "http://www.iso.org/iso/store.htm" to determine which particular standards have been published. [A1]

[A2] A requirement of a particular standard takes priority over this standard and applicable collateral standards. [A2]

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.

[A2]

ATTENTION: Additional collateral standards of the IEC 60601 series, which are issued subsequent to publication of this standard, shall apply together with this standard when applicable. They shall be considered as being included among the normative references below. See 1.3.

[A2]

NOTE Informative references are listed in the Bibliography on page 401.

[A1] IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* [4)]
Amendment 1:2005
Amendment 2:2010 [A1]

[A1] IEC 60068-2-2:2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat* [A1]

IEC 60079-0, *Electrical apparatus for explosive gas atmospheres – Part 0: General requirements*

IEC 60079-2, *Electrical apparatus for explosive gas atmospheres – Part 2: Pressurized enclosures "p"*

IEC 60079-5, *Electrical apparatus for explosive gas atmospheres – Part 5: Powder filling "q"*

IEC 60079-6, *Electrical apparatus for explosive gas atmospheres – Part 6: Oil-immersion "o"*

IEC 60083, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC*

IEC 60085, *Electrical insulation – Thermal classification*

IEC 60086-4, *Primary batteries – Part 4: Safety of lithium batteries*

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[A1] 4) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010). [A1]

IEC 60112, *Method for the determination of the proof and the comparative tracking indices of solid insulating materials*

IEC 60127-1, *Miniature fuses – Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links*

〈A1〉 IEC 60227-1:2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements* 〈A1〉

〈A1〉 IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*[5]
Amendment 1:2007 〈A1〉

IEC 60252-1, *AC motor capacitors – Part 1: General – Performance, testing and rating – Safety requirements – Guide for installation and operation*

IEC 60320-1, *Appliance couplers for household and similar general purposes – Part 1: General requirements*

〈A1〉 IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements* 〈A1〉

IEC 60364-4-41, *Electrical installations of buildings – Part 4-41: Protection for safety – Protection against electric shock*

IEC 60384-14:2005, *Fixed capacitors for use in electronic equipment – Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains*

〈A1〉 IEC 60417, *Graphical symbols for use on equipment.* Available from:
<http://www.graphical-symbols.info/equipment> 〈A1〉

IEC 60445, *Basic and safety principles for man-machine interface, marking and identification – Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system*

IEC 60447, *Basic and safety principles for man-machine interface, marking and identification – Actuating principles*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)* [6)]
Amendment 1 (1999)

〈A2〉 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*
Amendment 1:2020 〈A2〉

〈A2〉 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*
Amendment 1:2013 〈A2〉

〈A2〉 IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
Amendment 1:2013
Amendment 2:2020 〈A2〉

〈A1〉 5) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007). 〈A1〉

6) There exists a consolidated version 2.1, including IEC 60529:1989 and its Amendment 1 (1999).

[A2] 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*
Amendment 1:2012
Amendment 2:2020 [A2]

[A1] IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests* [A1]

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

[A1] IEC 60730-1:2010, *Automatic electrical controls for household and similar use – Part 1: General requirements* [A1]

[A2] IEC 60747-5-5:2007, *Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers* [A2]

[A1] IEC 60825-1:[A2] 2014 [A2], *Safety of laser products – Part 1: Equipment classification and requirements* [A1]

[A1] IEC 60851-3:2009, *Winding wires – Test methods – Part 3: Mechanical properties* [A1]

[A1] IEC 60851-5:2008, *Winding wires – Test methods – Part 5: Electrical properties* [A1]

IEC 60851-6:1996, *Winding wires – Test methods – Part 6: Thermal properties*
Amendment 1 (1997)

[A1] *deleted text* [A1]

IEC 60884-1, *Plugs and socket-outlets for household and similar purposes - Part 1: General requirements*

[A2] IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*
Amendment 1:2009
Amendment 2:2013 [A2]

[A1] IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements*[7)]
Amendment 1:2001
Amendment 2:2007 [A1]

[A1] *deleted text* [A1]

IEC 61558-2-1, *Safety transformers, power supply units and similar – Part 2: Particular requirements for separating transformers for general use*

IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

IEC 61672-2, *Electroacoustics – Sound level meters – Part 2: Pattern evaluation tests*

IEC 61965, *Mechanical safety of cathode ray tubes*

[A1] IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications* [A1]

[A1] 7) There exists a consolidated edition 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007) [A1]

[A2] IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems* [A2]

[A2] IEC 62304:2006, *Medical device software – Software life cycle processes*
Amendment 1:2015 [A2]

[A2] IEC 62368-1:2018, *Audio/video, information and communication technology equipment – Part 1: Safety requirements* [A2]

[A1] *deleted text* [A1]

ISO 780, *Packaging – Pictorial marking for handling of goods*

[A1] *deleted text* [A1]

ISO 1853, *Conducting and dissipative rubbers, vulcanized or thermoplastic – Measurement of resistivity*

ISO 2878, *Rubber, vulcanized – Antistatic and conductive products – Determination of electrical resistance*

ISO 2882 [8)], *Rubber, vulcanized – Antistatic and conductive products for hospital use – Electrical resistance limits*

ISO 3746, *Acoustics – Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane*

ISO 3864-1:2002, *Graphical symbols – Safety colours and safety signs – Part 1: Design principles for safety signs in workplaces and public areas*

ISO 5349-1, *Mechanical vibration – Measurement and evaluation of human exposure to hand-transmitted vibration – Part 1: General requirements*

[A2] ISO 7000, *Graphical symbols for use on equipment* [A2]

[A1] ISO 7010:[A2] 2019 [A2], *Graphical symbols – Safety colours and safety signs –Registered safety signs* [A1]

ISO 9614-1, *Acoustics – Determination of sound power levels of noise sources using sound intensity – Measurement at discrete points*

ISO 10993 (all parts), *Biological evaluation of medical devices*

[A1] *deleted text* [A1]

[A1] ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs* [A1]

8) ISO 2882 was withdrawn on 1 February 2005 and no replacement standard has been identified.

[A1] ISO 14971:[A2] 2019 [A2], *Medical devices – Application of risk management to medical devices* [A1]

[A1] ISO 15223-1:[A2] 2016 [A2], *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements* [A1]

[A1] ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices* [A1]

ISO 23529, *Rubber – General procedures for preparing and conditioning test pieces for physical test methods*

[A1] ISO 80000-1:2009, *Quantities and units – Part 1: General* [A1]

3 * Terminology and definitions

For the purposes of this document, the following terms and definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT (see 3.63) or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM (see 3.64).

[A1] NOTE 3 When the term "safety" is used in this document in roman or italic type, it does not mean "safety" as defined in ISO 14971, but rather is used to mean "the state of being protected from or guarded against hurt or injury; freedom from danger". [A1]

NOTE [A1] 4 [A1] An index is found beginning on page 749.

3.1
ACCESS COVER
part of an ENCLOSURE or GUARD providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

3.2
ACCESSIBLE PART
part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

NOTE See also 5.9.2.1.

3.3
ACCESSORY
additional part for use with equipment in order to:

– achieve the INTENDED USE,
– adapt it to some special use,
– facilitate its use,
– enhance its performance, or
– enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]