

**ELEKTRILISED MEDITSIIINISEADMED. OSA 1-11:
ÜLDISED NÕUDED ESMASELE OHUTUSELE JA
OLULISTELE TOIMIMISNÄITAJATELE.
KOLLATERAALSTANDARD: NÕUDED KODUSES
RAVIKESKKONNAS KASUTATAVATELE ELEKTRILISTELE
MEDITSIIINISEADMETELE JA -SÜSTEEMIDELE**

**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
(IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2020)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN 60601-1-11:2015 +A1:2021 sisaldab Euroopa standardi EN 60601-1-11:2015 ja selle muudatuse A1:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-11:2015 +A1:2021 consists of the English text of the European standard EN 60601-1-11:2015 and its amendment A1:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015, muudatus A1 16.07.2021.	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 22.05.2015, for A1 16.07.2021.
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ICS 11.040

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English Version

**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
(IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2020)**

Appareils électromédicaux - Partie 1-11: Exigences
générales pour la sécurité de base et les performances
essentielle - Norme Collatérale: Exigences pour les
appareils électromédicaux et les systèmes électromédicaux
utilisés dans l'environnement des soins à domicile
(IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2020)

Medizinische elektrische Geräte - Teil 1-11: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale - Ergänzungsnorm:
Anforderungen an medizinische elektrische Geräte und
medizinische elektrische Systeme für die medizinische
Versorgung in häuslicher Umgebung
(IEC 60601-1-11:2015 + IEC 60601-1-11:2015/A1:2020)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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

Foreword

The text of document 62A/959/FDIS, future edition 2 of IEC 60601-1-11, 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 60601-1-11:2015.

The following dates are fixed:

- latest date by which the document has to be implemented (dop) 2016-01-14
at national level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with (dow) 2018-12-31
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The text of the International Standard IEC 60601-1-11:2015 was approved by CENELEC as a European Standard without any modification.

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IEC 60038:2009	NOTE	Harmonized as EN 60038:2011 (modified).
IEC 60065:2014	NOTE	Harmonized as EN 60065:2014 (modified).
IEC 60335-1:2010	NOTE	Harmonized as EN 60335-1:2012 (modified).
IEC 60364	NOTE	Harmonized in HD 384 / HD 60364 series (partly modified).
IEC 60601-1-9	NOTE	Harmonized as EN 60601-1-9.
IEC 60721-3-7:1995	NOTE	Harmonized as EN 60721-3-7:1995 (not modified).
IEC 60950-1:2005 + A1:2009 + A2:2013	NOTE	Harmonized as EN 60950-1:2006 (modified) + A1:2010 (modified) + A2:2013 (modified).

IEC 61032:1997	NOTE	Harmonized as EN 61032:1998 (not modified).
ISO 10651-2:2004	NOTE	Harmonized as EN ISO 10651-2:2009 (not modified).

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A1 Amendment A1 European foreword

The text of document 62A/1395/FDIS, future IEC 60601-1-11/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 60601-1-11:2015/A1:2021.

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- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2022-01-16
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IEC 62368-1:2018 NOTE Harmonized as EN IEC 62368-1:2020 (not modified)

A1

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

Appareils électromédicaux –

Partie 1-11: Exigences générales pour la sécurité de base et les performances

essentiels – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile



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IEC 60601-1-11

Edition 2.1 2020-07
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

NORME INTERNATIONALE



**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**

**Appareils électromédicaux –
Partie 1-11: Exigences générales pour la sécurité de base et les performances
essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux
et les systèmes électromédicaux utilisés dans l'environnement des soins à
domicile**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**

FOREWORD

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International standard IEC 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee SC3: Lung ventilators and related devices, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

This second edition constitutes a collateral standard to IEC 60601-1 (third edition, including Amendment 1): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereafter referred to as the general standard.

This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

- correction of test method for relative humidity control at temperatures above 35 °C;
- redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
- harmonizing with the changes to the amendments to the general standard and other collateral standards.

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

FDIS	Report on voting
62A/959/FDIS	62A/978/RVD

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 P-members out of 17 having cast a vote.

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

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral 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 COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

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

- “clause” means one of the 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 7.3.1 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 collateral 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.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

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.

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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, and ISO subcommittee 3: Respiratory devices and related equipment used for patient care of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo amendment.

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

FDIS	Report on voting
62A/1395/FDIS	62A/1410/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. In ISO, the amendment has been approved by 15 P members out of 15 having cast a vote.

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NOTE The attention of 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.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT OR MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

A1 INTRODUCTION TO AMENDMENT 1

The second edition of IEC 60601-1-11 was published in 2015. Since the publication of IEC 60601-1-11:2015, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. 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 an amendment and should not wait until the third edition of IEC 60601-1-11, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 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, four items were presented to the National Committees present. All four items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the third edition of IEC 60601-1-11.

The "short list" of issues was documented in the design specification for Amendment 1. As IEC 60601-1-11 was jointly developed with ISO/TC 121/SC 3, the work was assigned to IEC/SC 62A-ISO/TC 121/SC 3 Joint Working Group (JWG) 6. JWG 6 was directed to consider each issue described 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 IEC 60601-1-11:2015, the style in force at the time of publication of IEC 60601-1-11 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.

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. **A1**

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

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 for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

The HOME HEALTHCARE ENVIRONMENT includes:

- the dwelling place in which a PATIENT lives;
- other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

NOTE HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone **[A1]**, including any amendments **[A1]**;
- "this collateral standard" designates IEC 60601-1-11 alone **[A1]**, including any amendments **[A1]**;

- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 61.

CISPR 11:2009, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*

IEC 60529:1989/AMD1:1999

IEC 60529:1989/AMD2:2013 ¹⁾

A1 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1:2005/AMD1:2012

IEC 60601-1:2005/AMD2:2020

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 60601-1-2:2014/AMD1:2020

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-6:2010/AMD1:2013

IEC 60601-1-6:2010/AMD2:2020

¹⁾ There exists a consolidated edition 2.2 (2013) including IEC 60529:1989 and its Amendment 1 (1999) and Amendment 2 (2013).

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012
IEC 60601-1-8:2006/AMD2:2020

IEC 60601-1-12:2014, *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*
IEC 60601-1-12:2014/AMD1:2020

IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*
IEC 62366-1:2015/AMD1:2020 ^{A1}

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*. Available from: <http://www.graphical-symbols.info/equipment>

^{A1} ISO 7010:2019, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

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

3 Terms and definitions

^{A1} For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 + IEC 60601-1:2005/AMD2:2020, IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 + IEC 60601-1-6:2010/AMD2:2020, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 + IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-12:2014 and IEC 60601-1-12:2014/AMD1:2020, IEC 62366-1:2015 and IEC 62366-1:2015/AMD1:2020, and the following definitions apply. ^{A1}

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 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.

NOTE 3 An index of defined terms used in this collateral standard is found beginning on page 67.

3.1

HOME HEALTHCARE ENVIRONMENT

dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present

EXAMPLES In a car, bus, train, boat or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this collateral standard, nursing homes are considered HOME HEALTHCARE ENVIRONMENTS.

Note 3 to entry: Other places where a PATIENT is present include the outdoor environment, while working and in vehicles.