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## **Elektrisk utrustning för medicinskt bruk – Del 1-11: Allmänna fordringar beträffande säkerhet och väsentlig prestanda – Tilläggsstandard för utrustning och system för användning i hemlik vårdmiljö**

*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*

Som svensk standard gäller europastandarden EN 60601-1-11:2010. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-1-11:2010.

### **Nationellt förord**

Europastandarden EN 60601-1-11:2010

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-1-11, First edition, 2010 - 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**

utarbetad inom International Electrotechnical Commission, IEC.

Standarden ska användas tillsammans med SS-EN 60601-1, utgåva 2, 2006.

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ICS 11.040

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Denna standard är fastställd av SEK Svensk Elstandard, som också kan lämna upplysningar om **sakinnehållet** i standarden.  
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Det finns många fördelar med att ha gemensamma tekniska regler för bl a säkerhet, prestanda, dokumentation, utförande och skötsel av elprodukter, elanläggningar och metoder. Genom att utforma sådana standarder blir säkerhetskraven tydliga och utvecklingskostnaderna rimliga samtidigt som marknadens acceptans för produkten eller tjänsten ökar.

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### **SEK Svensk Elstandard**

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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 60601-1-11:2010)**

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  
(CEI 60601-1-11:2010)

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 60601-1-11:2010)

This European Standard was approved by CENELEC on 2010-06-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

**CENELEC**

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

**Management Centre: Avenue Marnix 17, B - 1000 Brussels**

## Foreword

The text of document 62A/693/FDIS, future edition 1 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 was approved by CENELEC as EN 60601-1-11 on 2010-06-01.

This EN 60601-1-11:2010 constitutes a collateral standard to EN 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

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

In the 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 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 7.2.1 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 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 (\*).

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 60601-1-11:2010 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:

[2] IEC 60065:2001	NOTE	Harmonized as EN 60065:2002 (modified).
[3] IEC 60335-1:2001	NOTE	Harmonized as EN 60335-1:2002 (modified).
[4] IEC 60364 series	NOTE	Harmonized in HD 60364 series (partially modified).
[5] IEC 60721-3-7:1995	NOTE	Harmonized as EN 60721-3-7:1995 (not modified).
[7] IEC 60950-1:2005	NOTE	Harmonized as EN 60950-1:2006 (modified).
[8] IEC 61032:1997	NOTE	Harmonized as EN 61032:1998 (not modified).
[10] ISO 10651-2:2004	NOTE	Harmonized as EN ISO 10651-2:2004 (not modified).

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## Annex ZA (normative)

### Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
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	EN 60601-1-8 + corr. March	2007 2010
CISPR 11 (mod)	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2009

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## 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 3.2). 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.

## **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, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, which are intended by their MANUFACTURER for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.2, regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

NOTE 1 HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can also be intended for use in other environments, for example, in a professional healthcare facility.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use by emergency medical services or solely for use in professional healthcare facilities.

NOTE 2 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;
- "this collateral standard" designates IEC 60601-1-11 alone;
- "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 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.

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 54.

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – 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)*  
Amendment 1 (1999) <sup>1)</sup>

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

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

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

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*

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



<sup>1)</sup> There exists a consolidated edition 2.1 including IEC 60529:1989 and Amendment 1 (1999).