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Elektrisk utrustning för medicinskt bruk – Säkerhet och väsentliga prestanda – Del 2-4: Särskilda fordringar på defibrillatorer

Medical electrical equipment –

Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

Som svensk standard gäller europastandarden EN 60601-2-4:2011. Den svenska standarden innehåller den officiella engelska språkversionen av EN 60601-2-4:2011.

Nationellt förord

Europastandarden EN 60601-2-4:2011

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 60601-2-4, Third edition, 2010 - Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators**

utarbetad inom International Electrotechnical Commission, IEC.

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

Tidigare fastställd svensk standard SS-EN 60601-2-4, utgåva 1, 2003, gäller ej fr o m 2014-01-12.

Standarder underlättar utvecklingen och höjer elsäkerheten

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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Stora delar av arbetet sker internationellt

Utformningen av standarder sker i allt väsentligt i internationellt och europeiskt samarbete. SEK är svensk nationalkommitté av International Electrotechnical Commission (IEC) och Comité Européen de Normalisation Electrotechnique (CENELEC).

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**Medical electrical equipment -
Part 2-4: Particular requirements for the basic safety and essential
performance of cardiac defibrillators
(IEC 60601-2-4:2010)**

Appareils électromédicaux -
Partie 2-4: Exigences particulières pour la
sécurité de base et les performances
essentielle des défibrillateurs cardiaques
(CEI 60601-2-4:2010)

Medizinische elektrische Geräte -
Teil 2-4: Besondere Festlegungen für die
Sicherheit einschließlich der wesentlichen
Leistungsmerkmale von Defibrillatoren
(IEC 60601-2-4:2010)

This European Standard was approved by CENELEC on 2011-01-12. 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

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Foreword

The text of document 62D/857/FDIS, future edition 3 of IEC 60601-2-4, prepared by SC 62D, Electromedical 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 60601-2-4 on 2011-01-12.

This European Standard supersedes EN 60601-2-4:2003.

EN 60601-2-4:2011 constitutes a technical revision, revised to structurally align it with EN 60601-1:2006 and to implement the decision of IEC SC 62A that the clause numbering structure of particular standards written to EN 60601-1:2006 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The aim of this third edition is to bring this particular standard up to date with reference to the third edition of the general standard through reformatting and technical changes.

The principle technical changes are as follows:

- 201.8.8.3, test 4: added additional test options;
- Figure 201.105: provided example of stainless steel plates. Added note for 10 Hz generator or shockable rhythm generator;
- Figure 201.101: Changed orientation of the lower diode at the oscilloscope connection;
- 202.6.1, .2, .4: "Additions" and "Replacements" corrected to be as originally intended;
- 201.101.1: Clarified preconditioning of a non-rechargeable battery;
- 201.3.207: Clarified definition of DUMMY COMPONENT;
- 201.15.4.101: In paragraph b), added reduced flex requirements for sterilizable internal paddles with specified limit on sterilization cycles;
- 201.15.4.3.103: Added an option for devices having non-changeable pre-programmed energy-setting sequences;
- 201.102.3.1, 2: Changed from specified defibrillation cycles to use of pre-programmed defibrillation sequence;
- 202.6.2.2.1: Changed ESD discharge sequence to match EN 60601-1-2:2007.

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) | 2012-02-12 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2014-01-12 |

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.

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 MDD (93/42/EEC). See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-4:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

[2] IEC 60601-2-27 NOTE Harmonized as EN 60601-2-27.

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.

Annex ZA of EN 60601-1:2006 applies except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replace IEC 60601-1-2 by:</i>				
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
<i>Add:</i>				
IEC 61000-4-2	-	Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test	EN 61000-4-2	-
ISO 15223-1	2007	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	-	-

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of CARDIAC DEFIBRILLATORS, hereafter referred to as ME EQUIPMENT.

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 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to implantable defibrillators, remote control DEFIBRILLATORS, external transcutaneous pacemakers, or separate stand-alone cardiac monitors (which are standardized by IEC 60601-2-27 [2]²). Cardiac monitors which use separate ECG monitoring electrodes are not within the scope of this standard unless they are used as the sole basis for AED rhythm recognition detection or beat detection for synchronized cardioversion.

Defibrillation waveform technology is evolving rapidly. Published studies indicate that the effectiveness of waveforms varies. The choice of a particular waveform including waveshape, delivered energy, efficacy, and safety has been specifically excluded from the scope of this standard.

However, due to the critical importance of the therapeutic waveform, comments have been added to the rationale which addresses considerations in waveform selection.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for cardiac defibrillators as defined in 201.3.202.

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

² Numbers in square brackets refer to the bibliography.

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 applies as modified in Clause 202. 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.

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

NOTE Informative references are listed in the bibliography beginning on page 73.

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

Amendment:

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*

Addition:

IEC 61000-4-2, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

ISO 15223-1:2007, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*