Elektrilised meditsiiniseadmed. Osa 1-9: Üldnõuded esmasele ohutusele ja olulistele toimimisnäitajatele. Kollateraalstandard: Keskkonda arvestava projekteerimise nõuded

Medical electrical equipment -- Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 60601-1-9:2008 sisaldab Euroopa standardi EN 60601-1-9:2008 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-9:2008 consists of the English text of the European standard EN 60601-1-9:2008.
Standard on kinnitatud Eesti Standardikeskuse 24.07.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 24.07.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 29.04.2008.	Date of Availability of the European standard text 29.04.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040, 13.020

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-9

April 2008

ICS 11.040; 13.020

English version

Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design

(IEC 60601-1-9:2007)

Appareils électromédicaux - Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour une conception éco-responsable (CEI 60601-1-9:2007)

Medizinische elektrische Geräte - Teil 1-9: Allgemeine Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale - Ergänzungsnorm: Anforderungen zur Reduzierung von Umweltauswirkungen (IEC 60601-1-9:2007)

This European Standard was approved by CENELEC on 2008-04-16. 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, 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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Ref. No. EN 60601-1-9:2008 E

Foreword

The text of document 62A/571/FDIS, future edition 1 of IEC 60601-1-9, 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 60601-1-9 on 2008-04-16.

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)	2009-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2011-05-01

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

This European Standard constitutes a collateral standard to EN 60601-1:2006, hereafter referred to as the general standard.

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 four numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 4 includes Subclauses 4.1, 4.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 4.1, 4.5 and 4.5.1 are all subclauses of Clause 4).

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 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 (*).

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-9:2007 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:

ISO 14001	NOTE	Harmonized as EN ISO 14001:2004 (not modified).
ISO 14021	NOTE	Harmonized as EN ISO 14021:2001 (not modified).
ISO 14040	NOTE	Harmonized as EN ISO 14040:2006 (not modified).

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.

Publication	Year	Title	EN/HD	Year
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers the following essential requirements as given in Annex I of the EC Directive 93/42/EEC:

1, 2, 4, 7.1, 7.5, 12.7.2, 12.7.3, 13.1, 13.3 and 13.6.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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CONTENTS

INTRODUCTION

The objective of this collateral standard is to improve the ENVIRONMENTAL IMPACT for the entire range of MEDICAL ELECTRICAL EQUIPMENT, taking into account all stages of the product LIFE CYCLE:

– product specification;
– design;
– manufacturing;
– sales, logistics, installation;
– use;
– END OF LIFE management.

This means protecting the ENVIRONMENT and human health from HAZARDOUS SUBSTANCES, conserving raw materials and energy, minimizing the generation of WASTE, as well as minimizing the adverse ENVIRONMENTAL IMPACTS associated with WASTE. The criteria needed to reach this goal must be integrated into all stages of the MEDICAL ELECTRICAL EQUIPMENT LIFE CYCLE from the specification stage to END OF LIFE management.

The ENVIRONMENTAL IMPACTS of ME EQUIPMENT through all LIFE-CYCLE stages are determined from the MEDICAL ELECTRICAL EQUIPMENT'S ENVIRONMENTAL ASPECTS defined during the identification of need, product planning, and design stages (see Table A.1). Consideration of ENVIRONMENTAL ASPECTS as early as possible in these stages can produce numerous benefits that might include lower costs, stimulation of innovation and creativity, and increased knowledge about the product. It can also provide new business opportunities, and improved product quality as well as reduction of adverse ENVIRONMENTAL IMPACTS. The assessment of the ENVIRONMENTAL ASPECTS and IMPACTS of MEDICAL ELECTRICAL EQUIPMENT is a developing science and it is anticipated that this collateral standard will require periodic updating as the science develops.

The requirements given in this collateral standard do not replace national or international laws and regulations.

Environmental protection is one element of the overall RISK MANAGEMENT PROCESS as required by the general standard.

The acceptability of MEDICAL ELECTRICAL EQUIPMENT'S ENVIRONMENTAL IMPACTS are balanced against other factors, such as the product's intended function, performance, safety, cost, marketability, quality, legal and regulatory requirements. This balance can differ depending on the intended function of the MEDICAL ELECTRICAL EQUIPMENT. For example, a solution appropriate for life-saving or life-supporting MEDICAL ELECTRICAL EQUIPMENT might not be appropriate for a device intended to correct a minor ailment. A MANUFACTURER of MEDICAL ELECTRICAL EQUIPMENT might have to justify, as a result of RISK MANAGEMENT, that a medical benefit outweighs the associated adverse ENVIRONMENTAL IMPACTS.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-9: General requirements for basic safety and essential performance – Collateral Standard: Requirements for environmentally conscious design

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the reduction of adverse ENVIRONMENTAL IMPACTS of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

MEDICAL ELECTRICAL SYSTEMS are excluded from the scope of this collateral standard.

1.2 Object

The object of this collateral standard is to specify general requirements, in addition to those of the general standard, for the reduction of the adverse ENVIRONMENTAL IMPACT of ME EQUIPMENT, and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT, 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 60601-1-9 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.

1.3.3 Environmental standards

This standard takes into account the ISO 14000 series of environmental standards with particular emphasis on ISO 14062 [8][1)].

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.

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1) Figures in square brackets refer to the Bibliography.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and the following definitions apply.

NOTE An index of defined terms is found beginning on page 30.

3.1
DESIGN AND DEVELOPMENT
set of PROCESSES that transforms requirements into specified characteristics or into the specification of a product, PROCESS or system

NOTE 1 The terms “design” and “development” are sometimes used synonymously and sometimes used to define different stages of the overall PROCESS of turning an idea into a product.

NOTE 2 Product development is the PROCESS of taking a product idea from planning to market launch and post-market review of the product, in which business strategies, marketing considerations, research methods and design aspects are used to take a product to a point of practical use. It includes improvements or modifications to existing products or PROCESSES

NOTE 3 The integration of ENVIRONMENTAL ASPECTS into product DESIGN AND DEVELOPMENT can also be termed design for the ENVIRONMENT (DFE), eco-design, the environmental part of product stewardship, etc.

[ISO/TR 14062:2002, definition 3.3]

3.2
END OF LIFE
EOL
state of a ME EQUIPMENT when it is finally removed from its INTENDED USE

NOTE Adapted from IEC Guide 109:2003, Definition 3.1.

3.3
ENVIRONMENT
surroundings in which an ORGANIZATION operates, including air, water, land, natural resources, flora, fauna, humans and their interrelation

NOTE Surroundings in this context extend from within an ORGANIZATION to the global system.

[ISO 14001:2004, definition 3.5]

3.4
*** ENVIRONMENTAL ASPECT**
element of an ORGANIZATION’S activities, products or services that can interact with the ENVIRONMENT

NOTE A significant ENVIRONMENTAL ASPECT has or can have a significant ENVIRONMENTAL IMPACT.

[ISO 14001:2004, definition 3.6]

3.5
*** ENVIRONMENTAL IMPACT**
any change to the ENVIRONMENT, whether adverse or beneficial, wholly or partially resulting from an ORGANIZATION'S ENVIRONMENTAL ASPECTS

[ISO 14001:2004, definition 3.7]