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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 (IEC 60601-1-9:2007 + IEC 60601-1-9:2007/A1:2013 + IEC 60601-1-9:2007/A2:2020)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 60601-1-9:2008 +A1+A2:2020 sisaldab Euroopa standardi EN 60601-1-9:2008 ja selle muudatuste A1:2013 ja A2:2020 ingliskeelset teksti.	This Estonian standard EVS-EN 60601-1-9:2008 +A1+A2:2020 consists of the English text of the European standard EN 60601-1-9:2008 and its amendments A1:2013 and A2:2020.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.04.2008, muudatused A1 08.11.2013 ja A2 11.09.2020.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation. Date of Availability of the European standard is 29.04.2008, for A1 08.11.2013 and A2 11.09.2020.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A1] ⟨A1⟩. Muudatusega A2 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega [A2] ⟨A2⟩. Standard on kättesaadav Eesti Standardi-keskusest.	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 A2 is indicated in the text by tags [A2] ⟨A2⟩. The standard is available from the Estonian Centre for Standardisation.

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ICS 11.040.01; 13.020.01

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-1-9 + A1 + A2

April 2008, November 2013, September 2020

ICS 11.040.01; 13.020.01

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 + IEC 60601-1-9:2007/A1:2013 + IEC 60601-1-9:2007/A2:2020)

Appareils électromédicaux - Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles - Norme collatérale: Exigences pour une conception écoresponsable (CEI 60601-1-9:2007 + CEI 60601-1-9:2007/A1:2013 + IEC 60601-1-9:2007/A2:2020)

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 + IEC 60601-1-9:2007/A1:2013 + IEC 60601-1-9:2007/A2:2020)

This European Standard was approved by CENELEC on 2008-04-16. A mendment A1 was approved by CENELEC on 2013-07-23. Amendment A2 was approved by CENELEC on 2020-08-26. 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.

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 60601-1-9:2008 E + EN 60601-1-9:2008/A1:2013 E + EN 60601-1-9:2008/A2:2020 E

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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.

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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.

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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).

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〈A1〉 Amendment A1 foreword

The text of document 62A/874/FDIS, future IEC 60601-1-9:2007/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 60601-1-9:2008/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)	2014-04-23
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-12-31

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A2 Amendment A2 European foreword

The text of document 62A/1393/FDIS, future IEC 60601-1-9/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 60601-1-9:2008/A2:2020.

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) 2021-05-26
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2023-08-26

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IEC 60601-1-9

Edition 1.2 2020-07

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VERSION CONSOLIDÉE

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

Appareils électromédicaux –
Partie 1-9: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour une conception écoresponsable

IEC 60601-1-9:2007-07+A1:2013+AMD2:2020-07 CSV (en-fr)

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IEC 60601-1-9

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

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

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FOREWORD

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International standard IEC 60601-1-9 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

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

FDIS	Report on voting
62A/571/FDIS	62A/575/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 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 (*).

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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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;
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〈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〉

〈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/874/FDIS	62A/881/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

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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/1393/FDIS	62A/1408/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,
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- replaced by a revised edition, or
- amended.

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.

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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.

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⟨A1⟩ INTRODUCTION TO THE AMENDMENT 1

The first edition of IEC 60601-1-9 was published in 2007. This amendment is intended to update the references to IEC 60601-1:2005 to include Amendment 1:2012 and to make a few minor editorial updates. ⟨A1⟩

⟨A2⟩ INTRODUCTION TO AMENDMENT 2

The first edition of IEC 60601-1-9 was published in 2007 and amended in 2013. Since the publication of IEC 60601-1-9:2007+A1:2013, 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 second edition of IEC 60601-1-9, which is presently targeted for publication sometime after 2024.

As directed in item 1 of Kobe Resolution 1, the IEC/SC 62A Chairman Advisory Group (CAG) considered the 7 issues collected by the SC/62A Secretariat for IEC 60601-1-9:2007 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the reference to IEC 60601-1:2005+A1:2012 +A2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-9:2007+A1:2013.

Because this is an amendment to IEC 60601-1-9:2007, the style in force at the time of publication of IEC 60601-1-9 has been applied to this amendment. The 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. ⟨A2⟩

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MEDICAL ELECTRICAL EQUIPMENT –

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

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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:

– [A1] "the general standard" designates IEC 60601-1 alone [A2], including any amendments [A2]; [A1]

– [A1] "this collateral standard" designates IEC 60601-1-9 alone [A2], including any amendments [A2]; [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.

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)].

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1) Figures in square brackets refer to the Bibliography.

2 Normative references

A1 The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. A1 For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

A2 IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
Amendment 1:2012
Amendment 2:2020 A2

3 Terms and definitions

A2 For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 +A1:2012+A2:2020 and the following definitions apply. A2

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]

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