



BSI Standards Publication

Medical electrical equipment

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

National foreword

This British Standard is the UK implementation of EN 60601-1-9:2008+A2:2020. It is identical to IEC 60601-1-9:2007, incorporating amendments 1:2013 and 2:2020. It supersedes BS EN 60601-1-9:2008+A1:2013, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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EUROPEAN STANDARD

EN 60601-1-9:2008+A2

NORME EUROPÉENNE

EUROPÄISCHE NORM

September 2020

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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.



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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

EN 60601-1-9:2008+A2:2020 (E)

European 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.

EN 60601-1-9:2008+A2:2020 (E)

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).

Foreword to amendment A1

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.

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- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2018-12-31

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 60601-1-9:2007/A1:2013 was approved by CENELEC as a European Standard without any modification.

Foreword to amendment A2

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.

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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) 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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Endorsement notice

The text of the International Standard IEC 60601-1-9:2007/A2:2020 was approved by CENELEC as a European Standard without any modification.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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:

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- 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.
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- “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.);
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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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- “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.

IEC 60601-1-9:2007+A2:2020
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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;
- withdrawn;
- replaced by a revised edition, or
- amended.

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**

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.

INTRODUCTION to 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.

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.

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:

- [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⁾.

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

¹⁾ Figures in square brackets refer to the Bibliography.