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2007-07

Medical electrical equipment –

Part 1-9:

**General requirements for basic
safety and essential performance –**

**Collateral Standard: Requirements for
environmentally conscious design**
(standards.iteh.ai)

Appareils électromédicaux –

IEC 60601-1-9:2007
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Partie 1-9:

**Exigences générales pour la sécurité
de base et les performances essentielles –**

**Norme collatérale: Exigences pour une
conception éco-responsable**



Reference number
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Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

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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

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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.

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.

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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. <https://standards.iteh.ai/catalog/standards/sist/5c456151-bb82-441c-87e1-ee1003d2525/iec-60601-1-9-2007>

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

[IEC 60601-1-9:2007](https://standards.iteh.ai/catalog/standards/sist/5c456151-bb82-441c-87e1-cc100d32525/iec-60601-1-9-2007)

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.

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
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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]

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3.6

HAZARDOUS SUBSTANCE

substance which can affect human health or the ENVIRONMENT with an immediate or retarded effect

[IEC Guide 109: 2003, definition 3.6, modified]

3.7

LIFE CYCLE

consecutive and interlinked stages of a product system, from raw material acquisition or generation from natural resources to final disposal

[ISO 14040:2006, definition 3.1]

3.8

LIFE-CYCLE ASSESSMENT

LCA

compilation and evaluation of the inputs, outputs and the potential ENVIRONMENTAL IMPACTS of a product system throughout its LIFE CYCLE

[ISO 14040:2006, definition 3.2]

3.9

ORGANIZATION

company, corporation, firm, enterprise, authority or institution, or part or combination thereof, whether incorporated or not, public or private, that has its own functions and administration

NOTE For ORGANIZATIONS with more than one operating unit, a single operating unit may be defined as an ORGANIZATION.

[ISO 14001:2004, definition 3.16]

3.10

PACKAGING

material that is used to protect or contain a product during transportation, storage and marketing

NOTE 1 For the purposes of this standard, the term PACKAGING also includes any item that is physically attached to, or included with, a product or its container for the purpose of marketing the product.

NOTE 2 Adapted from ISO 14021:1999, definition 3.1.10.

3.11

RECYCLING

reprocessing in a production PROCESS of the WASTE materials for the original purpose or for other purposes but excluding energy recovery

[IEC Guide 109:2003, definition 3.16]

3.12

REUSE

utilization of ME EQUIPMENT or a part of ME EQUIPMENT, after it has been disposed of by the RESPONSIBLE ORGANIZATION as WASTE, for a similar purpose to that for which it was originally intended by the MANUFACTURER

3.13

SUPPLY CHAIN

those involved, through upstream and downstream linkages, in PROCESSES and activities delivering value in the form of products to the MANUFACTURER

NOTE 1 In practice, the expression “interlinked chain” applies from suppliers to those involved in END OF LIFE processing.

NOTE 2 In practice, the expressions “product chain”, “value chain” are often used.

NOTE 3 Adapted from ISO/TR 14062:2002, definition 3.9.

3.14

WASTE

substance or object which the holder disposes of, or is required to dispose of, pursuant to the provisions of national law in force

[IEC Guide 109:2003, definition 3.18]

4 Protection of the ENVIRONMENT

4.1 * Identification of ENVIRONMENTAL ASPECTS

THE MANUFACTURER shall establish, implement and maintain a PROCESS to identify and document the relevant ENVIRONMENTAL ASPECTS of ME EQUIPMENT across all LIFE-CYCLE stages. Examples of ENVIRONMENTAL ASPECTS are:

- use of HAZARDOUS SUBSTANCES;
- emissions to air;
- releases to surface water and ground water;
- WASTE, especially HAZARDOUS SUBSTANCES;
- use of natural resources, energy and raw materials;
- noise, vibration, odour, dust, electromagnetic fields etc.;
- transport (both for goods and services and employees);
- RISKS from environmental accidents and ENVIRONMENTAL IMPACTS arising, or likely to arise, as consequences of incidents, accidents and potential emergency situations; and
- use and contamination of the biosphere.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

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4.2 * Determination of significant ENVIRONMENTAL ASPECTS

The MANUFACTURER shall establish, implement and maintain a PROCESS to qualitatively or quantitatively determine and document the ENVIRONMENTAL ASPECTS that can have significant ENVIRONMENTAL IMPACTS (i.e. significant ENVIRONMENTAL ASPECTS) during all LIFE-CYCLE stages of the ME EQUIPMENT.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

4.3 * Information from the SUPPLY CHAIN

The MANUFACTURER shall establish, implement and maintain PROCESSES to:

- identify those suppliers (including services) that are likely to contribute significant ENVIRONMENTAL ASPECTS to the ME EQUIPMENT; and
- obtain from those SUPPLIERS the information necessary to assist the MANUFACTURER in identifying and assessing the ENVIRONMENTAL ASPECTS of the ME EQUIPMENT as required in 4.1 and 4.2.

If, despite the MANUFACTURER'S efforts, ORGANIZATIONS within the SUPPLY CHAIN fail to provide the information requested by the MANUFACTURER, the MANUFACTURER shall provide an estimation of the missing information and document the rationale.

NOTE To fully assess the ENVIRONMENTAL ASPECTS across the entire life of the ME EQUIPMENT it is necessary for the MANUFACTURER to gather information and involve the environmentally significant SUPPLIERS during the concept and design stage.

Compliance is checked by inspection of the relevant design documents and PROCESS description.

4.4 * Reduction of adverse ENVIRONMENTAL IMPACTS

The MANUFACTURER shall establish and document targets for the significant ENVIRONMENTAL ASPECTS of the ME EQUIPMENT to minimize as far as reasonable the adverse ENVIRONMENTAL IMPACTS across all LIFE-CYCLE stages. The documented targets shall be based on functional as well as environmental requirements, and, when available, previous product designs.

During the ME EQUIPMENT concept and specification setting stage, the MANUFACTURER shall consider, as far as reasonable, novel emerging or alternative technologies and/or solutions for the ME EQUIPMENT that reduce significant adverse ENVIRONMENTAL IMPACTS.

The MANUFACTURER shall assess and document the actual significant ENVIRONMENTAL ASPECTS across all LIFE-CYCLE stages of a representative prototype of the final design of the ME EQUIPMENT. Any deviations from the targets shall be assessed and documented for consideration in future designs.

Compliance is checked by inspection of the relevant design documents.

4.5 Environmental information

4.5.1 * PACKAGING of ME EQUIPMENT

The MANUFACTURER shall make available information on the type and mass of PACKAGING material(s).

NOTE 'Type' of PACKAGING refers, as a minimum, to the generic description (e.g. cardboard, plastic, wood, glass etc).

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Compliance is checked by verifying the availability of the information.

4.5.2 * Instructions for minimizing ENVIRONMENTAL IMPACT during NORMAL USE

The MANUFACTURER shall provide instructions for minimizing the ENVIRONMENTAL IMPACT of the ME EQUIPMENT during NORMAL USE in the ACCOMPANYING DOCUMENTS.

The instructions shall cover the following items where applicable:

- instructions on how to install the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;
- instructions on how to use and maintain the ME EQUIPMENT in order to minimize the ENVIRONMENTAL IMPACT during its EXPECTED SERVICE LIFE;
- consumption during NORMAL USE (e.g. energy, consumable materials/parts, disposables, water, gasses, chemicals/reagents etc.);
- emissions during NORMAL USE (e.g. WASTE water, WASTE consumable materials, acoustic energy, heat, gasses, vapours, particulates, HAZARDOUS SUBSTANCES and other WASTE); and
- information on the location within the ME EQUIPMENT of HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

4.5.3 * Information for END OF LIFE management

The MANUFACTURER shall provide the RESPONSIBLE ORGANIZATION with information for the proper disposal of the ME EQUIPMENT at END OF LIFE.

The MANUFACTURER shall make available information to WASTE treatment facilities necessary for the environmentally responsible management of END OF LIFE ME EQUIPMENT. The information shall contain:

- the location of components and parts within the ME EQUIPMENT that contain stored energy or pose other HAZARDS that can result in an unacceptable RISK to disassemblers or others and methods for controlling such RISKS;
- the identity and location of HAZARDOUS SUBSTANCES requiring special handling and treatment; and
- disassembly instructions sufficient for the safe removal of these HAZARDOUS SUBSTANCES including radioactive sources and induced radioactive materials within the ME EQUIPMENT.

Compliance is checked by verifying the availability of the information.

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Annex A (informative)

General guidance and rationale

A.1 General guidance

In the future, MANUFACTURERS and RESPONSIBLE ORGANIZATIONS will be required to holistically meet enhanced environmental criteria and to further improve product quality and safety. ME EQUIPMENT is intended to have beneficial effects on humans. However if the damage to the ENVIRONMENT caused by the ME EQUIPMENT outweighs the medical benefits, this is counter-productive to the intended function of the ME EQUIPMENT. ME EQUIPMENT should be designed, manufactured, used and discarded in a manner that is environmentally responsible.

The objective of this collateral standard is to reduce the ENVIRONMENTAL IMPACTS of the ME EQUIPMENT taking into account all the ME EQUIPMENT LIFE-CYCLE stages. Benefits of implementing this collateral standard include, for example, the reduction of potential sources of HARM, HAZARDOUS SUBSTANCES and WASTE, and savings of natural resources, raw materials and energy. Benefits can be grouped into transportation reduction, cost reduction and a positive public perception of the MANUFACTURER as a good corporate citizen.

LIFE-CYCLE ASSESSMENT is a tool that can be used to reduce the ENVIRONMENTAL IMPACT of ME EQUIPMENT. The principle and framework for LIFE-CYCLE ASSESSMENT is described in ISO 14040 [7]. MANUFACTURERS undertaking LIFE-CYCLE ASSESSMENT will have to select or develop their own PROCESSES and assessment tools to achieve product-related environmental improvements.

[https://standards.iteh.ai/catalog/standards/sist/5c456151-bb82-441c-87e1-](https://standards.iteh.ai/catalog/standards/sist/5c456151-bb82-441c-87e1-ee1003d2525/iec-60601-1-9-2007)

The ENVIRONMENTAL IMPACTS of ME EQUIPMENT are largely determined during the DESIGN AND DEVELOPMENT stage. Therefore, in order to reduce the adverse ENVIRONMENTAL IMPACTS of the new ME EQUIPMENT:

- adverse ENVIRONMENTAL IMPACT reduction should be seen as starting at the identification of need and flowing throughout DESIGN AND DEVELOPMENT;
- it is highly desirable to start the ENVIRONMENTAL ASPECT/IMPACT assessment as early as possible in product planning.

Typically the ME EQUIPMENT LIFE CYCLE includes the stages in Table A.1. Table A.1 contains both environmental considerations and, where applicable, examples of ENVIRONMENTAL ASPECTS for each LIFE-CYCLE stage.

Environmental protection is not a subject that is covered in all engineering training. Consequently this rationale is more detailed than normal for a standard of this type.

The following is one of many examples of the LIFE-CYCLE stages of ME EQUIPMENT.