IEC 60601-1-9

Edition 1.1 2013-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 éco-responsable

IEC 60601-1-9:2007+A1:2013

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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This consolidated version of IEC 60601-1-9 consists of the first edition (2007) [documents 62A/571/FDIS and 62A/575/RVD] and its amendment 1 (2013) [documents 62A/874/FDIS and 62A/881/RVD]. It bears the edition number 1.1.

The technical content is therefore identical to the base edition and its amendment and has been prepared for user convenience. A vertical line in the margin shows where the base publication has been modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through.

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.

The first edition of this publication 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.

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 the base publication and its amendment 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;
- withdrawn;
- replaced by a revised edition, or
- amended.

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.

IMPORTANT – The "colour inside" logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

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 THE AMENDMENT

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.

MEDICAL ELECTRICAL EQUIPMENT –

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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:

– "the general standard" designates IEC 60601-1 alone (IEC 60601-1:2005+A1:2012);

– "this collateral standard" designates IEC 60601-1-9 alone (IEC 60601-1-9:2007+A1:2013);

– "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, in whole or in part, are normatively referenced in this document and are indispensable for its application ~~of this document~~. For dated references,

1) Figures in square brackets refer to the Bibliography.

only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+A1:2012 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]

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.

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).

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.