IEC 60601-1-11

Edition 1.0 2010-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Appareils électromédicaux –
Partie 1-11: Exigences générales pour la sécurité de base et les performances essentielles – Norme Collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux utilisés dans l'environnement des soins à domicile

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

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 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: *Common aspects of electrical equipment used in medical practice* of IEC technical committee 62: *Electrical equipment in medical practice* and ISO subcommittee SC3: *Lung ventilators and related devices,* of ISO technical committee 121: *Anaesthetic and respiratory equipment*.

It is published as a double logo standard.

This first edition constitutes a collateral standard to IEC 60601-1:2005 (third edition): *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

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

FDIS	Report on voting
62A/693/FDIS	62A/696/RVD

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 17 P-members out of 17 having cast a vote.

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 numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral 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 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;
- withdrawn;
- replaced by a revised edition, or
- amended

NOTE The attention of Member Bodies and 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 ISO or IEC 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 implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the HOME HEALTHCARE ENVIRONMENT (see 3.2). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

The potential lack of training of the LAY OPERATOR and possibly of those supervising the use of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM and their level of education need to be addressed in the development of the ACCOMPANYING DOCUMENTS and in the relevant marking on the equipment itself so that this material can be understood. This collateral standard gives special guidance on how this should be addressed in the instructions for use.

This collateral standard was developed with contributions from clinicians, engineers and regulators. The terminology, requirements, general recommendations and guidance of this collateral standard are intended to be useful for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS and for technical committees responsible for the development of particular standards.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS, which are intended by their MANUFACTURER for use in the HOME HEALTHCARE ENVIRONMENT, as defined in 3.2, regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

NOTE 1 HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can also be intended for use in other environments, for example, in a professional healthcare facility.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use by emergency medical services or solely for use in professional healthcare facilities.

NOTE 2 HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can frequently be used in locations with unreliable electrical sources and poor electrical grounding.

1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, 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 60601-1-11 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.

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.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

NOTE 2 Informative references are listed in the bibliography on page 54.

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Ea and guidance: Shock*

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-64:2008, *Environmental testing – Part 2-64: Tests – Test Fh: Vibration, broadband random and guidance*

IEC 60529:1989, *Degrees of protection provided by enclosures (IP Code)*
Amendment 1 (1999) [1)]

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

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

CISPR 11:2009, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics - Limits and methods of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-6:2010, IEC 60601-1-8:2006 and the following definitions apply.

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the r.m.s. values of an alternating, direct or composite voltage or current unless stated otherwise.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This standard also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 3 An index of defined terms used in this collateral standard is found beginning on page 56.

1) There exists a consolidated edition 2.1 including IEC 60529:1989 and Amendment 1 (1999).

3.1
*** BODY-WORN**
term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing

NOTE TRANSPORTABLE equipment can be both BODY-WORN and HAND-HELD.

3.2
HOME HEALTHCARE ENVIRONMENT
dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present

NOTE 1 Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, multiple treatment facilities and emergency medical services.

NOTE 2 For the purpose of this collateral standard, nursing homes are considered the HOME HEALTHCARE ENVIRONMENT.

NOTE 3 Other places where PATIENTS are present include the outdoor environment and in vehicles.

EXAMPLES In a car, bus, train, boat or plane, in a wheelchair or walking outdoors

3.3
*** LAY**
term referring to nonprofessional or professional without relevant specialized training

EXAMPLES LAY OPERATOR, LAY RESPONSIBLE ORGANIZATION

3.4
LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM
ME EQUIPMENT or ME SYSTEM that includes at least one FUNCTION that is intended to actively keep alive or resuscitate a PATIENT and the failure of which is likely to lead to serious injury or death of a PATIENT

[IEC 60601-1-2:2007, definition 3.18, modified]

EXAMPLE A ventilator for a ventilator-dependent PATIENT intended for use in the HOME HEALTHCARE ENVIRONMENT.

3.5
SHELF LIFE
maximum period of time that an item can be stored prior to its first use under the conditions described in its labelling and remain suitable for use

3.6
TRANSIT-OPERABLE
term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while it is being moved

EXAMPLES TRANSPORTABLE ME EQUIPMENT that is BODY-WORN, HAND-HELD, attached to a wheelchair, or used in a car, bus, train, boat or plane.

NOTE For the purpose of this standard, TRANSIT-OPERABLE use in the HOME HEALTHCARE ENVIRONMENT can include use indoors, outdoors and in vehicles.

3.7
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, ME EQUIPMENT, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

3.8
USABILITY ENGINEERING FILE
set of RECORDS and other documents that are produced by USABILITY ENGINEERING activities

3.9
USABILITY SPECIFICATION
documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

3.10
VALIDATION
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term "validated" is used to designate the corresponding status.

NOTE 2 The use conditions for VALIDATION can be real or simulated.

[ISO 9000:2000, definition 3.8.5]

4 General requirements

4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT or ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT, the characteristics of the SUPPLY MAINS specified in 4.10.2 of the general standard apply, except for replacement of the fifth dash as follows:

– for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS, no voltage in excess of 110 % or lower than 85 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth; and

– for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS, no voltage in excess of 110 % or lower than 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth.

4.2 Environmental conditions for ME EQUIPMENT

NOTE In IEC 60601-1:2005, the MANUFACTURER specifies the permissible conditions of use, including conditions for transport and storage in the technical description (see 7.9.3.1, second dash). These conditions are referenced in requirements for testing throughout the general standard, (e.g. 5.3 and 11.1.1).

4.2.1 * Environmental conditions of transport and storage between uses

The instructions for use shall indicate the permissible environmental conditions of transport and storage of ME EQUIPMENT after the ME EQUIPMENT has been removed from its protective packaging and subsequently between uses.

Unless otherwise indicated in the instructions for use or if the ME EQUIPMENT is STATIONARY, the ME EQUIPMENT shall comply with this standard and shall remain operational in NORMAL USE within its specification after transport or storage in the following environmental temperature range:

– – 25 °C without relative humidity control; and

– + 70 °C at a relative humidity up to 93 %, non-condensing;

after having been removed from its protective packaging and subsequently between uses.

NOTE 1 This represents class 7K3 as described in IEC/TR 60721-4-7:2001 [6] [2)].

2) Figures in square brackets refer to the Bibliography.

If the instructions for use state a more restricted range of environmental transport and storage conditions between uses, these environmental conditions shall be:

– justified in the RISK MANAGEMENT FILE;
– marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and
– marked on the carrying case, if the instructions for use indicate the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses.

Compliance is checked by the following test and, when a more restricted range is stated in the instructions for use, inspection of the RISK MANAGEMENT FILE.

a) Prepare the ME EQUIPMENT for transportation or storage according to instructions for use.

EXAMPLES Removal of batteries, emptying fluid reservoirs

b) Expose the ME EQUIPMENT at its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C) for:

- *at least 24 h; or*
- *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

c) Then expose the ME EQUIPMENT at its highest specified environmental transport and storage conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %) for:

- *at least 24 h; or*
- *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h. The transition from low to high conditions should be made slowly enough to provide a non-condensing environment.*

NOTE 2 The intent of specifying a minimum duration of the exposure to both the low and high temperature conditions is to ensure that the entire ME EQUIPMENT reaches the stated conditions.

d) At the end of this conditioning period, allow the ME EQUIPMENT to return and stabilize at the operating conditions of NORMAL USE.

e) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.

4.2.2 * Environmental operating conditions

The instructions for use shall indicate the permissible environmental operating conditions of the ME EQUIPMENT.

NOTE 1 The environmental operating conditions should be marked on TRANSIT-OPERABLE ME EQUIPMENT, unless such marking is not practicable, in which case the environmental operating conditions need only be disclosed in the instructions for use.

Unless otherwise indicated in the instructions for use, the ME EQUIPMENT shall comply with its specifications and all the requirements of this standard when operated in NORMAL USE under the following environmental operating conditions:

– a temperature range of + 5 °C to + 40 °C;
– a relative humidity range of 15 % to 93 %, non-condensing; and
– an atmospheric pressure range of 700 hPa to 1 060 hPa.

NOTE 2 This represents class 7K1 as described in IEC/TR 60721-4-7:2001 [6].

If the instructions for use state a more restricted range of environmental operating conditions, these conditions shall be:

– justified in the RISK MANAGEMENT FILE;
– marked on the ME EQUIPMENT, unless such marking is not practicable, in which case the more restricted range need only be disclosed in the instructions for use; and
– marked on the carrying case if the instructions for use indicate the ME EQUIPMENT is intended to be operated in a carrying case.

The ME EQUIPMENT shall comply with its specifications and all the requirements of this standard when operated in NORMAL USE under the specified environmental operating conditions.

Compliance is checked by the following test and, when a more restricted range is stated in the instructions for use, inspection of the RISK MANAGEMENT FILE:

a) Expose the ME EQUIPMENT to the ambient conditions for:
   – *at least 6 h, or*
   – *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

b) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.

c) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure.

d) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure.

NOTE 3 For ME EQUIPMENT that utilizes or measures gas or pressures, evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE while the pressure changes can be needed.

e) Cool the ME EQUIPMENT to its lowest specified environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %).

f) Hold the ME EQUIPMENT at its lowest specified environmental operating conditions:
   – *for at least 6 h, or*
   – *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

g) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.

h) Warm the ME EQUIPMENT to its highest specified environmental operating conditions (temperature $^{+4}_{0}$ °C and relative humidity ± 3 %).

i) Hold the ME EQUIPMENT at its highest specified environmental operating conditions:
   – *for at least 6 h, or*
   – *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

j) Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.

4.2.3 * Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT

If the instructions for use state a wider range of environmental operating conditions than those indicated in 4.2.2, the TRANSIT-OPERABLE ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in the presence of condensation and thermal shock resulting from rapid changes in environmental temperature and humidity during INTENDED USE.

Compliance is checked by the following test: