IEC 60601-1-12

Edition 1.0 2014-06

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

Medical electrical equipment –
Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

Appareils électromédicaux –
Partie 1-12: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Exigences pour les appareils électromédicaux et les systèmes électromédicaux destinés à être utilisés dans l'environnement des services médicaux d'urgence

IEC 60601-1-12:2014-06(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services 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 60601-1-12 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.

This first edition constitutes a collateral standard to IEC 60601-1 (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:

FDIS	Report on voting
62A/932/FDIS	62A/938/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, this International Standard has been approved by 18 P-members out of 19 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 7.3.1 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 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.

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 document using a colour printer.

INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for monitoring, treatment or diagnosis of PATIENTS in the EMERGENCY MEDICAL SERVICES ENVIRONMENT (see 3.1). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled, rough environment is a cause for concern.

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 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services 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, as indicated in the instructions for use by their MANUFACTURER, for use in the EMS ENVIRONMENT (EMERGENCY MEDICAL SERVICES ENVIRONMENT), as defined in 3.1.

NOTE 1 For the purposes of this standard, the intent of the MANUFACTURER is indicated in the instructions for use. The RESPONSIBLE ORGANIZATION and the OPERATOR need to be aware that any other use outside the MANUFACTURER'S INTENDED USE can result in a HAZARDOUS SITUATION for the PATIENT.

The EMS ENVIRONMENT includes

– responding to and providing life support at the scene of an emergency to a PATIENT reported as experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care.

– providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the HOME HEALTHCARE ENVIRONMENT covered by IEC 60601-1-11 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-11 or this collateral standard. ME EQUIPMENT and ME SYSTEMS are often not solely intended for one environment. Such ME EQUIPMENT or ME SYSTEM can be intended for multiple use environments, and as such, if also intended for use in the EMS ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEM intended for both the EMS ENVIRONMENT and the professional healthcare facility environment.

NOTE 2 EMS ENVIRONMENT ME EQUIPMENT and ME SYSTEMS can be used in locations with unreliable electrical sources and outdoor environmental conditions.

1.2 * Object

The object of this collateral standard is to provide general requirements for ME EQUIPMENT and ME SYSTEMS carried to the scene of an emergency and used there, as well as in transport, in situations where the ambient conditions differ from indoor conditions.

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, hereafter referred to as the general standard.

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 60601-1-12 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 46.

IEC 60068-2-27:2008, *Environmental testing – Part 2-27: Tests – Test 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)*
IEC 60529:1989/AMD1:1999[1]

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012[2]

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

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1 There exists a consolidated edition 2.1(2001) including IEC 60529:1989 and its Amendment 1:1999.

2 There exists a consolidated edition 3.1(2012) including IEC 60601-1:2005 and its Amendment 1:2012.

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

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*
IEC 60601-1-8:2006/AMD1:2012[3]

IEC 60601-1-11:—[4], *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*

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

ISO 7000:2014, *Graphical symbols for use on equipment – Registered symbols*

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*
Amendment 1:2012
Amendment 2:2012
Amendment 3:2012
Amendment 4:2013
Amendment 5:2014

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

EUROCAE[5] ED-14G, *Environmental conditions and test procedures for airborne equipment*

RTCA[6] DO-160G, *Environmental Conditions and Test Procedures for Airborne Equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-6:2006 and IEC 60601-1-6:2006/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:— 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 48.

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3 There exists a consolidated edition 2.1(2012) including IEC 60601-1-8:2006 and Amendment 1:2012.

4 Second edition, to be published.

5 EUROCAE (European Organization for Civil Aviation Electronics), 102 rue Etienne Dolet, 92240 Malakoff, France.

6 RTCA (Radio Technical Commission for Aeronautics), 1150 18th St, NW., Suite 910, Washington, DC 20036, USA.

3.1
*** EMS ENVIRONMENT**
EMERGENCY MEDICAL SERVICES ENVIRONMENT
actual conditions and settings, in which OPERATORS interact with the ME EQUIPMENT or ME SYSTEM, in and around the scene of an emergency outside of a professional healthcare facility where a PATIENT can be given medical care, basic or advanced life support as well as during professional transport to a professional healthcare facility or between professional healthcare facilities

EXAMPLE 1 Responding to and providing life support at the scene of an emergency to a PATIENT reported as experiencing injury or illness in a pre-hospital setting, and transporting the PATIENT, while continuing such life support care, to an appropriate professional healthcare facility for further care.

EXAMPLE 2 Providing monitoring, treatment or diagnosis during transport between professional healthcare facilities.

Note 1 to entry: For the purposes of this standard, use of equipment intended for the EMS ENVIRONMENT and temporarily used in the HOME HEALTHCARE ENVIRONMENT by emergency medical personnel is considered use in the EMS ENVIRONMENT.

Note 2 to entry: For the purposes of this standard, the OPERATORS of equipment intended for the EMS ENVIRONMENT are presumed to be professional medical personnel or personnel with relevant specialized training.

Note 3 to entry: Professional healthcare facilities include hospitals, physician offices, freestanding surgical centres, dental offices, freestanding birthing centres, limited care facilities, first aid rooms or rescue rooms and multiple treatment facilities.

Note 4 to entry: Emergency medical services are known by various names in different countries and regions.

Note 5 to entry: For the purposes of this standard, transport includes road, rotary and fixed-wing ambulances.

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 EMS ENVIRONMENT, the characteristics of the SUPPLY MAINS specified in 4.10.2 of the general standard apply, with the following additions.

SUPPLY MAINS in the EMS ENVIRONMENT shall be assumed to have the following characteristics of 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.

The RATED range of NOMINAL voltage of the ME EQUIPMENT in the EMS ENVIRONMENT shall include at least 12,4 V to 15,1 V for operation from 12 V d.c. SUPPLY MAINS and at least 24,8 V to 30,3 V for operation from 24 V d.c. SUPPLY MAINS.

ME EQUIPMENT and ME SYSTEMS in the EMS ENVIRONMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE during and following a 30 s dip to 10 V from a 12 V d.c. SUPPLY MAINS and during and following a 30 s dip to 20 V for operation from a 24 V d.c. SUPPLY MAINS.

For ME EQUIPMENT or ME SYSTEMS intended to be powered from an aircraft, the SUPPLY MAINS shall comply with Section 16 of either EUROCAE ED-14G or RTCA DO-160G.

4.2 * Environmental conditions for ME EQUIPMENT

NOTE In IEC 60601-1:2005, the MANUFACTURER specifies the permissible environmental 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, 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 range:

– - 40 °C to + 5 °C without relative humidity control;

– + 5 °C to + 35 °C at a relative humidity up to 90 %, non-condensing;

– > 35 °C to 70 °C at a water vapour pressure up to 50 hPa;

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

NOTE 1 This represents class 7K4, as described in IEC TR 60721-4-7:2001 [6] [7].

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 that the ME EQUIPMENT is intended to be transported or stored in a carrying case between uses.

Symbols 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533) or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 may be used to mark the temperature range (see Table C.1, symbols 2, 3 and 4). Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 may be used to mark the humidity range (see Table C.1, symbol 5) and symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 may be used to mark the atmospheric pressure range (see Table C.1, symbol 6). Where ME EQUIPMENT has different markings for conditions of transport and storage between uses, continuous operating conditions (see 4.2.2.1) and transient operating conditions (see 4.2.2.2), those markings shall be accompanied by supplementary marking (e.g. appropriate wording) except where the respective applicability would be obvious (e.g. limits for transport and storage between uses on the carrying case and limits for operation on the ME EQUIPMENT itself).

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 transport 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 16 h; or*
- *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

c) Then expose the ME EQUIPMENT to 34 °C ± 4 °C and 93 % ± 3 % relative humidity until the test chamber reaches equilibrium. The transition from low to high conditions should be made slowly enough to provide a non-condensing environment. Hold for at least 2 h.

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7 Numbers in square brackets refer to the Bibliography.

d) Then expose the ME EQUIPMENT at its highest specified environmental transport and storage conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature $^{+4}_{0}$ °C) for:

- *at least 16 h; or*
- *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

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.

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

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

4.2.2 * Environmental operating conditions

4.2.2.1 Continuous operating conditions

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

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 0 °C to + 40 °C;
- a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; and
- an atmospheric pressure range of 620 hPa to 1 060 hPa.

NOTE 1 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 continuous 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.

Symbols 5.3.5 (ISO 7000-0534), 5.3.6 (ISO 7000-0533) or 5.3.7 (ISO 7000-0632) of ISO 15223-1:2012 may be used to mark the temperature range (see Table C.1, symbols 2, 3 and 4). Symbol 5.3.8 (ISO 7000-2620) of ISO 15223-1:2012 may be used to mark the humidity range (see Table C.1, symbol 5) and symbol 5.3.9 (ISO 7000-2621) of ISO 15223-1:2012 may be used to mark the atmospheric pressure range (see Table C.1, symbol 6). Where ME EQUIPMENT has different markings for continuous operating conditions and transient operating conditions (4.2.2.2), those markings shall be accompanied by supplementary marking (e.g. appropriate wording).

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. If readings or performance vary, a table of correcting values shall be disclosed in the instructions for use. This correction table shall indicate the extent of the variation between the actual values and the values indicated or set.

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: