IEC 60601-1-12

Edition 1.1 2020-07
CONSOLIDATED VERSION

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 IEC 60601-1-12:2014-06+AMD1:2020-07 CSV(en-fr)

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CONTENTS

FOREWORD 4
INTRODUCTION 7
INTRODUCTION to Amendment 1 7
1 Scope, object and related standards 8
1.1 * Scope 8
1.2 * Object 8
1.3 Related standards 9
1.3.1 IEC 60601-1 9
1.3.2 Particular standards 9
2 Normative references 9
3 Terms and definitions 10
4 General requirements 11
4.1 * Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS 11
4.2 * Environmental conditions for ME EQUIPMENT 12
4.2.1 * Environmental conditions of transport and storage between uses 12
4.2.2 * Environmental operating conditions 13
5 * Classification of ME EQUIPMENT and ME SYSTEMS 15
6 ME EQUIPMENT identification, marking and documents 16
6.1 * Additional requirements for legibility of markings 16
6.2 * Additional requirements for marking of IP classification 16
6.3 * Instructions for use 16
6.3.1 Additional general requirements 16
6.3.2 * Additional requirements for an electrical power source 17
6.3.3 Additional requirements for ME EQUIPMENT start-up PROCEDURE 17
6.3.4 * Additional requirements for operating instructions 18
6.3.5 Additional requirements for ME EQUIPMENT messages 18
6.4 Technical description – FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT 18
7 * Protection against electrical HAZARDS from ME EQUIPMENT 18
8 Protection against excessive temperatures and other HAZARDS 19
8.1 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS 19
8.1.1 * Ingress of water or particulate matter into ME EQUIPMENT 19
8.1.2 * Ingress of water or particulate matter into ME SYSTEMS 19
8.2 Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM 19
8.3 * Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT 20
9 * Accuracy of controls and instruments and protection against hazardous outputs 21
10 Construction of ME EQUIPMENT 21
10.1 * Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT 21
10.1.1 General requirements for mechanical strength 21
10.1.2 * Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance 22

AVA Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

10.1.3 * Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT 23
10.1.4 * Requirements for mechanical strength for ME EQUIPMENT intended for airborne use 24
10.2 Requirements for mounting of ME EQUIPMENT 25
11 Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 25
Annex A (informative) General guidance and rationale 26
A.1 General guidance 26
A.2 Rationale for particular clauses and subclauses 28
Annex B (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 42
B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 42
B.2 ACCOMPANYING DOCUMENTS, instructions for use 42
B.3 ACCOMPANYING DOCUMENTS, technical description 43
Annex C (informative) Symbols on marking 44
Bibliography 46
Index of defined terms used in this collateral standard 48

Figure A.1 – Saturation water vapour pressure as function of temperature 31

Table 1 – Mechanical strength test applicability 22
Table A.1 – Saturation water vapour pressure as function of temperature 32
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts 42
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use 42
Table B.3 – ACCOMPANYING DOCUMENTS, technical description 43
Table C.1 – General symbols 44

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-12 edition 1.1 contains the first edition (2014-06) [documents 62A/932/FDIS and 62A/938/RVD] and its amendment 1 (2020-07) [documents 62A/1396/FDIS and 62A/1411/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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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.

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.

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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 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.

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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.

INTRODUCTION to Amendment 1

The first edition of IEC 60601-1-12 was published in 2014. Since the publication of IEC 60601-1-12:2014, 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 60601-1-12, 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 27 issues collected by the SC/62A Secretariat for IEC 60601-1-12:2014 and determined that none met the selection criteria stated in Kobe Resolution 1.

However, an amendment is needed to update the references to IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020. In London in 2018, SC 62A approved the development of an administrative amendment to IEC 60601-1-12:2014.

Because this is an amendment to IEC 60601-1-12:2014, the style in force at the time of publication of IEC 60601-1-12 has been applied to this amendment. The style 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.

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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

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.

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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, including any amendments;
– "this collateral standard" designates IEC 60601-1-12 alone, including any amendments;
– "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 60601-1:2005/AMD2:2020

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*
IEC 60601-1-2:2014/AMD1:2020

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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.~~

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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 60601-1-6:2010/AMD2:2020

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 60601-1-8:2006/AMD1:2020

IEC 60601-1-11:—[4] 2015, *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*
IEC 60601-1-11:2015/AMD1:2020

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 7010:2019, *Graphical symbols – Safety colours and safety signs – Registered safety signs*

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.~~

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, IEC 60601-1-6:2006, IEC 60601-1-6:2006/AMD1:2013 and IEC 60601-1-6:2006/AMD2:2020, IEC 60601-1-8:2006,

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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.

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IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-11:2015 and IEC 60601-1-11:2015/AMD1:2020, 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.

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.

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Full document details: IEC 60601-1-12-2020

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.*

[7] Numbers in square brackets refer to the Bibliography.

Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

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.*

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.

Documents
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Full document details: IEC 60601-1-12-2020

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) Set up the ME EQUIPMENT *for operation according to its* INTENDED USE*.*

b) Expose the ME EQUIPMENT *to 20 °C ± 4 °C:*

- *for at least 6 h, or*
- *ensure that the* ME EQUIPMENT *reaches* THERMAL STABILITY *for at least 2 h.*

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

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

e) 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 2 For ME EQUIPMENT *that is pressure-sensitive (e.g. utilizes or measures gas or pressures or uses membrane switches) evaluation of* BASIC SAFETY *and* ESSENTIAL PERFORMANCE *while the pressure changes in either direction can be needed.*

f) Relieve the pressure in the pressure chamber.

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

h) Hold the ME EQUIPMENT *at its lowest specified continuous environmental operating conditions:*

- *for at least 6 h, or*
- *ensure that the* ME EQUIPMENT *reaches* THERMAL STABILITY *for at least 2 h.*

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

j) Warm the ME EQUIPMENT *to its highest specified continuous environmental operating conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature* $^{+4}_{0}$ *°C).*

k) Hold the ME EQUIPMENT *at the conditions of j):*

- *for at least 6 h, or*
- *ensure that the* ME EQUIPMENT *reaches* THERMAL STABILITY *for at least 2 h.*

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

4.2.2.2 * Transient operating conditions

The instructions for use shall indicate the permissible transient environmental operating conditions of EMS ENVIRONMENT 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 for a period not less than 20 min under the following environmental operating conditions:

- a temperature range of - 20 °C to + 50 °C;
- a relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa.

Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

If the instructions for use state a more restricted range of transient 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.

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 (see 4.2.2.1) and transient operating conditions, 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.

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 20 °C ± 4 °C:

- *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) Expose the ME EQUIPMENT to its lowest specified transient environmental operating conditions (temperature $^{0}_{-4}$ °C and relative humidity less than or equal to 15 %) while evaluating the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE for 20 min.

d) Expose the ME EQUIPMENT to 20 °C ± 4 °C:

- *for at least 6 h, or*
- *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

e) Expose the ME EQUIPMENT to its highest specified transient environmental operating conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature $^{+4}_{0}$ °C) while evaluating the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE for 20 min.

5 * Classification of ME EQUIPMENT and ME SYSTEMS

In addition to the requirements in 6.2 of the general standard, TRANSPORTABLE ME EQUIPMENT intended for the EMS ENVIRONMENT:

– shall be CLASS II or INTERNALLY POWERED;

– shall not have a FUNCTIONAL EARTH TERMINAL; and

– if equipped with APPLIED PARTS, shall have either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

NOTE 1 This requirement does not apply to FIXED or PERMANENTLY INSTALLED ME EQUIPMENT.

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Full document details: IEC 60601-1-12-2020

NOTE 2 INTERNALLY POWERED TRANSPORTABLE ME EQUIPMENT powered by a FIXED or PERMANENTLY INSTALLED CLASS I power source or CLASS II with FUNCTIONAL EARTH TERMINAL power source is regarded as FIXED or PERMANENTLY INSTALLED when docked.

Compliance is checked by inspection.

6 ME EQUIPMENT identification, marking and documents

6.1 * Additional requirements for legibility of markings

In addition to the requirements of 7.1.2 of the general standard, the markings, controls and displays on the outside of the ME EQUIPMENT necessary for operation of the ME EQUIPMENT shall be CLEARLY LEGIBLE in twilight and full daylight.

The ME EQUIPMENT or its part is positioned so that the viewpoint is the intended position of the OPERATOR. If the intended position of the OPERATOR is not specified or the position is not obvious, the viewpoint is at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m. The ambient illuminance is the least favourable level in the range of 10 lx to 10 000 lx.

The observer has a visual acuity, corrected if necessary, of:

– *0 on the log minimum angle of resolution (log MAR) scale or 6/6 (20/20), and*
– *is able to correctly read N6 of the Jaeger test card*,

in normal room lighting conditions (approximately 500 lx).

The observer correctly reads the marking from the viewpoint.

In case of doubt, 3 of 4 observers may be utilized.

6.2 * Additional requirements for marking of IP classification

In addition to the requirements of 7.2.9 of the general standard, if some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then

– the ENCLOSURE of the ME EQUIPMENT shall be marked with its degree of protection and safety sign ISO 7010-W001 (see IEC 60601-1:2005, Table D.2, safety sign 2),
  - as well as with 'keep dry', or
  - the symbol ISO 15223-1:2012, 5.3.4 (ISO 7000-0626) (see Table C.1, symbol 1);
– the carrying case shall be marked with its degree of protection.

A carrying case that is not intended to provide protection against the ingress of water or particulate matter need not be marked.

EXAMPLE If for ME EQUIPMENT, the ENCLOSURE provides the protection against the ingress of particulate matter and the carrying case provides the protection against the ingress of water, then the ENCLOSURE of the ME EQUIPMENT would be marked IP30 and the carrying case would be marked IP03.

Compliance is checked by inspection and by application of the tests and criteria of 7.1.2 and 7.1.3 of the general standard.

6.3 * Instructions for use

6.3.1 Additional general requirements

In addition to the requirements of 7.9.2.1 of the general standard, the use of the ME EQUIPMENT as intended by the MANUFACTURER shall include:

Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

– intended medical indication;

EXAMPLE 1 Conditions(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

– intended PATIENT population;

EXAMPLE 2 Age.

EXAMPLE 3 Weight.

EXAMPLE 4 Health.

EXAMPLE 5 Condition.

– intended part of the body or type of tissue applied to or interacted with;
– intended OPERATOR PROFILE; and
– intended conditions of use; including
  1) whether ME EQUIPMENT is to be FIXED, PERMANENTLY INSTALLED or TRANSPORTABLE, and
  2) the type of ambulance for which the ME EQUIPMENT is intended;

EXAMPLE 6 Environment including hygienic requirements.

EXAMPLE 7 Frequency of use.

EXAMPLE 8 FIXED to a rotary-wing aircraft.

EXAMPLE 9 TRANSPORTABLE in a road ambulance or fixed-wing aircraft.

6.3.2 * Additional requirements for an electrical power source

In addition to the requirements of 7.9.2.4 of the general standard, if ME EQUIPMENT is equipped with an INTERNAL ELECTRICAL POWER SOURCE and the BASIC SAFETY or ESSENTIAL PERFORMANCE is dependent on the INTERNAL ELECTRICAL POWER SOURCE, the instructions for use shall describe:

– the typical operation time or number of PROCEDURES;
– the typical service life of the INTERNAL ELECTRICAL POWER SOURCE; and
– for a rechargeable INTERNAL ELECTRICAL POWER SOURCE, the behaviour of the ME EQUIPMENT while the rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging.

EXAMPLE 1 Number of years after which a rechargeable battery needs to be replaced.

EXAMPLE 2 Number of discharge cycles after which a rechargeable battery needs to be replaced.

Compliance is checked by inspection of the instructions for use.

6.3.3 Additional requirements for ME EQUIPMENT start-up PROCEDURE

In addition to the requirements of 7.9.2.8 of the general standard, the instructions for use shall include:

– understandable diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment;
– the time from switching “ON” or “starting” until the ME EQUIPMENT is ready for NORMAL USE, if that time exceeds 15 s (see 15.4.4 of the general standard);
– the time required for the ME EQUIPMENT to warm from the minimum storage temperature between uses (4.2.1) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C; and
– the time required for the ME EQUIPMENT to cool from the maximum storage temperature between uses (4.2.1) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C.

AVA Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

Compliance is checked by inspection of the instructions for use and the USABILITY ENGINEERING FILE.

6.3.4 * Additional requirements for operating instructions

In addition to the requirements of 7.9.2.9 of the general standard, the instructions for use shall include a description of generally known conditions in the EMS ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the OPERATOR to identify and resolve these conditions, and shall include, where applicable, at least the following issues:

– the effects of lint, dust, light (including sunlight), etc.;
– a list of known devices or other sources that can potentially cause interference problems;
– the effects of degraded sensors and electrodes, or loosened electrodes, which can degrade performance or cause other problems.

The instructions for use shall explain the meaning of the IP classification marked on the ME EQUIPMENT and, if applicable, on any carrying case provided with the ME EQUIPMENT.

Compliance is checked by inspection of the instructions for use and by inspection of the RISK MANAGEMENT FILE.

6.3.5 Additional requirements for ME EQUIPMENT messages

In addition to the requirements of 7.9.2.10 of the general standard, the instructions for use shall include a troubleshooting guide for use when there are indications of a ME EQUIPMENT malfunction during start-up or operation. The troubleshooting guide shall disclose the necessary steps to be taken in the event of each TECHNICAL ALARM CONDITION.

NOTE See also IEC 60601-1-8.

Compliance is checked by inspection of the instructions for use.

6.4 Technical description – FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT

In addition to the requirements of 7.9.3.1 of the general standard, to ensure that FIXED or PERMANENTLY INSTALLED CLASS I ME EQUIPMENT is PROPERLY INSTALLED, the technical description shall include:

– a warning to the effect that the ME EQUIPMENT installation, including a correct PROTECTIVE EARTH CONNECTION, must only be carried out by qualified SERVICE PERSONNEL.
– the specifications of the FIXED or PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR.
– a warning to verify the integrity of the external protective earthing system.
– a warning to connect and verify that the PROTECTIVE EARTH TERMINAL of the FIXED or PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system.

Compliance is checked by inspection of the technical description.

7 * Protection against electrical HAZARDS from ME EQUIPMENT

In addition to the requirements of 8.9.1.8 of the general standard for ME EQUIPMENT intended for the EMS ENVIRONMENT that is not PERMANENTLY INSTALLED or FIXED, the pollution degree classification of insulation for MEANS OF OPERATOR PROTECTION within ME EQUIPMENT shall be pollution degree 3 unless the ENCLOSURE of insulation relied upon provides IP54 ingress protection.

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Full document details: IEC 60601-1-12-2020

8 Protection against excessive temperatures and other HAZARDS

8.1 Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS

8.1.1 * Ingress of water or particulate matter into ME EQUIPMENT

In addition to the requirements of 11.6.5 of the general standard, TRANSPORTABLE ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 for at least IP33. For PORTABLE ME EQUIPMENT that is only intended to be used while inside a carrying case, this requirement may be met while the ME EQUIPMENT is inside the carrying case.

FIXED or PERMANENTLY INSTALLED ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 for at least IP22.

NOTE These levels of ENCLOSURE stresses are considered to be reflective of NORMAL USE in the EMS ENVIRONMENT.

Compliance is checked by inspection and by application of the tests of IEC 60529:1989 *and IEC 60529:1989/AMD1:1999 with the* ME EQUIPMENT *placed in the least favourable position of* NORMAL USE. *Verify that* BASIC SAFETY *and* ESSENTIAL PERFORMANCE *are maintained.*

8.1.2 * Ingress of water or particulate matter into ME SYSTEMS

In addition to the requirements for ENCLOSURES in 16.4 of the general standard, the ENCLOSURES of the non-ME EQUIPMENT parts of the ME SYSTEMS shall provide the degree of protection against harmful ingress of water or particulate matter equivalent to equipment complying with their respective IEC or ISO safety standards.

Compliance is checked by the tests of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 with the equipment placed in the least favourable position of NORMAL USE *and by inspection.*

Ingress tests that have already been performed on individual equipment of an ME SYSTEM *according to relevant standards need not be repeated. See also 5.1 of the general standard.*

8.2 Additional requirements for interruption of the power supply to ME EQUIPMENT and ME SYSTEM

In addition to the requirements of 11.8 and 16.8 of the general standard, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall maintain its ESSENTIAL PERFORMANCE for a sufficient time or for a sufficient number of PROCEDURES, when loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE occurs. The time or number of PROCEDURES remaining shall allow alternative life-supporting methods to be employed.

NOTE 1 For most ME EQUIPMENT or ME SYSTEMS, ESSENTIAL PERFORMANCE is providing an intended clinical function within specified limits or alerting the OPERATOR of the loss or degradation of that function with an ALARM SIGNAL.

NOTE 2 Requirements for loss or failure of SUPPLY MAINS for very short periods are found in IEC 60601-1-2.

An INTERNAL ELECTRICAL POWER SOURCE may be utilized to maintain ESSENTIAL PERFORMANCE. Independent means may also be utilized to provide ESSENTIAL PERFORMANCE.

EXAMPLE 1 Manually-driven resuscitator.

The instructions for use shall disclose the time or number of PROCEDURES available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE. The instructions for use shall describe the alternative life-supporting methods to be

AVA Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

employed. The technical description shall describe methods that can be employed for longer periods.

NOTE 3 Electrical power supply failure includes failure of the SUPPLY MAINS or any near depletion of INTERNAL ELECTRICAL POWER SOURCES.

If an INTERNAL ELECTRICAL POWER SOURCE is not provided, ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY ALARM CONDITION that indicates a power supply failure.

EXAMPLE 2 The SUPPLY MAINS voltage falls below the minimum value required for normal operation.

If an INTERNAL ELECTRICAL POWER SOURCE is provided, the ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an automatic switchover from the SUPPLY MAINS to the INTERNAL ELECTRICAL POWER SOURCE.

NOTE 4 A visual indication of this charging mode is required in 15.4.4 of the general standard.

If an INTERNAL ELECTRICAL POWER SOURCE is used, the ME EQUIPMENT or ME SYSTEM with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION that indicates that the INTERNAL ELECTRICAL POWER SOURCE is nearing insufficient remaining power for ME EQUIPMENT operation. This TECHNICAL ALARM CONDITION shall provide for a sufficient time or for a sufficient number of PROCEDURES for an OPERATOR to act. A TECHNICAL ALARM CONDITION of at least LOW PRIORITY shall remain active until the INTERNAL ELECTRICAL POWER SOURCE is returned to a level that is above the ALARM LIMIT or until it is depleted. It shall not be possible to inactivate the visual ALARM SIGNAL of this TECHNICAL ALARM CONDITION.

Compliance is checked by inspection, functional testing and inspection of the RISK MANAGEMENT FILE.

8.3 * Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT

ME EQUIPMENT that is not FIXED or PERMANENTLY INSTALLED shall be capable of being powered in its INTENDED USE for at least 20 min from an INTERNAL ELECTRICAL POWER SOURCE.

If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of ESSENTIAL PERFORMANCE, the ME EQUIPMENT shall be equipped with a means for the OPERATOR to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated as:

– a number of PROCEDURES remaining;
– the remaining operating time;
– the percentage of the remaining operating time or energy; or
– a "fuel" gauge.

The state of the INTERNAL ELECTRICAL POWER SOURCE may be indicated continuously or by OPERATOR action.

The instructions for use shall describe how to determine the state of the INTERNAL ELECTRICAL POWER SOURCE.

Compliance is checked by inspection and by functional testing.

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Full document details: IEC 60601-1-12-2020

9 * Accuracy of controls and instruments and protection against hazardous outputs

In addition to the requirements of 12.2 of the general standard, when performing the USABILITY ENGINEERING PROCESS, the RISKS associated with USABILITY in the EMS ENVIRONMENT shall include consideration of at least:

– changes of controls;
– unexpected movement;
– potential for misconnection;
– potential for improper operation, or unsafe use;
– potential for confusion as to current operational mode;
– need for an indication to ensure that state of a control is correctly perceived by the OPERATOR;
– exposure to environmental conditions specified in this standard;
– change in the transfer of energy or substance; and
– exposure to biological materials.

Particular emphasis shall be placed on the situational urgency of the EMS ENVIRONMENT.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

10 Construction of ME EQUIPMENT

10.1 * Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT

10.1.1 General requirements for mechanical strength

Table 1 shows the relationship between the mechanical strength test of the general standard and this standard.

For the purposes of the tests of Clause 10, HAND-HELD ME EQUIPMENT shall be considered TRANSPORTABLE ME EQUIPMENT.

Documents
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Full document details: IEC 60601-1-12-2020

Table 1 – Mechanical strength test applicability

ME EQUIPMENT usage and type	Test from the general standard	Additional tests from this standard
FIXED or PERMANENTLY INSTALLED road ambulance ME EQUIPMENT and mounting ACCESSORIES	Push (15.3.2)	-
	Impact (15.3.3)	-
	Molding stress relief (15.3.6)	-
	-	Shock (10.1.2 a))
	-	Vibration (10.1.2 b))
TRANSPORTABLE	Push (15.3.2)	-
	Impact (15.3.3)	-
	-	Free fall (10.1.3 c))
	-	Shock (10.1.3 a))
	-	Vibration (10.1.3 b))
	Rough handling (15.3.5)	-
	Molding stress relief (15.3.6)	-
Airborne ME EQUIPMENT and mounting ACCESSORIES	Push (15.3.2)	-
	Impact (15.3.3)	-
	-	Shock (10.1.4 a))
	-	Vibration (10.1.4 b))
	Molding stress relief (15.3.6)	-
NOTE 1 STATIONARY ME EQUIPMENT is not considered appropriate for this environment unless it is FIXED. NOTE 2 More than one category can apply to a single ME EQUIPMENT. EXAMPLE PORTABLE ME EQUIPMENT used in an airborne application. NOTE 3 Additional information is found in 5.1 of the general standard.		

10.1.2 * Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance

In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended to be FIXED or PERMANENTLY INSTALLED ME EQUIPMENT and mounting ACCESSORIES in a road ambulance shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, and rough handling. This requirement also applies to the means to permit the attachment (see 10.2) of mounting ACCESSORIES of TRANSPORTABLE ME EQUIPMENT.

After the following tests, ME EQUIPMENT and mounting ACCESSORIES shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by performing the following tests:

a) Shock test in accordance with IEC 60068-2-27:2008, using the following conditions:

NOTE 1 This represents Class 7M2 as described in IEC TR 60721-4-7:2001 [6].

1) test type: Type 1;

- *peak acceleration: 150 m/s^2 (15 g),*
- *duration: 11 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total).*

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or

2) test type: Type 2;

- *peak acceleration: 300 m/s^2 (30 g),*
- *duration: 6 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total).*

b) Broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:

NOTE 2 This represents Class 7M2 as described in IEC TR 60721-4-7:2001.

- *acceleration amplitude:*
  - *10 Hz to 100 Hz: 1,0 (m/s^2)^2/Hz;*
  - *100 Hz to 200 Hz: – 3 dB per octave;*
  - *200 Hz to 2 000 Hz: 0,5 (m/s^2)^2/Hz;*
- *duration: 30 min per perpendicular axis (3 total).*

Verify that BASIC SAFETY *and* ESSENTIAL PERFORMANCE *are maintained following these tests.*

10.1.3 * Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT

In addition to the requirements of 15.3 of the general standard, TRANSPORTABLE ME EQUIPMENT and its parts, including mounting ACCESSORIES, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping, and rough handling during transportation.

EXAMPLES Transportation by carrying, stretchers, trolleys, carts and vehicles

After the following tests, ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 1 The levels of mechanical stresses utilized in the test methods of this subclause are considered to be reflective of NORMAL USE for TRANSPORTABLE ME EQUIPMENT in the EMS ENVIRONMENT.

Compliance is checked by performing the following tests:

a) For ME EQUIPMENT *and its parts, including mounting* ACCESSORIES, *shock test in accordance with IEC 60068-2-27:2008, using the following conditions:*

NOTE 2 This represents Class 7M3 as described in IEC TR 60721-4-7:2001 [6].

1) test type: Type 1;

- *peak acceleration: 300 m/s^2 (30 g),*
- *duration: 11 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total);*

or

2) test type: Type 2;

- *peak acceleration: 1 000 m/s^2 (100 g),*
- *duration: 6 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total).*

Documents
Document Sharing Hub
Full document details: IEC 60601-1-12-2020

b) For ME EQUIPMENT *and its parts, including mounting* ACCESSORIES, *broad-band random vibration test in accordance with IEC 60068-2-64:2008, using the following conditions:*

NOTE 3 This represents Class 7M3 as described in IEC TR 60721-4-7:2001.

– *acceleration amplitude:*
  - *10 Hz to 100 Hz: 5,0 $(m/s^2)^2/Hz$,*
  - *100 Hz to 200 Hz: -7 dB per octave,*
  - *200 Hz to 2 000 Hz: 1,0 $(m/s^2)^2/Hz$,*
– *duration: 30 min per perpendicular axis (3 total).*

c) For ME EQUIPMENT *and its parts, including mounting* ACCESSORIES, *free fall to IEC 60068-2-31:2008, using Procedure 1 and the following conditions:*

NOTE 4 This represents Class 7M3 as described in IEC TR 60721-4-7:2001.

– *fall height:*
  - *for mass ≤ 1 kg, 1,0 m,*
  - *for mass > 1 kg and ≤ 10 kg, 0,5 m,*
  - *for mass > 10 kg and ≤ 50 kg, 0,25 m,*
  - *for mass > 50 kg, 0,1 m,*
– *number of falls: 2 in each specified attitude.*

For PORTABLE ME EQUIPMENT *that is intended to be used only with a carrying case, that case may be applied to the equipment during this test.*

Verify that BASIC SAFETY *and* ESSENTIAL PERFORMANCE *are maintained following these tests.*

10.1.4 * Requirements for mechanical strength for ME EQUIPMENT intended for airborne use

In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended for airborne use, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling. The technical description shall disclose the type of aircraft for which the ME EQUIPMENT has been qualified.

After the following tests, ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

NOTE 1 The levels of mechanical stresses utilized in the test methods of this subclause are considered to be reflective of NORMAL USE for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT in an air ambulance.

Compliance is checked by performing the following tests:

a) For ME EQUIPMENT *and its parts, including mounting* ACCESSORIES, *shock test in accordance with IEC 60068-2-27:2008, using the following conditions:*

NOTE 2 This represents Class 7M3 as described in IEC TR 60721-4-7:2001 [6].

1) test type: Type 1;
  – *peak acceleration: 300 m/s^2 (30 g),*
  – *duration: 11 ms,*
  – *pulse shape: half-sine,*
  – *number of shocks: 3 shocks per direction per axis (18 total);*

or

2) test type: Type 2;

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Full document details: IEC 60601-1-12-2020

- *peak acceleration: 1 000 m/s^2 (100 g),*
- *duration: 6 ms,*
- *pulse shape: half-sine,*
- *number of shocks: 3 shocks per direction per axis (18 total).*

b) For ME EQUIPMENT *and its parts, including mounting* ACCESSORIES*, vibration tests in accordance with Section 8, Table 8-1, of either EUROCAE ED-14G or RTCA DO-160G for a fuselage location of the aircraft type (Category S for fixed wing or Category U for rotary wing) as indicated in the technical description.*

Verify that BASIC SAFETY *and* ESSENTIAL PERFORMANCE *are maintained following these tests.*

10.2 Requirements for mounting of ME EQUIPMENT

ME EQUIPMENT, other than HAND-HELD or BODY-WORN ME EQUIPMENT, shall be equipped with means to permit the attachment of mounting ACCESSORIES.

Compliance is checked by inspection.

11 Additional requirements for electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

In addition to the requirements of 7.1.1 of IEC 60601-1-2:2014, ME EQUIPMENT and ME SYSTEMS intended for the EMS ENVIRONMENT shall be classified as Class B according to CISPR 11:2009.

NOTE 1 Use in the EMS ENVIRONMENT includes use in the vicinity of 'domestic establishments'.

In addition to the requirements of 7.1.1 of IEC 60601-1-2:2014, ME EQUIPMENT and ME SYSTEMS intended for aircraft use shall comply with EUROCAE ED-14G or RTCA DO-160G, Section 21, Category M for ELECTROMAGNETIC EMISSIONS.

NOTE 2 The requirements for IMMUNITY for ME EQUIPMENT intended for the EMS ENVIRONMENT are found in 8.1 of IEC 60601-1-2:2014 and they are the same as the requirements for the HOME HEALTHCARE ENVIRONMENT.

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Full document details: IEC 60601-1-12-2020

Annex A
(informative)

General guidance and rationale

A.1 General guidance

During the development of IEC 60601-1:2005, there was considerable discussion about the increasing use of ME EQUIPMENT and ME SYSTEMS outside professional healthcare facilities or without direct medical supervision.

Some of this equipment was seen as falling outside the formal scope of earlier editions of IEC 60601-1 and its collateral and particular standards because the definition of ME EQUIPMENT in IEC 60601-1:1988 included the phrase "PATIENT under medical supervision".

A number of subsequent questions arose, including the following:

– Should the scope of the third edition of IEC 60601-1 be expanded to include ME EQUIPMENT intended for use without direct medical supervision?
– Should the new standard(s) include specific requirements for ME EQUIPMENT intended by its MANUFACTURER for the HOME HEALTHCARE ENVIRONMENT or EMS ENVIRONMENT?
– Should such requirements vary depending on the level of medical supervision or the environment in which the ME EQUIPMENT is intended to be used?
– Does the introduction of RISK MANAGEMENT address these issues or is there still a need for additional technical requirements?

The question of what was originally meant by medical supervision remained unanswered but will still be relevant if the term is retained to differentiate proposed technical requirements for ME EQUIPMENT intended for environments other than professional healthcare facilities. Medical supervision could mean direct supervision by a doctor or it could include supervision by an allied health professional or a medical institution; it could be taken to mean real time supervision or it could include indirect supervision.

In reality, the level of medical supervision of ME EQUIPMENT used outside professional healthcare facilities and the environments in which it is used cover a wide range, as demonstrated by the following examples:

– Cardiac defibrillators of various kinds are used in all sorts of locations by doctors and nurses, ambulance paramedics, airline crews and even the general public.
– Emergency use of ME EQUIPMENT at the scene of an accident or mass casualty event.
– HOME HEALTHCARE ENVIRONMENT dialysis equipment is prescribed by a medical practitioner and is often installed and used under strict guidelines.
– Respiratory care equipment (bottles or oxygen concentrators, ventilators, nasal CPAP, etc.) is often prescribed by a medical practitioner but can be used by the PATIENT without following the prescription.
– Many types of ME EQUIPMENT such as sphygmomanometers, clinical thermometers and transcutaneous nerve stimulators are purchased from pharmacy stores or over the internet without a medical prescription and used without any instructions or precautions other than those provided by the MANUFACTURER.

Developing tried-and-true answers to various issues associated with ME EQUIPMENT and ME SYSTEMS intended for environments other than professional healthcare facilities should certainly reduce the need for individual MANUFACTURERS' RISK CONTROL measures and might improve the safety of some equipment. However, the scope of the technical requirements

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Full document details: IEC 60601-1-12-2020

needs to be carefully specified because the degree of medical supervision varies so widely. For example cardiac defibrillators may be used by:

– hospital doctors: some might see this as full medical supervision while a doctor such as a dermatologist might say that medical supervision implies use by or under the direction of an appropriately qualified specialist;
– non-hospital doctors: the same dermatologist might be less qualified than an ambulance paramedic to use a defibrillator;
– hospital nurses: ready access to medical staff in some professional healthcare facilities;
– emergency medical technicians: somewhat slower access to direct medical supervision. Large diversity in training between various emergency services, i.e. wide range in quality of indirect medical supervision;
– airline crews: automatic external defibrillator – probably used under policies and PROCEDURES developed by the airline's medical adviser. Some might say this is medical supervision;
– general public: automatic external defibrillator – possibly used according to short-form instructions printed on the unit or the cabinet or verbal instructions from the device itself.

Likewise, test requirements need to differentiate between the use environments such as:

– the uncontrolled outdoor environment at the scene of an emergency;
– the extreme stress of a mass casualty event;
– the care capability based on the severity of the condition of the intended PATIENT;
– the mechanical stresses associated with emergency TRANSIT-OPERABLE use;
– the controlled environment in (some) healthcare facilities;
– the possibly less well controlled environment of a PATIENT'S home in which installation and use of ME EQUIPMENT is administered by SERVICE PERSONNEL from a healthcare facility;
– the even less well controlled environment of a PATIENT'S home in which ME EQUIPMENT that has been prescribed by a medical practitioner is used without any direct supervision.

One early step in addressing these issues was made when the scope of IEC 60601-1:2005 was extended by removing "under medical supervision" from the definition of ME EQUIPMENT. However there are only oblique references to environments other than professional healthcare facilities in IEC 60601-1:2005:

– One of the notes to the definition of RESPONSIBLE ORGANIZATION states that in "home use applications" the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.
– A note that SUPPLY MAINS can include the power distribution in an ambulance.
– The rationale for the definition of OPERATOR states that in the "home-care environment" this could be either the PATIENT or a LAY OPERATOR assisting the PATIENT.
– The rationale for 14.13 of the general standard (PEMS intended to be incorporated into an IT-network) states that many hospitals operate ME EQUIPMENT in a networked environment within the hospital, between hospitals and from home.

In the development of IEC 60601-1-11 several experts observed that with the development of requirements for the HOME HEALTHCARE ENVIRONMENT, there was a need to cover the major environment that was not yet addressed in the 60601 family of standards, the EMS ENVIRONMENT.

This collateral standard was developed with these considerations in mind. It is intended to bridge the gap between the technical requirements in IEC 60601-1:2005 and those needed for ME EQUIPMENT or ME SYSTEMS intended by their MANUFACTURERS to be used in the EMS ENVIRONMENT.

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Full document details: IEC 60601-1-12-2020

A.2 Rationale for particular clauses and subclauses

The following are rationales for specific clauses and subclauses in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

Subclause 1.1 – Scope

For the purposes of this standard, the EMS ENVIRONMENT is treated as an adjunct to a professional healthcare facility. The goal of emergency medical services is to either provide treatment to those in need of urgent medical care, with the goal of satisfactorily treating the malady, or arranging for timely movement of the PATIENT from the scene of an emergency to the next point of care. Emergency medical services are also used for the scheduled transport of PATIENTS between professional healthcare facilities.

This standard covers both the environment at the scene of emergency, which can be anywhere, as well as the environment of transport from the scene of emergency to a professional healthcare facility. The transport conditions from the scene of an emergency can often not be distinguished from the transport conditions for planned inter-hospital transport (e.g. pot-holes in the road, electrical connection in the ambulance, electromagnetic environment). This standard covers all professional transport situations where ME EQUIPMENT is used outside of professional healthcare environments. LAY OPERATOR use in transport of ME EQUIPMENT is considered HOME HEALTHCARE ENVIRONMENT use for which IEC 60601-1-11 applies.

Many times additional ME EQUIPMENT, not intended for use in transport situations, is loaded with the PATIENT for scheduled transport. This ME EQUIPMENT, not intended for the EMS ENVIRONMENT, poses a significant RISK to the PATIENT, OPERATOR and environment due to the uncontrolled conditions and settings in which these vehicles operate (e.g. EMC, temperatures, precipitation, motion, fixation for movement and crash protection). It is important that ME EQUIPMENT used in the transport situations is safe for this use. It is also likely that the TRANSPORTABLE ME EQUIPMENT in ambulances intended for the scheduled transport of PATIENTS between professional healthcare facilities is moved outdoors with the PATIENT during loading and unloading.

In some regions, separate vehicles are allocated for the scheduled transport of PATIENTS between professional healthcare facilities. Nonetheless in mass casualty situations it is reasonably foreseeable that these vehicles will be used. In this situation, the TRANSPORTABLE ME EQUIPMENT is likely to be removed from the vehicle and exposed to the full range of environmental HAZARDS and use environments described in this standard.

Emergency medical services are known by various names in different countries and regions. Although emergency medical services are frequently delivered to PATIENTS in a home, for the purposes of this standard such urgent and temporary use in a home is not considered use in the HOME HEALTHCARE ENVIRONMENT.

For the purposes of this standard, public access ME EQUIPMENT such as automated external defibrillators (AEDs) are considered equipment intended for the HOME HEALTHCARE ENVIRONMENT and not for the EMS ENVIRONMENT. For example, public access AEDs are intended to be operated by LAY OPERATORS and not necessarily OPERATORS with relevant specialized training.

Subclause 1.2 – Object

The objective of emergency medical services is to either provide treatment to those in need of urgent medical care, with the goal of satisfactorily treating the malady, or arranging for timely removal of the PATIENT to the next point of definitive care.

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Full document details: IEC 60601-1-12-2020

Definition 3.1 – EMS ENVIRONMENT

The conditions and settings of the EMS ENVIRONMENT include, *inter alia*:

– temperature variation and extremes;
– humidity;
– pressure variation and extremes (altitude);
– precipitation;
– ambient light levels;
– ambient noise (variable/loud) levels;
– motion (vibration);
– fixation for movement and crash protection (shock);
– EMC;
– emergency use environment (OPERATOR stress).

ME EQUIPMENT used in the EMS ENVIRONMENT is exposed to all of these conditions and settings. ME EQUIPMENT used in the EMS ENVIRONMENT can be FIXED or PERMANENTLY INSTALLED in ambulances, as well as TRANSPORTABLE ME EQUIPMENT which is used inside and outside the ambulance. The OPERATOR expects that this equipment performs as intended in all of these conditions and emergency situations.

Though infrequent, all types of ambulances, including those primarily used for scheduled transport of PATIENTS are utilized during a mass casualty situation for emergency response. As a result it is reasonably foreseeable that the ME EQUIPMENT in such an ambulance is exposed to all of the conditions and settings above.

It is understood there are relatively few ME EQUIPMENT intended for use on rail or watercraft ambulances compared to road, rotary, and fixed-wing ambulances, in the world. As a result, this standard does not address any specific requirements for ME EQUIPMENT intended for use in rail or watercraft environments. MANUFACTURERS intending ME EQUIPMENT for rail or watercraft environments should use RISK MANAGEMENT to expand the requirements of this standard to address the special requirements of those environments. MANUFACTURERS intending ME EQUIPMENT for difficult terrain vehicles also should use RISK MANAGEMENT to expand the requirements of this standard to address the special requirements of this environment. The following requirements should be assessed for adequacy:

– 7, * Protection against electrical HAZARDS from ME EQUIPMENT, salt spray and pollution degree;
– 8.1, Additional requirements for ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS, potential submersion and conductive particulate matter; and
– 10.1, * Additional requirements for mechanical strength of me equipment intended for the EMS ENVIRONMENT, different profiles for shock and vibration due different vehicle profiles.

First aid rooms or rescue rooms in facilities (e.g. in airports, railway stations, factories, shopping centres or sports facilities) are regarded as professional healthcare facilities. For ME EQUIPMENT exclusively and permanently used inside of these locations the requirements of IEC 60601-1 apply without additional requirements of this collateral standard. This is due to the fact that professional maintenance of these locations and their installations is assumed to be present.

However, these rooms also are often equipped with TRANSPORTABLE ME EQUIPMENT which is intended to be taken to the scene of an emergency. This equipment should be considered EMS ENVIRONMENT ME EQUIPMENT.

Documents
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Full document details: IEC 60601-1-12-2020

Subclause 4.1 – Additional requirements for SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS

Most electrical equipment standards, such as IEC 60950-1 [7], IEC 60335-1 [3] and IEC 60065 [2] have a ± 10 % SUPPLY MAINS variation for equipment. The – 15 % to + 10 % SUPPLY MAINS variation was considered more appropriate for ME EQUIPMENT intended for the EMS ENVIRONMENT given the nature of emergency SUPPLY MAINS. The – 15% SUPPLY MAINS variation addresses the use of inexpensive generators for emergency power generation.

For d.c. SUPPLY MAINS, the requirements support operation from lead-acid batteries and automobiles. A typical 12 V lead-acid battery has an open circuit voltage of approximately 12,65 V when fully charged. This voltage drops to approximately 12,06 V when 25 % charged. Furthermore while cranking the engine, automotive lead-acid batteries are RATED for their ampacity while maintaining 7,2 V. MANUFACTURERS need to consider whether or not their equipment needs to operate under this condition. While the engine is running, the battery charging system typically maintains the .d.c. voltage between 12,8 V and 14,8 V. [12] [15] The values for d.c. operation are consistent with the European standard medical devices carried in an air ambulance as described in EN 13718-1:2008.

Subclause 4.2 – Environmental conditions for ME EQUIPMENT

Several test sequences of this standard combine elevated temperature and elevated relative humidity (unless indicated and marked otherwise). This combination is a severe condition that does not occur in actual use environments. For example MIL-HDBK-310, subclause 5.1.3.1 shows a maximum world-wide absolute humidity corresponding to a dew point of 34°C. When air at the extreme 34 °C and 93 % relative humidity is warmed to 70 °C, the relative humidity will drop to a lower value of about 16 % because the vapour pressure at this temperature is 312 hPa.[20] This is why the committee has chosen to limit the water vapour partial pressure to 50 hPa. This needs to be considered when setting the control for relative humidity during the tests.

The partial pressure of a gas or vapour is the pressure that this gas would assume when no other gases were present in the given volume, i.e. all other gases being removed. So the partial pressure of oxygen in dry air at a pressure of 1 013 hPa is approximately equal to 210 hPa.

The saturation vapour pressure P_s of a liquid is the partial pressure of the vapour of that liquid in thermal equilibrium with its liquid. This saturation vapour pressure depends strongly on temperature. Saturation vapour pressure is low at low temperatures and reaches atmospheric pressure at the boiling temperature. A mathematical description of this temperature dependence was first developed by B. Clapeyron and later on derived by R. Clausius from the theory of thermodynamics.

$$P_s = K_1 \times e^{-K_2/T} \tag{A.1}$$

where

T = the absolute temperature

K_1 and K_2 = are constants relating to boiling point and heat of evaporation

This can be reorganized as:

$$P_s = 1013hPa \times e^{-\frac{K_2 \times (T_b - T)}{T_b \times T}} \tag{A.2}$$

where

K_2 = $\Delta H/R$

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Full document details: IEC 60601-1-12-2020

ΔH = heat of evaporation

R = universal gas constant

T = the absolute temperature

T_b = the absolute boiling temperature

This equation is based on assumptions that only are valid over a limited temperature range. The most important assumption is that the heat of evaporation is temperature-independent, which is not exactly the case. Therefore other formulas have been developed – either based on a more detailed theory taking into account what has been neglected before or on experimental data – that cover a larger temperature range. However, within the limited temperature range of 10 °C to 80 °C the original and simple Clausius-Clapeyron-equation can be used, albeit with slightly different constants.

Figure A.1 and Table A.1 show the saturation water vapour pressure as function of temperature.

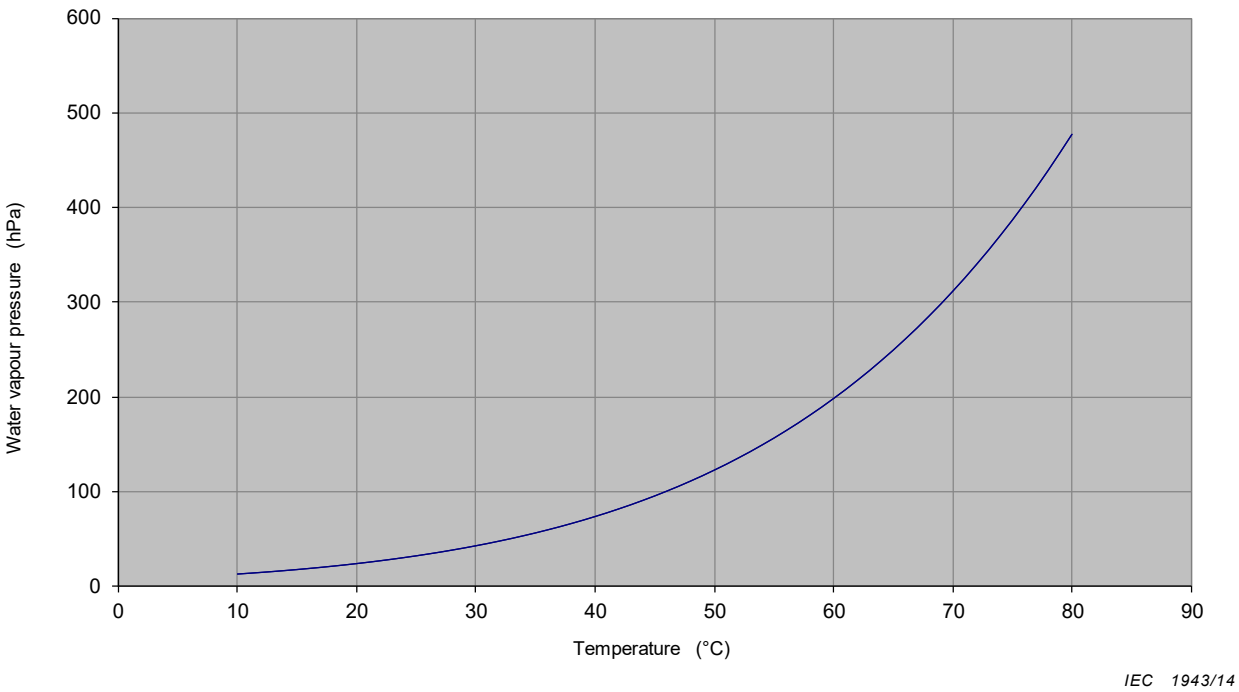

Figure A.1 – Saturation water vapour pressure as function of temperature

The relative humidity RH is given as the ratio of the actual partial pressure of the water vapour and the saturation vapour pressure.

$$RH = P_v / P_s$$

where

P_v = actual partial pressure of the water vapour

P_s = saturation vapour pressure

When one knows the actual temperature and thereby P_s, RH can be calculated from P_v and vice versa.

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Full document details: IEC 60601-1-12-2020

Table A.1 – Saturation water vapour pressure as function of temperature

Temperature °C	Saturation water vapour pressure P_s hPa	Equivalent relative humidity at an actual partial pressure of the water vapour of 50hPa %
10	12,28	-
12	14,03	-
14	15,99	-
16	18,19	-
18	20,64	-
20	23,39	-
22	26,45	-
24	29,85	-
26	33,63	-
28	37,82	-
30	42,46	-
32	47,58	-
34	53,23	94
36	59,45	84
38	66,30	75
40	73,81	68
42	82,05	61
44	91,08	55
46	100,94	50
48	111,71	45
50	123,44	41
52	136,23	37
54	150,12	33
56	165,22	30
58	181,59	28
60	199,32	25
62	218,51	23
64	239,25	21
66	261,63	19
68	285,76	17
70	311,76	16
72	339,72	15
74	369,78	14
76	402,05	12
78	436,65	11
80	473,73	11

Subclause 4.2.1 – Environmental conditions of transport and storage between uses

The environmental ranges defined in IEC TR 60721-4-7 [6] Class 7K4 are not uncommon in storage locations where the ME EQUIPMENT might be stored or transported between uses in the EMS ENVIRONMENT. Outdoor temperatures and particularly temperatures found in vehicles

Documents
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Full document details: IEC 60601-1-12-2020

during transport and storage can easily reach these extremes. To prevent damage to the ME EQUIPMENT, the ME EQUIPMENT either needs to be able to survive these conditions or the OPERATOR needs to be continually reminded by the required marking to protect the ME EQUIPMENT from these conditions.

IEC TR 60721-4-7 was chosen since it is designed to provide specific test limits to match the intended environments of use expected by various use cases in the EMS ENVIRONMENT. Marking of the range of environmental transport and storage conditions between uses on the ME EQUIPMENT can be impossible because of the very small size of the ME EQUIPMENT, a part or ACCESSORY, or because such markings would interfere with the INTENDED USE of the ME EQUIPMENT, part or ACCESSORY.

To aid MANUFACTURERS of small ME EQUIPMENT in reducing test time, two options for the soak period are provided. The general requirement is to soak the ME EQUIPMENT at a set of conditions for 16 h. The alternative is to permit the MANUFACTURER to measure the internal temperature of the ME EQUIPMENT at an appropriate location and then terminate the soak after THERMAL STABILITY has been reached for a period of 2 h.

Subclause 4.2.2 – Environmental operating conditions

These environmental ranges are commonly found in areas where ME EQUIPMENT is operated in the EMS ENVIRONMENT. It is not reasonable to treat a PATIENT indefinitely at temperatures below 0 °C. The model chosen in this standard is to require that the equipment operate for a transient period from ‘normal’ ambulance operational temperature to the outdoor extreme (see. 4.2.2.2). 0 °C is considered an adequate lower limit for continuous operation.

This subclause specifies a set of environmental operating conditions (temperature, relative humidity, atmospheric pressure) under which ME EQUIPMENT is required to maintain its BASIC SAFETY and ESSENTIAL PERFORMANCE. These conditions are wider than those that are required by the general standard because the environmental conditions in the EMS ENVIRONMENT are typically wider or less controlled than those of a professional healthcare facility. To maintain its BASIC SAFETY and ESSENTIAL PERFORMANCE, the ME EQUIPMENT either needs to be able to function under the conditions specified in this subclause or the OPERATOR needs to be continually reminded to operate the ME EQUIPMENT within the more restricted range of conditions marked on the ME EQUIPMENT during use.

In order to evaluate the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT, PATIENT simulation might be needed to approximate a worst-case PATIENT use scenario so that the test can be performed without connecting the ME EQUIPMENT to a PATIENT. The MANUFACTURER will need to determine which functionality of the ME EQUIPMENT can appropriately be used for evaluation of its BASIC SAFETY and ESSENTIAL PERFORMANCE. Some ME EQUIPMENT needs to be sequentially activated and can require some modification in order to complete these tests. MANUFACTURERS are reminded that subclause 5.4 a) of the general standard requires testing to be performed "under the least favourable working conditions ... that are identified during the RISK ANALYSIS". This means that these tests also need to be performed at any intermediate point that is suspected or known to be less favourable than those explicitly specified in this subclause.

Marking of the range of environmental operating conditions of use on the ME EQUIPMENT can be impossible because of the very small size of the ME EQUIPMENT, a part or ACCESSORY, or because such markings would interfere with the INTENDED USE of the ME EQUIPMENT, part or ACCESSORY.

To aid MANUFACTURERS of small ME EQUIPMENT in reducing test time, two options for the soak period are provided. The general requirement is to soak the ME EQUIPMENT at a set of conditions for 6 h. The alternative is to permit the MANUFACTURER to measure the internal temperature of the ME EQUIPMENT at an appropriate location and then terminate the soak after THERMAL STABILITY has been reached for a period of 2 h.

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In the EMS ENVIRONMENT, significant atmospheric pressure changes can occur. ME EQUIPMENT where concerns about environmental atmospheric pressure changes need explicit investigation include air handling systems, such as ventilators and associated ACCESSORIES. Additionally, ME EQUIPMENT with membrane switches are known to have performance issues during pressure changes.

Subclause 4.2.2.2 – Transient operating conditions

EMS ENVIRONMENT ME EQUIPMENT is likely to see rapid changes in environmental temperature and humidity while operating – for example, when the ME EQUIPMENT is moved from a climate-controlled ambulance into the cold, dry conditions found outdoors in the winter at the scene of an accident and then some time later when the PATIENT and ME EQUIPMENT is moved back into a climate-controlled ambulance. EMS ENVIRONMENT ME EQUIPMENT has to continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE during those transitions even if there is condensation on or in the ME EQUIPMENT. Similarly, EMS ENVIRONMENT ME EQUIPMENT is also likely to see movement from a climate-controlled ambulance into relatively warm and moist conditions. The committee considers 20 min to be a typical long duration for emergency treatment at the scene prior to timely removal of the PATIENT to the next point of care.

EMS ENVIRONMENT ME EQUIPMENT needs a sufficient power capacity to provide its intended function for 20 min. It is not reasonable to treat a PATIENT indefinitely at temperatures below 0 °C or above 40 °C. The more extreme the outside temperature, the faster the PATIENT, the ME EQUIPMENT and the OPERATOR need to be moved to a more controlled environment. The committee chose 20 min at -20 °C and +50 °C as an adequate test.

Most of this equipment is PORTABLE or HAND-HELD and preconditioning for 6 h should be more than sufficient to ensure THERMAL STABILITY prior to the 20 min transient operational test.

Moving from warm and moist conditions to cooler, dryer conditions might result in some safety and performance difficulties (e.g. degradation or loss) due to contraction and increased brittleness of materials. Safety and performance difficulties can include sticking valves, belts slipping or O-rings leaking. Solid insulation between conductive parts has more severe 30-day thermal cycling testing in the 8.9.3 of the general standard, making concerns in this area minimal.

The committee considers that EMS ENVIRONMENT ME EQUIPMENT that is designed to operate within the standard operating environmental conditions given in 4.2.2 is unlikely to have difficulty with environmental shock due to rapid temperature and humidity changes within that range. If the ME EQUIPMENT design incorporates non-standard technologies or materials, the MANUFACTURER can decide that additional testing is prudent, but it is not required by this standard.

Clause 5 – Classification of ME EQUIPMENT and ME SYSTEMS

PORTABLE and MOBILE electrical generators do not necessarily have a ground connection that can be relied upon for safety. As a result CLASS I construction is not permitted unless the equipment is FIXED or PERMANENTLY INSTALLED in an ambulance.

The committee concluded that it is unacceptable to base the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT intended for the EMS ENVIRONMENT on a PROTECTIVE EARTH CONNECTION considering the facts that:

– it can be reasonably foreseen that ME EQUIPMENT in the EMS ENVIRONMENT will often be used with electrical installations that lack effective PROTECTIVE EARTH CONNECTIONS; and
– the typical use of ME EQUIPMENT in the EMS ENVIRONMENT is in emergency situations where the OPERATOR will not be able to determine the quality of an available PROTECTIVE EARTH CONNECTION.

Consequently the RISK CONTROL measures for protection against electrical shock for TRANSPORTABLE ME EQUIPMENT intended for the EMS ENVIRONMENT should not depend on a

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PROTECTIVE EARTH CONNECTION (i.e. be of CLASS I construction). Similarly, the designer of the TRANSPORTABLE ME EQUIPMENT should not depend on the presence of a FUNCTIONAL CONNECTION to earth in order to comply with EMC requirements or to maintain ESSENTIAL PERFORMANCE.

An exception is made for ME EQUIPMENT that is FIXED or PERMANENTLY INSTALLED since such equipment is required to be installed or electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL. When that installation or connection is made, which is normally performed by SERVICE PERSONNEL, the adequacy of the PROTECTIVE EARTH CONNECTION can be verified. There are specific disclosure requirements included in 6.4 to ensure specifically that the appropriate information is available for this check or important connection.

The committee concluded that excluding TYPE B APPLIED PARTS and allowing only F-TYPE APPLIED PARTS provided practical RISK CONTROL for the following reasonably foreseeable HAZARDOUS SITUATIONS in the EMS ENVIRONMENT:

a) It was felt that ME EQUIPMENT in the EMS ENVIRONMENT would likely have NETWORK/DATA COUPLING ports for ACCESSORIES, including connections to a communication network, a printer, etc. While the instructions for use will specify that only appropriate safety compliant equipment is to be connected to such ports, it is reasonably foreseeable that some ACCESSORIES will not have appropriate TOUCH CURRENT limits. An F-TYPE APPLIED PART insulation barrier separates the APPLIED PART from the equipment chassis by insulation equivalent to a data separation barrier on user SIP/SOP ACCESSORY ports.

b) The total PATIENT LEAKAGE CURRENT from APPLIED PARTS contacting an earthed PATIENT will increase as the number of APPLIED PARTS increases. In a professional healthcare facility this is supervised by healthcare professionals. In the EMS ENVIRONMENT this level of biomedical engineering supervision can be missing. An F-TYPE APPLIED PART insulation barrier separates the APPLIED PART from earth, and therefore the total PATIENT LEAKAGE CURRENT from multiple F-TYPE APPLIED PARTS to earth is greatly reduced by design.

The exclusion of TYPE B APPLIED PARTS is felt to be the best practical mitigation strategy for the above HAZARDOUS SITUATIONS. The committee acknowledges that depending on the specific ME EQUIPMENT type, some or all of the RISKS associated with these HAZARDOUS SITUATIONS could be controlled by alternative means. For example, some ME EQUIPMENT does not have NETWORK/DATA COUPLING ports, or if they do, these ports have a suitable data separation barrier. Some ME EQUIPMENT is unlikely to be used while simultaneously contacting other APPLIED PARTS, such as a heating blanket. INTERNALLY POWERED products will have negligible PATIENT LEAKAGE CURRENT.

The exception for ME EQUIPMENT that is FIXED or PERMANENTLY INSTALLED applies since such equipment is required to be reliably electrically connected to the SUPPLY MAINS by means of a permanent connection that can only be detached by the use of a TOOL. Such ME EQUIPMENT is allowed to have a TYPE B APPLIED PART. For some ME EQUIPMENT with a TYPE B APPLIED PART, the protective earth provides a single MEANS OF PROTECTION. As such equipment is installed by SERVICE PERSONNEL, one can assume that it has a reliable protective earth. As a result, a TYPE B APPLIED PART is acceptable for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT.

The MANUFACTURER of FIXED or PERMANENTLY INSTALLED ME EQUIPMENT should still consider the HAZARDS noted for cord-connected ME EQUIPMENT, which the committee feels are best mitigated by allowing only F-TYPE APPLIED PARTS.

Subclause 6.1 – Additional requirements for legibility of markings

In the EMS ENVIRONMENT it is important for safe operation of the ME EQUIPMENT that the displays, controls and warnings be CLEARLY LEGIBLE. This environment often includes uncontrolled natural or artificial light sources that can be dim or very bright whether outdoors or in the PATIENT compartment of the ambulance.

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It is important for the OPERATOR to be able to discern the controls, safety warnings and display output throughout a very broad range of lighting conditions from 10 lx (twilight) to 10 000 lx (bright daylight, but not direct sunlight). [17]

Subclause 6.2 – Additional requirements for marking of IP classification

Subclause 8.1.1 requires a minimum IP classification for ME EQUIPMENT. IEC 60529 offers the MANUFACTURER a common marking for conveying to an OPERATOR the IP classification. Parties other than the OPERATOR (such as the ambulance service, clinician or RESPONSIBLE ORGANIZATION) can be involved in selecting equipment for the EMS ENVIRONMENT. Conveying IP classification is necessary for these parties and permits choosing the appropriate equipment for a specific application. Such marking is also consistent with the requirements for ME EQUIPMENT intended for use in the professional healthcare facility. Where part of the protection against the ingress of water or particulate matter is provided by a carrying case, both the carrying case and the ME EQUIPMENT are required to be marked with their respective degree of protection so that the OPERATOR is aware and can take appropriate action.

Subclause 6.3 – Instructions for use

Space is limited in ambulances and frequently the full instructions for use are not stored in the ambulance, but in the facility where the ambulance is stationed. The MANUFACTURER of ME EQUIPMENT intended for the EMS ENVIRONMENT should consider creating a shortened instructions for use that contains the most essential operating instructions. This shortened instructions for use is more likely to follow the equipment into the ambulance. The information in this shortened instructions for use should include items such as the start-up PROCEDURE, the most common operating instruction and controls for any ALARM SYSTEMS. Additionally, troubleshooting instructions and, if applicable, altitude compensation tables should be included.

Subclause 6.3.2 – Additional requirements for an electrical power source

The intent of this subclause is to give the OPERATOR a reasonable expectation of how long the ME EQUIPMENT will operate. This permits the OPERATOR to know how many extra batteries to have available or how long the ME EQUIPMENT will last before the battery needs replacing.

ME EQUIPMENT intended for the EMS ENVIRONMENT that utilizes an INTERNAL ELECTRICAL POWER SOURCE, that is not periodically or automatically maintained, can usually be powered with batteries that are readily available to the general public. For example, some equipment designed for use in the EMS ENVIRONMENT can be powered by a primary type battery using a Zinc-Carbon or an Alkaline type cell, or by a secondary (rechargeable) type of battery using a Nickel-Metal Hydride type cell. The characteristics for these batteries differ significantly from cell type to cell type as well as within one cell type from one battery manufacturer to another. The capacities (i.e. operation time or number of PROCEDURES), SHELF LIFE (for primary types) and for rechargeable types, how many times the battery can be charged and discharged before it becomes unusable (good cycle life) are significantly different from one cell type to another.

Because many INTERNAL ELECTRICAL POWER SOURCES use electrochemical battery technologies, these disclosures are likely to be based on a combination of measurements, specifications and calculations, all of which are based on a set of typical operating conditions for the specified cell type. The MANUFACTURER should consider the technical characteristics of a particular battery type in reference to the NORMAL USE of the ME EQUIPMENT, as well as usage pattern information, temperature during use, electrical load conditions, etc., in developing the disclosure required in this subclause.

As there are several possibilities for INTERNAL ELECTRICAL POWER SOURCES, the required disclosures in the instructions for use should be determined under one of the following conditions:

– for a non-rechargeable INTERNAL ELECTRICAL POWER SOURCE:

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a) for a non-replaceable INTERNAL ELECTRICAL POWER SOURCE, the operation time or number of PROCEDURES and the typical service life is determined using a new and unused INTERNAL ELECTRICAL POWER SOURCE; or

b) for a replaceable INTERNAL ELECTRICAL POWER SOURCE, the operation time or number of PROCEDURES is determined using an unused INTERNAL ELECTRICAL POWER SOURCE, as specified in the instructions for use, that is within the SHELF LIFE of the INTERNAL ELECTRICAL POWER SOURCE; or

NOTE Consideration should also be given to whether or not a separate disclosure is needed for conditions where the INTERNAL ELECTRICAL POWER SOURCE is at the end of its SHELF LIFE.

– for a rechargeable INTERNAL ELECTRICAL POWER SOURCE, the operation time or number of PROCEDURES of the specified rechargeable INTERNAL ELECTRICAL POWER SOURCE when installed in the ME EQUIPMENT is determined for both:

c) a new and fully charged INTERNAL ELECTRICAL POWER SOURCE, and

d) a fully charged INTERNAL ELECTRICAL POWER SOURCE at the specified point of replacement of the INTERNAL ELECTRICAL POWER SOURCE or ME EQUIPMENT.

Subclause 6.3.4 – Additional requirements for operating instructions

The operating instructions for ME EQUIPMENT intended for the EMS ENVIRONMENT need to address topics beyond those for typical professional healthcare facility ME EQUIPMENT. The uncontrolled environment and changing environment requires that the OPERATOR has additional information available to ensure the safety of the PATIENT. Since the OPERATOR cannot change the environment, but needs to adapt to the environment while using the ME EQUIPMENT, this information is required in the operating instruction.

Subclause 7 – Protection against electrical HAZARDS from ME EQUIPMENT

Moving from cold and dry conditions to warmer and moister conditions, might result in some safety and performance difficulties due to wetness caused by condensation. Some safety and performance difficulties can include problems with moving parts and failure of electronics due to shorting of functional insulation. Requirements for CREEPAGE DISTANCES and AIR CLEARANCES in the general standard are based on a pollution degree 2 environment. The typical EMS ENVIRONMENT is expected to be a pollution degree 3 environment, i.e. an environment with dust, which when dry is non-conductive, but can be moist, and when moist is considered conductive. The CREEPAGE DISTANCES and AIR CLEARANCES for such pollution degree 3 environments are established taking into account temporary condensation periods. Subclause 8.9 of the general standard establishes suitable CREEPAGE DISTANCES and AIR CLEARANCES for MEANS OF OPERATOR PROTECTION (MOOP), and more conservative distances for MEANS OF PATIENT PROTECTION (MOPP). Similarly concerns about the integrity of solid insulation are considered minimal because of required humidity conditioning testing required by the general standard.

Subclause 8.1.1 – Ingress of water or particulate matter into ME EQUIPMENT

ME EQUIPMENT intended for use in the EMS ENVIRONMENT can face many situations because of the emergency nature of its use which ME EQUIPMENT intended for use only in professional healthcare facilities is not likely to encounter due to environmental controls and the use environment of professional healthcare facilities.

The EMS ENVIRONMENT includes use outdoors in emergency situations, and has a higher probability of exposure to dust, dirt and rain. This is especially true for ME EQUIPMENT intended to be removed from the ambulance and taken to the PATIENT. It is reasonably foreseeable that the OPERATOR will not be able to keep the ME EQUIPMENT dry in an emergency situation at the scene of an accident. In fact, it is likely that such ME EQUIPMENT will be used during heavy rain conditions. The committee considers IP33 appropriate for ME EQUIPMENT that can be removed from the ambulance. Under these conditions, ME EQUIPMENT is expected to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

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When a carrying case is used during IP testing, it should be the same case that is used during mechanical strength testing.

The PATIENT compartment of an ambulance is an area where there is the potential for significant fluid dripping (e.g. from blood and other body fluid spray, partially disconnected IV bags, etc.). It is more than just vertical drips. FIXED and PERMANENTLY INSTALLED ME EQUIPMENT is typically not removed from the ambulance between PATIENTS when the PATIENT compartment is cleaned and disinfected. The committee considers at least IP22 appropriate for ME EQUIPMENT that is FIXED or PERMANENTLY INSTALLED. Under these conditions, ME EQUIPMENT is expected to maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 8.1.2 – Ingress of water or particulate matter into ME SYSTEMS

As with the analysis in the rationale to Clause 5, the committee concluded that most ME SYSTEMS comprise ME EQUIPMENT in combination with ACCESSORIES such as connections to a communication network, a printer, etc. The committee considered it unlikely that the non-ME EQUIPMENT would be removed from the ambulance and carried to the scene of an accident. Consistent with the philosophy of the general standard, this standard relies on the requirements for resistance to ingress of water or particulate matter of other IEC product safety standards (e.g. IEC 60335-1 [3] and IEC 60950-1 [7]) for non-ME EQUIPMENT parts of ME SYSTEMS. Information technology communication (ITC) equipment, such as computers, cable boxes and modems should not have new or additional requirements just because they have a FUNCTIONAL CONNECTION to ME EQUIPMENT.

The MANUFACTURER should identify what ingress protection is appropriate for non-medical equipment and non-medical ACCESSORIES used in a ME SYSTEM. It is not expected that non-medical equipment or ACCESSORIES necessarily require the same ingress protection as the ME EQUIPMENT. The relative proximity of non-medical equipment and ACCESSORIES to the ME EQUIPMENT and PATIENT can demand a lesser or greater ingress requirement. While the non-ME EQUIPMENT parts of the ME SYSTEM can share a conductive connection (electrical or fluid) with the ME EQUIPMENT, the non-medical equipment and ACCESSORIES do not share a conductive connection to the PATIENT. In accordance with Clause 5, all cord-connected ME EQUIPMENT for use in the EMS ENVIRONMENT are required to have F-TYPE APPLIED PARTS.

Subclause 8.3 – Additional requirements for INTERNAL ELECTRICAL POWER SOURCE for ME EQUIPMENT

See also rationale for subclause 4.2.2.2. The MANUFACTURER needs to consider the worst-case operating conditions as specified in INTENDED USE when determining that performance is maintained for 20 min.

Providing a means to determine the state of the INTERNAL ELECTRICAL POWER SOURCE allows the OPERATOR to plan for replacement so that continuous operation remains possible. It can also be important for the OPERATOR to be aware of the state of the INTERNAL ELECTRICAL POWER SOURCE while the ME EQUIPMENT is powered from SUPPLY MAINS.

Many simple measuring devices, e.g. a thermometer, do not have display space to indicate this continuously, and are used aperiodically. An OPERATOR needs to look at the display to know the state; it is little different to press a button to see this indication. As a result, permitting OPERATOR action to indicate the state of the INTERNAL ELECTRICAL POWER SOURCE is acceptable. Continuous display when the thermometer is in the drawer is of no value.

It should be understood that both 12.1 and 12.2 of the general standard can also apply to the MANUFACTURER'S implementation of the means of indicating the state of the INTERNAL ELECTRICAL POWER SOURCE, e.g. the MANUFACTURER needs to determine how accurate this indication needs to be and that the intended OPERATOR can understand the indication.

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Subclause 9 – Accuracy of controls and instruments and protection against hazardous outputs

The use environment found in the EMS ENVIRONMENT is substantially different than that of the typical professional healthcare facility. When an ambulance arrives at the scene of an emergency, the first task of the OPERATORS is to assess the situation to ensure their own safety and to secure the scene. Only then can they safely begin the PROCESS of delivering care and operating equipment. The situational urgency associated with this use environment needs particular emphasis by the MANUFACTURER when conducting the USABILITY ENGINEERING PROCESS for ME EQUIPMENT intended for the EMS ENVIRONMENT [21].

In mass casualty situations, the situational urgency associated with the needed triage and the potential for overwhelming the capacity of the available resources also needs particular emphasis by the MANUFACTURER when conducting the USABILITY ENGINEERING PROCESS for ME EQUIPMENT intended for the EMS ENVIRONMENT.

Subclause 10.1 – Additional requirements for mechanical strength of ME EQUIPMENT intended for the EMS ENVIRONMENT

ME EQUIPMENT in NORMAL USE is subjected to mechanical stresses (e.g. vibration, shock) and will likely be subjected to additional stresses due to the EMS ENVIRONMENT. NORMAL USE in the EMS ENVIRONMENT includes rough handling beyond that anticipated in a professional healthcare facility. Therefore, ME EQUIPMENT intended for the EMS ENVIRONMENT needs to be robust enough to withstand the shock, vibration and drops that it will encounter in NORMAL USE.

Test methods considered representative have been specified based on usage categories having to do with whether the ME EQUIPMENT is FIXED or PERMANENTLY INSTALLED in the ambulance or not and the type of ambulance in which the equipment is used.

Consistent with the philosophy of the general standard, this standard relies on the mechanical strength requirements of other IEC product safety standards (e.g. IEC 60335-1 [3] and IEC 60950-1 [7]) for non-ME EQUIPMENT parts of ME SYSTEMS. Information technology communication (ITC) equipment, such as computers, cable boxes and modems should not have new or additional requirements just because they have a FUNCTIONAL CONNECTION to ME EQUIPMENT. MANUFACTURERS of EMS ENVIRONMENT ME EQUIPMENT parts of ME SYSTEMS should consider whether or not additional mechanical strength testing of the non-ME EQUIPMENT parts of ME SYSTEMS is necessary to ensure BASIC SAFETY and ESSENTIAL PERFORMANCE.

Subclause 10.1.2 – Requirements for mechanical strength for FIXED or PERMANENTLY INSTALLED ME EQUIPMENT intended for use in a road ambulance

After qualitative assessment, the committee assessed the International Standards in the IEC 60068 series relevant for environmental testing, and their respective rationales, as well as the IEC 60721 series of guidance documents. In selecting the requirements, the committee reviewed other sources for material related to these tests (e.g. MIL-STD-810G [19], etc.) but found the best fit was with IEC 60721-3-7:2002 [5]. For road ambulances, this International Standard mapped well to those requirements. There is also a guidance document, IEC TR 60721-4-7:2001 [6] that helps to correlate environmental condition classes of IEC 60721-3-7 to environmental tests according the IEC 60068 series.

The aforementioned International Standards specify 3 classes of mechanical conditions: 7M1, 7M2 and 7M3. The committee found the class 7M2 to represent the conditions seen during use in the EMS ENVIRONMENT for road ambulance use. The committee agreed that additional tests (7M3) should be applied to ME EQUIPMENT that is TRANSPORTABLE versus equipment that is FIXED or PERMANENTLY INSTALLED.

As required in the general standard, ME EQUIPMENT is required to be equipped with its intended ACCESSORIES, as indicated in the instructions for use, during mechanical strength

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testing. ME EQUIPMENT such as beds, PATIENT transport equipment and wheelchairs, are loaded with the intended PATIENT load, as indicated in the instructions for use, during free fall, shock, and vibration testing.

The committee decided to test the ME EQUIPMENT to the appropriate TRANSPORTABLE equipment tests since airborne TRANSPORTABLE ME EQUIPMENT can be moved outside the airborne ambulance. All equipment intended for airborne use is required to meet the fuselage location requirements for the aircraft type intended by the MANUFACTURER.

Determining that rough handling (shock, vibration and drop) testing has not resulted in an unacceptable RISK, includes determining that BASIC SAFETY and ESSENTIAL PERFORMANCE have been maintained. Engineering judgment can be used to formulate a practical test methodology for verifying acceptable RISK during and after rough handling. For ME EQUIPMENT, such as ME EQUIPMENT with mechanical moving parts, (i.e. ventilators, overflow switch), it can be necessary to have the ME EQUIPMENT operate as intended and maintain ESSENTIAL PERFORMANCE while undergoing the tests. For other ME EQUIPMENT, it is only necessary to verify BASIC SAFETY and ESSENTIAL PERFORMANCE after the rough handling tests.

Temporary interruptions of intended operation can be tolerated if consistent with ESSENTIAL PERFORMANCE.

Subclause 10.1.3 – Requirements for mechanical strength for TRANSPORTABLE ME EQUIPMENT

ME EQUIPMENT which in NORMAL USE is intended to be removed from the ambulance and taken to the scene to be used on the PATIENT will be subjected to these mechanical stresses (e.g. shock, vibration and drop) and could randomly be subjected to additional stresses. Therefore, ME EQUIPMENT intended to be used while the PATIENT is moving needs to be robust enough to withstand the mechanical strength testing described by IEC 60721-3-7:2002 [5] level 7M3. IEC 60721-3-7 indicates that in addition to the conditions covered by class 7M2, the class 7M3 applies to use at, and direct transfer between, locations with significant vibrations, or with high-level shocks. Rough handling and transfer of ME EQUIPMENT is expected in these environments such as use in ambulances and on stretchers. Free fall 7M3 is less severe than the 1 m drop already specified in the general standard for HAND-HELD ME EQUIPMENT. The committee retained the drop test in the general standard.

It is essential that thorough analysis is used to assess the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT use during its transportation from one location to another. ME EQUIPMENT used in the EMS ENVIRONMENT is expected to provide emergency care and treatment to PATIENTS. The evaluation of ESSENTIAL PERFORMANCE should be considered as appropriate for certain ME EQUIPMENT during the performance of these tests.

For free-fall testing described in IEC 60068-2-31:2008, the committee used the rationale for the various levels to gauge the severity of the test. The severity of the drop (the drop height) was based on the mass of the ME EQUIPMENT. The committee agreed that some ME EQUIPMENT is likely to be supplied with a protective or carrying case for PORTABLE use. When a carrying case is used during mechanical strength testing, it should be the same case that is used during testing of the protection against ingress of water or particulate matter.

Where the Test 1 or Test 2 test method is specified in this subclause, the intent is that the MANUFACTURER is permitted to select the test method that is more practical or otherwise advantageous to them. The test methods are considered equivalent methods to verify the effectiveness of RISK CONTROL measure(s) for rough handling.

Subclause 10.1.4 – Requirements for mechanical strength for ME EQUIPMENT intended for airborne use

The committee decided that requirements specified in the international standards for environmental conditions and test PROCEDURES for airborne equipment were appropriate for

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testing ME EQUIPMENT intended for airborne use in the EMS ENVIRONMENT. Although it appears that there are two different test methods, they are, in fact, identical. EUROCAE ED-14G is the European version and RTCA DO-160G is the US published version of the same requirements.

For safety reasons, ME EQUIPMENT has to be secured to prevent unintentional movement during transit. This is accomplished either by having the equipment FIXED or otherwise attached to the airframe fuselage. Thus the fuselage vibrations are directly coupled to the equipment. Airframe fuselage vibrations vary by airframe type and the aforementioned standards have specific test profiles for airframe types. Since this testing is airframe type-dependent, the technical description needs to indicate for which airframes the equipment has been qualified.

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Annex B
(informative)

Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS

B.1 Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

The requirements for marking on the outside of ME EQUIPMENT and their parts are found in 7.2 and in Table C.1 of the general standard. Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS intended for use in the EMS ENVIRONMENT are found in the subclauses listed in Table B.1.

Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts

Description of marking	Subclause
Environmental conditions of transport and storage on ME EQUIPMENT	4.2.1
Environmental conditions of transport and storage on carrying case, if provided	4.2.1
Environmental operating conditions on ME EQUIPMENT	4.2.2.1
Environmental operating conditions on carrying case, if provided	4.2.2.1
IP classification on ENCLOSURE and safety sign	6.2
IP classification on carrying case, if provided	6.2
'Keep dry' or symbol on ENCLOSURE, if required	6.2
Supplemental indication of environmental conditions of transport and storage on ME EQUIPMENT, if more than one is provided	4.2.1
Supplemental indication of environmental conditions of transport and storage on ME EQUIPMENT, if more than one is provided	4.2.2.1
Supplemental indication of environmental conditions of transport and storage on ME EQUIPMENT, if more than one is provided	4.2.2.2
Transient operating conditions on ME EQUIPMENT	4.2.2.2

B.2 ACCOMPANYING DOCUMENTS, instructions for use

The requirements for information to be included in the instructions for use are found in 7.9.2 and Table C.5 of the general standard. Additional requirements for information to be included in the instructions for use are found in the subclauses listed in Table B.2.

Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use *(1 of 2)*

Description of requirement	Subclause
Alternative life-supporting methods to be employed following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE	8.2
Conditions that can unacceptably affect the ME EQUIPMENT: – effects of lint, dust, light – list of known devices or other sources that can potentially cause interference problems – effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems	6.3.4
Diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment	6.3.3

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Table B.2 *(2 of 2)*

Description of requirement	Subclause
Environmental conditions of transport and storage of ME EQUIPMENT	4.2.1
Environmental operating conditions of ME EQUIPMENT, continuous	4.2.2.1
Environmental operating conditions of ME EQUIPMENT, transient	4.2.2.2
If applicable, table of correcting values	4.2.2.1
Meaning of the IP classification marking	6.3.4
Requirements for INTERNAL ELECTRICAL POWER SOURCE, where applicable: – typical operation time or number of PROCEDURES – typical service life – behaviour while a rechargeable INTERNAL ELECTRICAL POWER SOURCE is charging	6.3.2
State of the INTERNAL ELECTRICAL POWER SOURCE, if applicable: how to determine	8.3
Time from switching “ON” until the ME EQUIPMENT is ready for NORMAL USE, if exceeding 15 s	6.3.3
Time required to cool from maximum storage temperature to operation	6.3.3
Time required to warm from minimum storage temperature to operation	6.3.3
Time or number of PROCEDURES available following a loss or failure of the SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER SOURCE	8.2
Troubleshooting guide including necessary steps to be taken in the event of an ALARM CONDITION	6.3.5
Use of the ME EQUIPMENT as intended by the MANUFACTURER: – intended medical indication – intended PATIENT population – intended part of the body or type of tissue applied to or interacted with – intended OPERATOR PROFILE – intended conditions of use, including • whether ME EQUIPMENT is to be FIXED, PERMANENTLY INSTALLED or TRANSPORTABLE • the type of ambulance for which the ME EQUIPMENT is intended	6.3.1

B.3 ACCOMPANYING DOCUMENTS, technical description

The requirements for general information to be included in the technical description are found in subclause 7.9.3 and in Table C.6 of the general standard. Additional requirements for information to be included in the technical description are found in the subclauses listed in Table B.3.

Table B.3 – ACCOMPANYING DOCUMENTS, technical description

Description of requirement	Subclause
Alternative life-supporting methods that can be employed for longer periods of loss or failure of the electrical power supply	8.2
Connect and verify that the PROTECTIVE EARTH TERMINAL is connected to the external protective earthing system warning	6.4
ME EQUIPMENT installation, including correct protective earth (PE) connection, must only be carried out by qualified SERVICE PERSONNEL warning	6.4
Specifications of the PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR	6.4
Types of aircraft for which the ME EQUIPMENT is qualified	10.1.4
Verify the integrity of the external protective earthing system warning	6.4

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Annex C
(informative)

Symbols on marking

In addition to the symbols described in Annex D of the general standard, the symbols described in Table C.1 can be used on ME EQUIPMENT intended for use in the EMS ENVIRONMENT.

Table C.1 – General symbols *(1 of 2)*

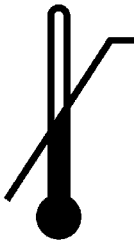
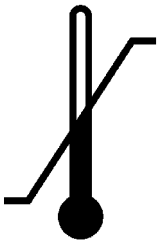
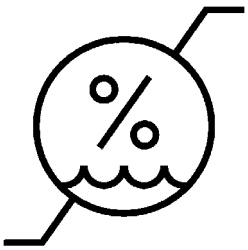
No.	Symbol	Reference	Title
1		ISO 15223-1:2012, 5.3.4 (ISO 7000-0626)	Keep dry
2		ISO 15223-1:2012, 5.3.5 (ISO 7000-0534)	Lower limit of temperature NOTE The lower limit of temperature should be indicated adjacent to the lower horizontal line.
3		ISO 15223-1:2012, 5.3.6 (ISO 7000-0533)	Upper limit of temperature NOTE The upper limit of temperature should be indicated adjacent to the upper horizontal line.
4		ISO 15223-1:2012, 5.3.7 (ISO 7000-0632)	Temperature limit NOTE The upper and lower limits of temperature should be indicated adjacent to the upper and lower horizontal lines.
5		ISO 15223-1:2012, 5.3.8 (ISO 7000-2620)	Humidity limitation NOTE The humidity limitation should be indicated adjacent to the upper and lower horizontal lines.

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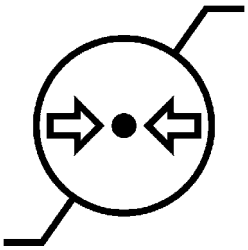
Table C.1 *(2 of 2)*

No.	Symbol	Reference	Title
6		ISO 15223-1:2012, 5.3.9 (ISO 7000-2621)	Atmospheric pressure limitation NOTE The atmospheric pressure limitations should be indicated adjacent to the upper and lower horizontal lines.

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Bibliography

[1] IEC 60038:2009, *IEC standard voltages*

[2] IEC 60065, *Audio, video and similar electronic apparatus – Safety requirements*

[3] IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

[4] IEC 60364 (series), *Low-voltage electrical installations*

[5] IEC 60721-3-7:1995, *Classification of environmental conditions – Part 3: Classification of groups of environmental parameters and their severities – Section 7: Portable and non-stationary use*
IEC 60721-3-7:1995/AMD1:1996 [8]

[6] IEC TR 60721-4-7:2001, *Classification of environmental conditions – Part 4-7: Guidance for the correlation and transformation of environmental condition classes of IEC 60721-3 to the environmental tests of IEC 60068 – Portable and non-stationary use*
IEC TR 60721-4-7:2001/AMD1:2003

[7] IEC 60950-1:2005, *Information technology equipment – Safety – Part 1: General requirements*

[8] IEC 61032:1997, *Protection of persons and equipment by enclosures – Probes for verification*

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

[10] ISO 10651-2:2004, *Lung ventilators for medical use – Particular requirements for basic safety and essential performance – Part 2: Home care ventilators for ventilator-dependent patients*

[11] ISO/TR 16142:2006, *Medical devices – Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

[12] ASTM F1288-1990, *Standard Guide for Planning for and Response to a Multiple Casualty Incident*

[13] ASTM F1339-1992, *Standard Guide for Organization and Operation of Emergency Medical Services Systems*

[14] ASTM F2020-2002, *Standard Practice for Design, Construction, and Procurement of Emergency Medical Services Systems (EMSS) Ambulances* [9]

[15] EN 1789:2007, *Medical vehicles and their equipment – Road ambulances*

[16] EN 13718-1:2008, *Medical vehicles and their equipment – Air ambulances – Part 1: Requirements for medical devices used in air ambulances*

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8 There exists a consolidated edition 2.1 including IEC 60721-3-7:1995 and its Amendment 1:1996.

9 Available at: http://www.astm.org

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