

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –

Part 1-11: General requirements for basic safety and essential performance –

Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

Appareils électromédicaux –

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



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domicile**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as “IEC Publication(s)”). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 60601-1-11 has been prepared by a joint working group of IEC subcommittee 62A: *Common aspects of electrical equipment used in medical practice* of IEC technical committee 62: *Electrical equipment in medical practice* and ISO subcommittee SC3: *Lung ventilators and related devices*, of ISO technical committee 121: *Anaesthetic and respiratory equipment*.

It is published as a double logo standard.

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

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

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

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. ALARM SYSTEMS).

In this collateral standard, the following print types are used:

- requirements and definitions: roman type.
- *test specifications: italic type.*
- informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended

NOTE The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

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

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

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

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-11: General requirements for basic safety and essential performance –

Collateral Standard:

Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

1 Scope, object and related standards

1.1 * Scope

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

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

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

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

1.2 Object

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

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-11 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

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

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

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

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

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

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

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

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

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

3 Terms and definitions

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

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

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

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

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

3.1

* BODY-WORN

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

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

3.2

HOME HEALTHCARE ENVIRONMENT

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

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

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

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

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

3.3

* LAY

term referring to nonprofessional or professional without relevant specialized training

EXAMPLES LAY OPERATOR, LAY RESPONSIBLE ORGANIZATION

3.4

LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM

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

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

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

3.5

SHELF LIFE

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

3.6

TRANSIT-OPERABLE

term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while it is being moved

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

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

3.7

USABILITY ENGINEERING

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

3.8

USABILITY ENGINEERING FILE

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

3.9

USABILITY SPECIFICATION

documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

3.10

VALIDATION

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

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

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

[ISO 9000:2000, definition 3.8.5]

4 General requirements

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

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

- for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS, no voltage in excess of 110 % or lower than 85 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth; and
- for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS, no voltage in excess of 110 % or lower than 80 % of the NOMINAL voltage between any of the conductors of the system or between any of these conductors and earth.

4.2 Environmental conditions for ME EQUIPMENT

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

4.2.1 * Environmental conditions of transport and storage between uses

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

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

- – 25 °C without relative humidity control; and
- + 70 °C at a relative humidity up to 93 %, non-condensing;

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

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

²⁾ Figures in square brackets refer to the Bibliography.

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

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

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

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

EXAMPLES Removal of batteries, emptying fluid reservoirs

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

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

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

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

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

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

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

4.2.2 * Environmental operating conditions

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

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

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

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

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

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

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

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

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

- a) *Expose the ME EQUIPMENT to the ambient conditions for:*
 - *at least 6 h, or*
 - *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*
- b) *Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.*
- c) *Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure.*
- d) *Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the highest specified atmospheric pressure.*

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

- e) *Cool the ME EQUIPMENT to its lowest specified environmental operating conditions (temperature ${}_{-4}^0$ °C and relative humidity less than or equal to 15 %).*
- f) *Hold the ME EQUIPMENT at its lowest specified environmental operating conditions:*
 - *for at least 6 h, or*
 - *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*
- g) *Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.*
- h) *Warm the ME EQUIPMENT to its highest specified environmental operating conditions (temperature ${}_{0}^{+4}$ °C and relative humidity ± 3 %).*
- i) *Hold the ME EQUIPMENT at its highest specified environmental operating conditions:*
 - *for at least 6 h, or*
 - *ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*
- j) *Evaluate the ME EQUIPMENT to its specifications and ensure that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.*

4.2.3 * Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT

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

Compliance is checked by the following test:

- a) Set up the ME EQUIPMENT for operation according to INTENDED USE.
- b) Expose the ME EQUIPMENT to its lowest specified environmental operating conditions (temperature $_{-4}^0$ °C and relative humidity less than or equal to 15 %).
- c) Hold the ME EQUIPMENT at its lowest specified environmental operating conditions:
 - for at least 6 h, or
 - ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.
- d) Expose the ME EQUIPMENT to its highest specified environmental operating conditions within 5 min (temperature $_{0}^{+4}$ °C and relative humidity ± 3 %).
- e) While maintaining the environment of the ME EQUIPMENT to the conditions in d), evaluate the ME EQUIPMENT to its specifications and ensure that it continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reaches THERMAL STABILITY or for at least 2 h. The evaluation of BASIC SAFETY need not include LEAKAGE CURRENT and dielectric strength testing because of the pollution degree ratings required by the general standard.

A separate test sample may be used for the following tests.

- f) Set up the ME EQUIPMENT for operation according to INTENDED USE.
- g) Expose the ME EQUIPMENT to its highest specified environmental operating conditions (temperature $_{0}^{+4}$ °C and relative humidity ± 3 %).
- h) Hold the ME EQUIPMENT at its highest specified environmental operating conditions:
 - for at least 6 h, or
 - ensure that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.
- i) Expose the ME EQUIPMENT to its lowest specified environmental operating conditions within 5 min (temperature $_{-4}^0$ °C and relative humidity less than or equal to 15 %).
- j) While maintaining the environment of the ME EQUIPMENT to the conditions in i), evaluate the ME EQUIPMENT to its specifications and ensure that it continues to provide BASIC SAFETY and ESSENTIAL PERFORMANCE until the ME EQUIPMENT reaches THERMAL STABILITY or for at least 2 h.

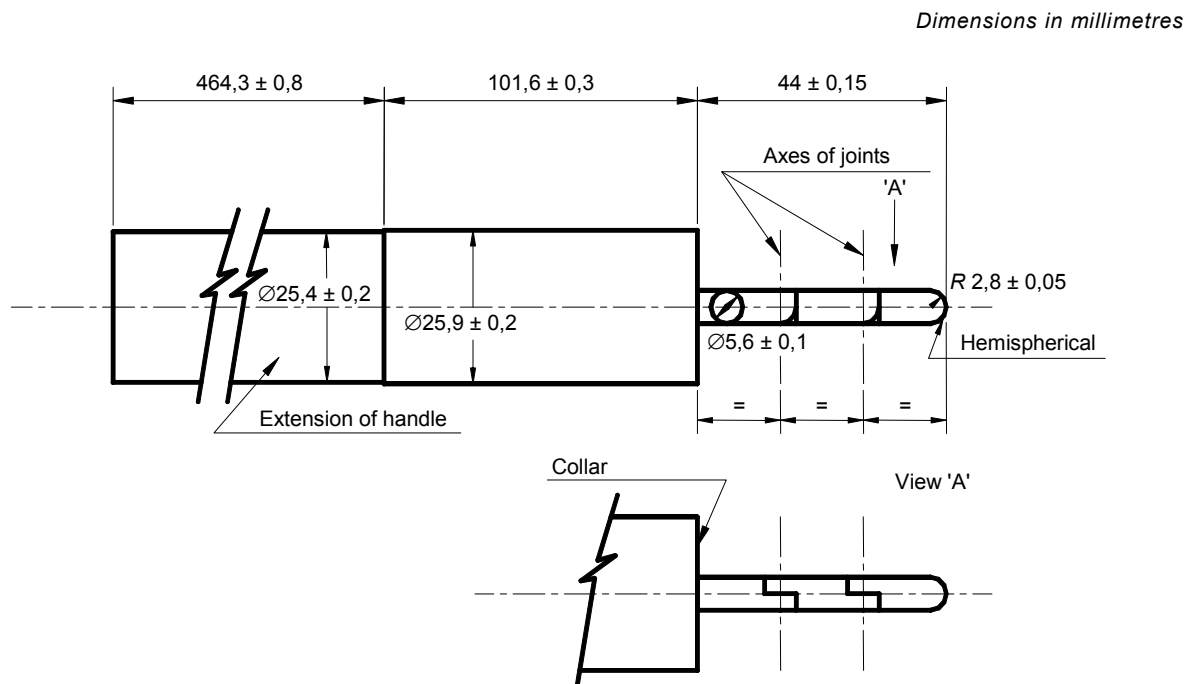
NOTE While the ME EQUIPMENT is warming or cooling, the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE is repeated for two hours or until THERMAL STABILITY is reached.

5 * General requirements for testing ME EQUIPMENT

In addition to the requirements of 5.9.2.1 of the general standard, accessibility is also determined as indicated below.

Parts of ME EQUIPMENT that are to be regarded as ACCESSIBLE PARTS are identified by inspection and, where necessary, by testing. In case of doubt, a part of ME EQUIPMENT that is to be regarded as an ACCESSIBLE PART is determined by a test with the small finger probe shown in Figure 1, applied in a bent or straight position:

- for all positions of the ME EQUIPMENT when operated as in NORMAL USE, and
- after opening ACCESS COVERS and removal of parts, including lamps, fuses and fuse holders, when:
 - i) the ACCESS COVERS can be opened without the use of a TOOL, or
 - ii) the instructions for use instruct a LAY OPERATOR to open the relevant ACCESS COVER.



IEC 998/10

- Finger: metal material
- Handle: insulating material

NOTE 1 The extension of the handle represents the arm of the child.

The handle is provided with an extension 464,3 mm long, and the probe should be applied with or without this extension, whichever is the more onerous condition. Both joints shall permit movement in the same plane and the same direction through an angle of 90°.

NOTE 2 This probe is intended to simulate access to hazardous parts by children of 36 months or less.

[IEC 61032:1997 [8], Figure 13]

Figure 1 – Small finger probe Ø 5,6

6 * Classification of ME EQUIPMENT and ME SYSTEMS

Notwithstanding the requirements in 6.2 of the general standard, unless the ME EQUIPMENT intended for the HOME HEALTHCARE ENVIRONMENT is PERMANENTLY INSTALLED, it:

- 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.

Compliance is checked by inspection.

7 ME EQUIPMENT identification, marking and documents

7.1 * USABILITY of the ACCOMPANYING DOCUMENTS

In addition to the requirements of 7.1.1 of the general standard, the USABILITY of the identification, marking and ACCOMPANYING DOCUMENTS intended for the LAY OPERATOR OF LAY

RESPONSIBLE ORGANIZATION shall be evaluated based on an OPERATOR PROFILE that includes a maximum of eight years of education.

ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT should be designed to be simple to use and not require reference to complex ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the results of the USABILITY ENGINEERING PROCESS.

7.2 * Additional requirements for marking of IP classification

Notwithstanding the requirements of 7.2.9 of the general standard, the ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 8.3.1. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and the degree of protection provided by the carrying case shall be marked on the carrying case. 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 TRANSIT-OPERABLE 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, the ENCLOSURE of the ME EQUIPMENT would be marked IP20 and the carrying case would be marked IP02.

If an ENCLOSURE does not provide the minimum required degree protection against the ingress of water, it shall be marked 'keep dry' or with symbol ISO 7000-0626 (2004-01) (see Table C 1, symbol 1).

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.

7.3 ACCOMPANYING DOCUMENTS

7.3.1 Contact information

In addition to the requirements of 7.9.1 and 16.2 of the general standard, the ACCOMPANYING DOCUMENTS shall indicate that the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION should contact the MANUFACTURER or the MANUFACTURER'S representative:

- for assistance, if needed, in setting up, using or maintaining the ME EQUIPMENT or ME SYSTEM; or
- to report unexpected operation or events.

The ACCOMPANYING DOCUMENTS shall include a postal address and either a telephone number or web address through which the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION can contact the MANUFACTURER or the MANUFACTURER'S representative.

7.3.2 LAY OPERATOR briefing information

When appropriate in addition to the requirements of 7.9.1 and 16.2 of the general standard, the ACCOMPANYING DOCUMENTS shall include the details necessary for the healthcare professional to brief the LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION on any known contraindication(s) to the use of the ME EQUIPMENT or ME SYSTEM and any precautions to be taken. This shall include:

- precautions to be taken in the event of changes in the performance of the ME EQUIPMENT or ME SYSTEM;
- precautions to be taken regarding the exposure of the ME EQUIPMENT or ME SYSTEM to reasonably foreseeable environmental conditions (e.g. to magnetic fields, electromagnetic fields, external electrical influences, ELECTROSTATIC DISCHARGE, pressure or variations in pressure, acceleration, thermal ignition sources);

- adequate information regarding any medicinal substances that the ME EQUIPMENT is designed to administer, including any limitations in the choice of substances to be delivered;
- information on any medicinal substances or human blood derivatives incorporated into the ME EQUIPMENT or ACCESSORIES as an integral part; and
- the degree of accuracy claimed for ME EQUIPMENT with a measuring FUNCTION.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS.

7.4 Instructions for use

7.4.1 Additional requirements for warning and safety notices

In addition to the requirements of 7.9.2.2 and 16.2 c) of the general standard, for each warning and safety sign, the instructions for use shall describe the nature of the HAZARD, likely consequences that could occur if the advice is not followed, and the precautions for reducing the RISK.

If applicable, the instructions for use shall address the issues of:

- strangulation due to cables and hoses, particularly due to excessive length.

EXAMPLE 1 Strangulation resulting from baby or child entanglement in monitoring cables.

EXAMPLE 2 Strangulation resulting from breathing system hoses.

- small parts being inhaled or swallowed.

EXAMPLE 3 Choking resulting from a child swallowing a small part that has become detached from the ME EQUIPMENT.

- potential allergic reactions to accessible materials used in the ME EQUIPMENT.

EXAMPLE 4 Natural rubber latex sensitivity.

- contact injuries.

EXAMPLE 5 Skin irritation due to prolonged exposure to APPLIED PARTS or other ACCESSORIES.

If applicable, the instructions for use shall include warnings to the effect that it can be unsafe to:

- use ACCESSORIES, detachable parts and materials not described in the instructions for use (see 7.9.2.14 of the general standard).
- interconnect this equipment with other equipment not described in the instructions for use (see 16.2 c) indent 9) of the general standard).
- modify the equipment.
- use the ME EQUIPMENT outside its carrying case if some part of the protection required by this standard is provided by that carrying case (see 8.3.1 and 10.1).

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

7.4.2 * 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; and

- for a rechargeable INTERNAL ELECTRICAL POWER SOURCE, the behavior 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.

7.4.3 Additional requirements for ME EQUIPMENT description

In addition to the requirements of 7.9.2.5 of the general standard, the instructions for use shall include easily understood diagrams, illustrations, or photographs of the fully assembled and ready-to-operate ME EQUIPMENT including all controls, visual INFORMATION SIGNALS, and indicators provided with the ME EQUIPMENT (see 7.1).

Compliance is checked by inspection of the instructions for use.

7.4.4 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:

- easily understood diagrams, illustrations, or photographs showing proper connection of the PATIENT to the ME EQUIPMENT, ACCESSORIES and other equipment (see 7.1); and
- the time from switching “ON” until the ME EQUIPMENT is ready for NORMAL USE, if that time exceeds 15 s (see 15.4.4 of the general standard).

Compliance is checked by inspection of the instructions for use.

7.4.5 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 HOME HEALTHCARE ENVIRONMENT that can unacceptably affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT and the steps that can be taken by the LAY 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

EXAMPLE 1 Heat from a fireplace or radiant heater.

EXAMPLE 2 Moisture from a nebuliser or steam kettle.

- the effects of degraded sensors and electrodes, or loosened electrodes, that can degrade performance or cause other problems
- the effects caused by pets, pests or children

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.

7.4.6 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 an ALARM CONDITION.

NOTE See also IEC 60601-1-8.

Compliance is checked by inspection of the instructions for use.

7.4.7 * Additional requirements for cleaning, disinfection and sterilization

In addition to the requirements of 7.9.2.12 and 16.2 c) Indent 3 of the general standard, for ME EQUIPMENT, ME SYSTEMS, their parts or ACCESSORIES that are intended for other than single use and that can become contaminated through contact with the PATIENT or with body fluids or expired gases during INTENDED USE, the instructions for use shall:

either,

- indicate the frequency of cleaning, cleaning and disinfection or cleaning and sterilization, as appropriate, of the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES used on the same PATIENT including methods for rinsing, drying, handling and storage between uses (see 8.1 and 8.2); and

EXAMPLE 1 Periodic cleaning and disinfection of a breathing system to prevent infection of a PATIENT during chronic care

- if intended for multiple PATIENT use, indicate that it is necessary to clean and disinfect or clean and sterilize the ME EQUIPMENT, ME SYSTEMS, parts or ACCESSORIES between uses on different PATIENTS, including methods for rinsing, drying, handling and storage until re-use (see 8.1 and 8.2);

EXAMPLE 2 Cleaning and disinfection of a thermometer following use to prevent PATIENT cross infection

or,

- indicate that the ME EQUIPMENT, ME SYSTEMS or ACCESSORIES require professional hygienic maintenance prior to re-use and provide contact details for the source of these services (see 7.5.2).

Compliance is checked by inspection of the instructions for use.

7.4.8 Additional requirements for maintenance

In addition to the requirements of 7.9.2.13 of the general standard, the instructions for use shall include:

- the EXPECTED SERVICE LIFE of the ME EQUIPMENT;
- the EXPECTED SERVICE LIFE of parts or ACCESSORIES shipped with the ME EQUIPMENT; and
- where the SHELF LIFE is less than the EXPECTED SERVICE LIFE, the SHELF LIFE of parts or ACCESSORIES shipped with the ME EQUIPMENT.

Compliance is checked by inspection of the instructions for use.

7.4.9 Additional requirements for environmental protection

In addition to the requirements of 7.9.2.15 of the general standard, the instructions for use shall include:

- information concerning the proper disposal of the ME EQUIPMENT, its parts or ACCESSORIES (see IEC 60601-1-9); and
- where applicable, a statement to the effect that the LAY RESPONSIBLE ORGANIZATION must contact its local authorities to determine the proper method of disposal of potentially bio-hazardous parts and ACCESSORIES.

Compliance is checked by inspection of the instructions for use.

7.4.10 Additional requirements for ME EQUIPMENT and ME SYSTEMS

For ME EQUIPMENT or an ME SYSTEM utilizing a DISTRIBUTED ALARM SYSTEM, the instructions for use shall include the recommended placement of the remote parts of the DISTRIBUTED ALARM SYSTEM to ensure that an OPERATOR can be notified at all times by an appropriate element of the DISTRIBUTED ALARM SYSTEM within its specified range.

Compliance is checked by inspection of the instructions for use.

7.5 Technical description

7.5.1 PERMANENTLY INSTALLED CLASS I ME EQUIPMENT

In addition to the requirements of 7.9.3.1 of the general standard to ensure that 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 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 PERMANENTLY INSTALLED ME EQUIPMENT is connected to the external protective earthing system.

Compliance is checked by inspection of the technical description.

7.5.2 Additional requirements for professional hygienic maintenance

For ME EQUIPMENT or ACCESSORIES that require professional hygienic maintenance prior to re-use (see 7.4.7), the technical description shall include methods for cleaning and disinfection or cleaning and sterilization:

- before and after any type of service PROCEDURE.
- when the ME EQUIPMENT is transferred to another PATIENT.

Compliance is checked by inspection of the technical description.

8 Protection against excessive temperatures and other HAZARDS

8.1 * Additional requirements for cleaning, disinfection of ME EQUIPMENT and ME SYSTEMS

In addition to the requirements of 11.6.6 of the general standard, the cleaning or cleaning and disinfection PROCESSES intended to be performed in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR shall be capable of being performed by a LAY OPERATOR in the HOME HEALTHCARE ENVIRONMENT (see 7.4.7). The USABILITY of each such PROCESS as it pertains to a LAY OPERATOR shall be investigated by the USABILITY ENGINEERING PROCESS.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

8.2 * Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS

In addition to the requirements of 11.6.7 of the general standard, the cleaning and sterilization PROCESSES intended to be performed in the HOME HEALTHCARE ENVIRONMENT by a LAY OPERATOR shall be capable of being performed by a LAY OPERATOR in the HOME HEALTHCARE

ENVIRONMENT (see 7.4.7). The USABILITY of each such PROCESS as it pertains to a LAY OPERATOR shall be investigated by the USABILITY ENGINEERING PROCESS.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

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

8.3.1 * Ingress of water or particulate matter into ME EQUIPMENT

Notwithstanding the requirements of 11.6.5 of the general standard, TRANSIT-OPERABLE, HAND-HELD, and BODY-WORN ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP22. All other ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 for IP21. For PORTABLE ME EQUIPMENT that is only intended to be used with a carrying case, this requirement may be met while the ME EQUIPMENT is inside the carrying case.

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

Compliance is checked by inspection and by application of the tests of IEC 60529:1989. VERIFY that BASIC SAFETY and ESSENTIAL PERFORMANCE are maintained.

8.3.2 * 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 with the equipment placed in the least favorable position of NORMAL USE and by inspection.

NOTE Ingress tests that have already been performed on individual equipment of an ME SYSTEM according to relevant standards need not be repeated.

8.4 Additional requirements for interruption of the power supply/SUPPLY MAINS to ME EQUIPMENT and ME SYSTEM

In addition to the requirements of 11.8 and 16.8 of the general standard, a LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM 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 INTERNAL ELECTRICAL POWER SOURCE occurs. The time or number of PROCEDURES remaining shall allow alternative life-supporting methods to be employed.

NOTE 1 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 pump or resuscitator

The instructions for use shall disclose the time or number of procedures available following a loss or failure of the electrical power supply. The instructions for use shall describe the alternative life-supporting methods to be employed. The technical description shall describe methods that can be employed for longer periods.

NOTE 2 Electrical power supply failure includes failure of the SUPPLY MAINS or any INTERNAL ELECTRICAL POWER SOURCES.

If an INTERNAL ELECTRICAL POWER SOURCE is not used, the LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM 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 used, the LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM shall be equipped with an automatic switchover to the INTERNAL ELECTRICAL POWER SOURCE and an ALARM SYSTEM that includes at least a LOW PRIORITY ALARM CONDITION that indicates the switchover to the INTERNAL ELECTRICAL POWER SOURCE.

If an INTERNAL ELECTRICAL POWER SOURCE is used, the LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM 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 or ME SYSTEM operation. This TECHNICAL ALARM CONDITION shall provide for a sufficient time or for a sufficient number of procedures for a LAY 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.

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 HOME HEALTHCARE 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;
- change in the transfer of energy or substance;
- exposure to biological materials; and
- small parts being inhaled or swallowed.

Particular emphasis shall be placed on the limited training of a LAY OPERATOR with respect to the ability to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

10 Construction of ME EQUIPMENT

10.1 * Additional requirements for mechanical strength

10.1.1 General requirements for mechanical strength

Replace Table 28 of the general standard with Table 1 and Table 2.

Table 1 – Mechanical strength test applicability, non-TRANSIT-OPERABLE

ME EQUIPMENT usage and type	Test from the general standard	Test from this standard
Non-TRANSIT-OPERABLE and HAND-HELD	Push (15.3.2)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.2 a))
	-	Vibration (10.1.2 b))
	Molding stress relief (15.3.6)	-
Non-TRANSIT-OPERABLE and BODY-WORN	Push (15.3.2)	-
	Impact (15.3.3)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.2 a))
	-	Vibration (10.1.2 b))
	Molding stress relief (15.3.6)	-
Non-TRANSIT-OPERABLE and PORTABLE	Push (15.3.2)	-
	Impact (15.3.3)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.2 a))
	-	Vibration (10.1.2 b))
	Molding stress relief (15.3.6)	-
Non-TRANSIT-OPERABLE and MOBILE	Push (15.3.2)	-
	Impact (15.3.3)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.2 a))
	-	Vibration (10.1.2 b))
	Rough handling (15.3.5)	-
	Molding stress relief (15.3.6)	-
FIXED or STATIONARY	Push (15.3.2)	-
	Impact (15.3.3)	-
	Molding stress relief (15.3.6)	-

Table 2 – Mechanical strength test applicability, TRANSIT-OPERABLE

ME EQUIPMENT usage and type	Test from the general standard	Test from this standard
TRANSIT-OPERABLE and HAND-HELD	Push (15.3.2)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.3 b))
	-	Vibration (10.1.3 c))
	Molding stress relief (15.3.6)	-
TRANSIT-OPERABLE and BODY-WORN	Push (15.3.2)	-
	Impact (15.3.3)	-
	Drop (15.3.4.1)	-
	-	Shock (10.1.3 a))
	-	Vibration (10.1.3 c))
	Molding stress relief (15.3.6)	-
TRANSIT-OPERABLE and PORTABLE	Push (15.3.2)	-
	-	Free fall (10.1.3 d))
	-	Shock (10.1.3 a))
	-	Vibration (10.1.3 c))
	Molding stress relief (15.3.6)	-
TRANSIT-OPERABLE and MOBILE	Push (15.3.2)	-
	Impact (15.3.3)	-
	-	Free fall (10.1.3 d))
	-	Shock (10.1.3 a))
	-	Vibration (10.1.3 c))
	Rough handling (15.3.5)	-
	Molding stress relief (15.3.6)	-

10.1.2 * Requirements for mechanical strength for non-TRANSIT-OPERABLE ME EQUIPMENT

In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended for non-TRANSIT-OPERABLE use shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping and rough handling. FIXED and STATIONARY ME EQUIPMENT are exempt from the requirements of this subclause.

After the following tests, ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE. OPERATOR-resettable protective devices that can be reset without the use of a TOOL may be reset prior to the evaluation of 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 7M1 as described in IEC TR 60721-4-7:2001 [6].

- *peak acceleration: 150 m/s² (15 g);*
- *duration: 11 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 7M1 and 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.

10.1.3 * Requirements for mechanical strength for TRANSIT-OPERABLE ME EQUIPMENT

In addition to the requirements of 15.3 of the general standard, ME EQUIPMENT and its parts, including mounting ACCESSORIES, intended for TRANSIT-OPERABLE use, shall have adequate mechanical strength when subjected to mechanical stress caused by NORMAL USE, including pushing, impact, dropping, and rough handling and by rigorous conditions of PATIENT movement as well as transportation by trolleys, carts, road vehicles, trains, ships, and aircraft.

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 TRANSIT-OPERABLE ME EQUIPMENT.

NOTE 2 ME EQUIPMENT tested and complying with the relevant requirement in this subclause is considered to comply with the corresponding requirement of 10.1.1.

Compliance is checked by performing the following tests:

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

NOTE 3 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);*

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

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

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/s² (100 g),
- duration: 6 ms,
- pulse shape: half-sine,
- number of shocks: 3 shocks per direction per axis (18 total).

c) 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 5 This represents Class 7M1 and 7M2 as described in IEC/TR 60721-4-7:2001.

- acceleration amplitude:
 - 10 Hz to 100 Hz: 1,0 (m/s²)²/Hz,
 - 100 Hz to 200 Hz: –3 db per octave,
 - 200 Hz to 2 000 Hz: 0,5 (m/s²)²/Hz,
- duration: 30 min per perpendicular axis (3 total).

d) For PORTABLE and MOBILE ME EQUIPMENT and its parts, including mounting ACCESSORIES, free fall to IEC 60068-2-31:2008, using PROCEDURE 1 and the following conditions:

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

- fall height:
 - for mass ≤ 1 kg, 0,25 m,
 - for mass > 1 kg and ≤ 10 kg, 0,1 m,
 - for mass > 10 kg and ≤ 50 kg, 0,05 m,
 - for mass > 50 kg, 0,01 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.

10.2 * Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE

In addition to the requirements of 15.4.3 of the general standard, 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.

10.3 Additional requirements for actuating parts of controls of ME EQUIPMENT

In addition to the requirements of 15.4.6 1 b) of the general standard, controls of ME EQUIPMENT that can affect BASIC SAFETY or ESSENTIAL PERFORMANCE shall be protected from accidental or unauthorized changes or adjustments.

NOTE 1 Unauthorized changes or adjustments relate to modifications made without authorization of the intended OPERATOR or RESPONSIBLE ORGANIZATION.

EXAMPLE A child playing with the controls

NOTE 2 Means to prevent unauthorized changes or adjustments include:

- access controlled by a TOOL;
- access controlled by RESPONSIBLE ORGANIZATION password and a technical description that is separate from the instructions for use;
- access controlled by individual OPERATOR password;
- access controlled by voice recognition; or
- access controlled by fingerprints.

NOTE 3 For a password to be considered secure, the owner of the password needs to be capable of changing the password.

NOTE 4 Multiple means of restriction can be needed, e.g., one for the RESPONSIBLE ORGANIZATION and one for each OPERATOR.

OPERATOR-adjustable controls used for calibration shall include a means to prevent unintentional changes from the intended position.

Compliance is checked by inspection.

11 * Protection against strangulation or asphyxiation

Means shall be provided to control the RISK of strangulation and asphyxiation of the PATIENT and others to an acceptable level.

EXAMPLE 1 By routing wires or tubing.

EXAMPLE 2 Using retention devices.

EXAMPLE 3 Providing the option of multiple length ACCESSORIES.

EXAMPLE 4 Not providing removable small parts for ME EQUIPMENT.

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

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

IEC 60601-1-2:2007 applies except as follows:

Addition:

12.1 Emissions classification

Notwithstanding the requirements of 6.1.1.1 of IEC 60601-1-2:2007, ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT shall be classified as Class B according to CISPR 11:2009.

NOTE Use in the HOME HEALTHCARE ENVIRONMENT includes use 'in domestic establishments'.

12.2 Protection of the PUBLIC MAINS NETWORK

NOTE Mains powered ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT are connected to the PUBLIC MAINS NETWORK. This means that for equipment for the HOME HEALTHCARE ENVIRONMENT the PUBLIC MAINS NETWORK requirements of 6.1.3 of IEC 60601-1-2:2007 apply.

12.3 * Additional technical description requirements applicable to ME EQUIPMENT and ME SYSTEMS

Subclauses 5.2.2.1 and 5.2.2.2 of IEC 60601-1-2:2007 do not apply. Instead, the instructions for use shall include:

- a) a statement to the effect that this equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS; and
- b) a statement to the effect that wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 800 MHz to 2,5 GHz column of Table 5 or Table 6 of IEC 60601-1-2:2007, as appropriate.

EXAMPLE 1 As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 3,3$ m at an IMMUNITY LEVEL of 3 V/m.

EXAMPLE 2 As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d = 0,5$ m at an IMMUNITY LEVEL of 20 V/m.

Compliance is checked by inspection of the instructions for use.

12.4 * Additional requirements applicable to ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location

Subclause 5.2.2.3 of IEC 60601-1-2:2007 does not apply.

12.5 * Additional requirements for ELECTROSTATIC DISCHARGE (ESD) tests

For the purposes of the ESD testing in 6.2.2.2 of IEC 60601-1-2:2007, ACCESSIBLE PARTS are determined by points accessible by the standard test finger specified in Figure 6 of the general standard.

In 6.2.2.2 c) of IEC 60601-1-2:2007, delete the second sentence.

13 Additional requirements for ALARM SYSTEMS of ME EQUIPMENT and ME SYSTEMS

IEC 60601-1-8:2006 applies except as follows:

Addition:

13.1 * Additional requirement for generation of ALARM SIGNALS

Notwithstanding the requirements of 6.3.1 of IEC 60601-1-8:2006, for the ALARM SYSTEM of ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT, unless they are connected to a DISTRIBUTED ALARM SYSTEM that includes the generation of audible alarm

SIGNALS as specified in IEC 60601-1-8:2006, each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION shall cause the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006.

Compliance is checked by inspection.

13.2 * Additional requirement for ALARM SIGNAL volume

Notwithstanding the requirements of 6.3.3.2 of IEC 60601-1-8:2006, for the ALARM SYSTEM of ME EQUIPMENT and ME SYSTEMS intended for the HOME HEALTHCARE ENVIRONMENT reducing the auditory ALARM SIGNAL volume below audible levels shall:

- activate the indication of ALARM OFF or AUDIO OFF as specified in IEC 60601-1-8:2006.
- for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM not be possible unless the ALARM SYSTEM is connected to a DISTRIBUTED ALARM SYSTEM that includes the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006.

NOTE Guidance on suitable auditory ALARM SIGNAL volumes is found in the rationale for 6.3.3.2 of IEC 60601-1-8:2006

Compliance is checked by functional testing.

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?
- 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 the HOME HEALTHCARE ENVIRONMENT. 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:

- 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 used without strict guidelines.
- 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.
- 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 the HOME HEALTHCARE ENVIRONMENT 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 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.
- paramedics: 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 a range of use environments such as:

- 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 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.
- the uncontrolled environment in which some ME EQUIPMENT purchased without a prescription is used.

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 the HOME HEALTHCARE ENVIRONMENT 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.
- 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 (Connection of a PEMS by NETWORK/DATA COUPLING to other equipment) states that many hospitals operate ME EQUIPMENT in a networked environment within the hospital, between hospitals and from home.

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 HOME HEALTHCARE ENVIRONMENT.

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

The definition of ME EQUIPMENT in IEC 60601-1:2005 contains very specific criteria that can be used to determine if a specific piece of equipment is MEDICAL ELECTRICAL EQUIPMENT. That definition is repeated below.

MEDICAL ELECTRICAL EQUIPMENT:

electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

- a) provided with not more than one connection to a particular SUPPLY MAINS; and
- b) intended by its MANUFACTURER to be used:
 - 1) in the diagnosis, treatment, or monitoring of a PATIENT; or
 - 2) for compensation or alleviation of disease, injury or disability

In order to determine if equipment is ME EQUIPMENT, one needs to demonstrate that:

- the ME EQUIPMENT has an APPLIED PART; or
- the ME EQUIPMENT transfers energy to or from the PATIENT; or
- the ME EQUIPMENT detects the energy transfer to or from the PATIENT.

If the equipment meets this criterion, then one needs to determine whether or not the MANUFACTURER of the equipment intends that:

- the ME EQUIPMENT is used for diagnosis, treatment, or monitoring of a PATIENT; or
- the ME EQUIPMENT is used for compensation or alleviation of disease, injury or disability.

Excluded from the scope are aids without an APPLIED PART, and where according to the INTENDED USE, the safety is fully covered by IEC 60950-1 [7], IEC 60065 [2] or IEC 60335-1 [3]. Examples of such equipment are the following:

- a reading aid with a digital camera and a monitor for enlargement of text for persons with impaired vision could be fully covered by IEC 60950-1 or IEC 60065 and related EMC standards;
- a flashing light to indicate that the phone is ringing for persons with impaired hearing could be covered by IEC 60065 and related EMC standards
- an amplifier for connection to radio or TV sets with wireless transmission to a BODY-WORN hearing aid could be covered by IEC 60065 and related EMC standards.
- a can opener for persons with impaired hand/finger motion ability is better covered by IEC 60335-1 and related part-2 and EMC standards

These types of products are in fact home electronics or household appliances rather than medical equipment, even though they might fall within the regulatory definition of a medical device in some countries. Hence, these products should comply with the relevant standard for such products e.g. IEC 60950-1 for the reading aid, IEC 60065 for the TV sound amplifier and IEC 60335-1 for the can opener. Persons handling such aids are not PATIENTS in the concept of IEC 60601-1, i.e. these persons are not more sensitive/vulnerable than people in general. The "patient" operates these products, but they have in many cases no APPLIED PART.

There is no logical reason to require that a TV sound amplifier or a can opener for home use comply with IEC 60601-1 or with IEC 60601-1-2. EMC is not more critical for these products than for other generic products and there are no 'medical' APPLIED PARTS.

For the purposes of this standard, the emergency medical services environment is treated as 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 removal of the PATIENT to the next point of definitive care. Emergency medical services are known by various names in different countries and regions.

Definition 3.1 – BODY-WORN

BODY-WORN is intended to describe ME EQUIPMENT that is wholly worn by the PATIENT. It is not intended to describe ME EQUIPMENT that is not worn by the PATIENT but has an APPLIED PART which might be worn, for example a MOBILE monitor with PATIENT leads or a non-

TRANSIT OPERABLE, but PORTABLE oxygen concentrator with a nasal canula or mask are not considered to be BODY-WORN ME EQUIPMENT.

Definition 3.3 – LAY

This term was introduced as an adjective into this collateral standard to emphasize the difference between the characteristics of the OPERATOR and the RESPONSIBLE ORGANIZATION present in the HOME HEALTHCARE ENVIRONMENT versus the environment of the professional healthcare facility. It was not introduced to remove or modify requirements from the general standard.

An important difference is the requirement for the USABILITY of the ME EQUIPMENT or ME SYSTEM, including its labeling, to address the intended OPERATOR who is presumed to not be a professional, medically trained individual or an expert in the operating principles and medical use of the ME EQUIPMENT or ME SYSTEM.

Additionally, the RESPONSIBLE ORGANIZATION, which can include the PATIENT or OPERATOR in the HOME HEALTHCARE ENVIRONMENT, most likely will not have the background to properly care for and maintain the ME EQUIPMENT or ME SYSTEM in the same way a professional healthcare facility is expected to do by its regulators and accrediting bodies. The results of the USABILITY ENGINEERING PROCESS for ME EQUIPMENT or an ME SYSTEM intended for the LAY RESPONSIBLE ORGANIZATION can lead the MANUFACTURER to develop a product that is easier to maintain than when the only intended RESPONSIBLE ORGANIZATION is a professional healthcare facility and its personnel.

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

Most household appliance standards, such as IEC 60950-1 [7], IEC 60335-1 [3] and IEC 60065 [2] have a $\pm 10\%$ SUPPLY MAINS variation for household equipment. The -15% to $+10\%$ SUPPLY MAINS variation was considered more appropriate for ME EQUIPMENT intended for the HOME HEALTHCARE ENVIRONMENT given the more critical need for maintaining ESSENTIAL PERFORMANCE. The -15% low line SUPPLY MAINS variation is based on the -10% low line considered normal, and the additional -4% drop allowed for wiring in the electrical installations of buildings [1] [4] plus another 1% for margin.

The -20% SUPPLY MAINS variation for LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEM allows operation during 'brown-out' conditions and permits the use of inexpensive generators for emergency backup. This is consistent with requirements in existing standards for ventilators intended for the HOME HEALTHCARE ENVIRONMENT for ventilator-dependent PATIENTS [10].

For DC 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 DC voltage between 12,8 V and 14,8 V. [12] [13]

Subclause 4.2.1 – Environmental conditions of transport and storage between uses

These environmental ranges defined in IEC/TR 60721-4-7 [6] level 7K3 are not uncommon in storage locations where the ME EQUIPMENT might be stored or transported between uses in the HOME HEALTHCARE ENVIRONMENT. Outdoor temperatures and particularly temperatures found in automobiles 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. Consideration should be given to ranges greater than those required by this standard, such as either those covered by

IEC/TR 60721-4-7, for example level 7K4, or alternatively defined through evaluation of intended environments of use by the MANUFACTURER.

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 HOME HEALTHCARE 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 24 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 HOME HEALTHCARE ENVIRONMENT.

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 had been required because the environmental conditions in the HOME HEALTHCARE 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 favorable 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 favorable 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 24 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 4.2.3 – Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT

TRANSIT-OPERABLE ME EQUIPMENT is likely to see rapid changes in environmental temperature and humidity while operating—for example, when the PATIENT moves from the cold, dry conditions found outdoors in the winter into the relatively warm, moist conditions inside a home or other heated structure. The TRANSIT-OPERABLE ME EQUIPMENT has to continue to provide BASIC SAFETY and ESSENTIAL PERFORMANCE during that transition even if there is condensation on or in the ME EQUIPMENT. TRANSIT-OPERABLE ME EQUIPMENT is also likely to see movement from relatively warm and moist conditions into cooler, dryer conditions.

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 HOME HEALTH CARE ENVIRONMENT is expected to be a pollution degree 2 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 2 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 integrity of solid insulation are considered minimal because of required humidity conditioning testing required by the general standard.

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. Some 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 TRANSIT OPERABLE 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.

For TRANSIT OPERABLE ME EQUIPMENT that is RATED for more extreme environmental conditions than those specified in 4.2.2, this standard requires environmental shock testing.

When environmental shock testing is conducted, the MANUFACTURER needs to consider compliance criteria for BASIC SAFETY that include such issues as, inter alia:

- degradation or loss of seals (which could be a RISK CONTROL measure for O₂ separation, or providing ingress protection),
- degradation or loss of protective covers (which could be a RISK CONTROL measure for casualty HAZARDS, or providing fire containment).

The concerns about condensation degrading or shorting CREEPAGE DISTANCES and AIR CLEARANCES are minimal because the distances specified in the general standard are appropriate for their intended pollution degree. Similarly, concerns about safety about integrity of solid insulation are considered minimal because of required humidity testing and, where appropriate, 30-day thermal cycling testing required in the general standard. The committee considers the requirements in the general standard to be suitable RISK CONTROL measures to deal with environment shock and conducting LEAKAGE CURRENT and dielectric strength testing are considered unnecessary after these tests.