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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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 60601-1-11:2015-01 RLV(en)

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INTERNATIONAL
ELECTROTECHNICAL
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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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

This second edition cancels and replaces the first edition of IEC 60601-1-11, published in 2010, and constitutes a technical revision.

The most significant changes with respect to the previous edition include the following modifications:

– correction of test method for relative humidity control at temperatures above 35 °C;
– redrafting of subclauses that altered instead of adding to the general standard or other collateral standards; and
– harmonizing with the changes to the amendments to the general standard and other collateral standards.

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

FDIS	Report on voting
62A/959/FDIS	62A/978/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 IEC 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 collateral 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).

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

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

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

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

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

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

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

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

NOTE The attention of Member Bodies and National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO or IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory 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 HOME HEALTHCARE ENVIRONMENT (see 3.1). 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.

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MEDICAL ELECTRICAL EQUIPMENT –

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

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 3.1, and specified by the MANUFACTURER in the instructions for use. This International Standard applies regardless of whether the ME EQUIPMENT or ME SYSTEM is intended for use by a LAY OPERATOR or by trained healthcare personnel.

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

– the dwelling place in which a PATIENT lives;

– other places where PATIENTS are present both indoors and outdoors, excluding professional healthcare facility environments where OPERATORS with medical training are continually available when PATIENTS are present.

This International Standard does not apply to ME EQUIPMENT and ME SYSTEMS intended solely for use in the EMERGENCY MEDICAL SERVICES ENVIRONMENT, covered by IEC 60601-1-12 or solely for use in professional healthcare facilities covered by IEC 60601-1 without the additions of IEC 60601-1-12 or this collateral standard. Nonetheless, ME EQUIPMENT or ME SYSTEMS can be intended for multiple use environments, and as such, if also intended for use in the HOME HEALTHCARE ENVIRONMENT, are within the scope of this standard.

EXAMPLE ME EQUIPMENT or ME SYSTEMS intended for both the HOME HEALTHCARE ENVIRONMENT and the professional healthcare facility environment.

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;

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– "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 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 61.

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

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)*
~~Amendment 1 (1999)~~ ~~[1]~~
IEC 60529:1989/AMD1:1999
IEC 60529:1989/AMD2:2013 [2]

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 [3]

IEC 60601-1-2:~~2007~~ 2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic~~ compatibility~~ disturbances –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 60601-1-6:2010/AMD1:2013) [4]

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

[2] There exists a consolidated edition 2.2 (2013) including IEC 60529:1989 and its Amendment 1 (1999) and Amendment 2 (2013).

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

[4] There exists a consolidated edition 3.1 (2013) including IEC 60601-1-6:2010 and its Amendment 1 (2013).

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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 [5)]

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-2: 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*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*
IEC 62366:2007/AMD1:2014 [6)]

ISO 7000, *Graphical symbols for use on equipment — Registered symbols.* Available from: http://www.graphical-symbols.info/equipment

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs – Registered safety signs*
ISO 7010:2011/AMD1:2012
ISO 7010:2011/AMD2:2012
ISO 7010:2011/AMD3:2012
ISO 7010:2011/AMD4:2013
ISO 7010:2011/AMD5:2014

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

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 60601-1-2:~~2007~~ 2014, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-12:2014, IEC 62366:2007 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 63.

~~**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.~~

3.1
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

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

6) There exists a consolidated edition 2.1 (2014) including IEC 62366:2007 and Amendment 1 (2014).

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

Note 1 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, multiple treatment facilities and emergency medical services.

Note 2 to entry: For the purpose of this collateral standard, nursing homes are considered HOME HEALTHCARE ENVIRONMENTS.

Note 3 to entry: Other places where a PATIENT is present include the outdoor environment, while working and in vehicles.

3.2
*** LAY**
<adj> term referring to non-professional 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.~~

3.3
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

3.4
TRANSIT-OPERABLE
<adj> 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 1 to entry: 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~~

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~~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:~~ with the following additions.

~~– for non-LIFE-SUPPORTING ME EQUIPMENT or ME SYSTEMS,~~ SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT shall be assumed to have the following characteristics: 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.

~~– for LIFE-SUPPORTING~~ For ME EQUIPMENT or ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT, SUPPLY MAINS in the HOME HEALTHCARE ENVIRONMENT shall be assumed to have the following characteristics: 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.

The RATED range of NOMINAL voltage of the ME EQUIPMENT in the HOME HEALTHCARE 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 HOME HEALTHCARE 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.

4.2 * Environmental conditions for ME EQUIPMENT

4.2.1 General

All environmental tests at temperatures below +5 °C need not be performed with humidity control of the test chamber.

NOTE In IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, 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).

4.2.2 * 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 and the requirements of this standard after transport or storage in the following environmental ~~temperature~~ range:

– – 25 °C ~~without relative humidity control;~~ to + 5 °C, and

– ~~+ 70~~ + 5 °C to + 35 °C at a relative humidity up to ~~93~~ 90 %, non-condensing;

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

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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 [7] [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 (2004-01)), 5.3.6 (ISO 7000-0533 (2004-01)) or 5.3.7 (ISO 7000-0632 (2004-01)) 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 4.2.3.1) and transient operating conditions (see 4.2.3.2), 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 to its lowest specified environmental transport and storage conditions (temperature $^{0}_{-4}$ °C):

– *for at least ~~24~~ 16 h; or*
– *confirm that the ME EQUIPMENT reaches THERMAL STABILITY for at least 2 h.*

c) Then expose the ME EQUIPMENT to 34 °C ± 4 °C and 90 % – 0 % + 6 % relative humidity until the test chamber reaches equilibrium. The transition from low to high temperature conditions should be made slowly enough to provide a non-condensing environment. Hold for at least 2 h.

d) Then expose the ME EQUIPMENT to its highest specified environmental transport and storage conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature $^{+4}_{0}$ °C ~~and relative humidity ± 3 %) for~~):

– *for at least ~~24~~ 16 h; or*
– *confirm 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.

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 confirm that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE.*

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7) Figures in square brackets refer to the Bibliography.

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4.2.3 * Environmental operating conditions

4.2.3.1 Continuous 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~~ 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa; 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 [7].

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 that the ME EQUIPMENT is intended to be operated in a carrying case.

Symbols 5.3.5 (ISO 7000-0534 (2004-01)), 5.3.6 (ISO 7000-0533 (2004-01)) or 5.3.7 (ISO 7000-0632 (2004-01)) 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 (2004-01)) 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 (2004-01)) 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 (4.2.3.2), 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.

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 ~~the ambient conditions for~~ 20 °C ± 4 °C:

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

c) Evaluate the ME EQUIPMENT to its specifications and confirm that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE. The evaluation of BASIC SAFETY need not include LEAKAGE CURRENT and dielectric strength testing.

d) Evaluate the ME EQUIPMENT to its specifications and confirm that it provides BASIC SAFETY and ESSENTIAL PERFORMANCE while at the lowest specified atmospheric pressure. The evaluation of BASIC SAFETY need not include LEAKAGE CURRENT and dielectric strength testing.

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e) Evaluate the ME EQUIPMENT *to its specifications and confirm that it provides* BASIC SAFETY *and* ESSENTIAL PERFORMANCE *while at the highest specified atmospheric pressure. The evaluation of* BASIC SAFETY *need not include* LEAKAGE CURRENT *and dielectric strength testing.*

NOTE 3 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 environmental operating conditions (temperature* $^{0}_{-4}$ *°C and relative humidity less than or equal to 15 %).*

NOTE 4 Some test chambers can require a mode change to reach this combination of temperature and humidity.

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

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

i) Evaluate the ME EQUIPMENT *to its specifications and confirm that it provides* BASIC SAFETY *and* ESSENTIAL PERFORMANCE. *The evaluation of* BASIC SAFETY *need not include* LEAKAGE CURRENT *and dielectric strength testing.*

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 ~~and relative humidity ± 3 %~~). The transition from low to high conditions should be made slowly enough to provide a non-condensing environment.*

k) Hold the ME EQUIPMENT *at ~~its highest specified environmental operating~~ the conditions of j):*

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

l) Evaluate the ME EQUIPMENT *to its specifications and confirm that it provides* BASIC SAFETY *and* ESSENTIAL PERFORMANCE. *The evaluation of* BASIC SAFETY *need not include* LEAKAGE CURRENT *or dielectric strength testing.*

4.2.3.2 * Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT

If the instructions for use state a wider range of continuous environmental operating conditions than those indicated in 4.2.3.1, 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 its* INTENDED USE.

b) Expose the ME EQUIPMENT *to its lowest specified environmental operating conditions (temperature* $^{0}_{-4}$ *°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*
- *confirm that the* ME EQUIPMENT *reaches* THERMAL STABILITY *for at least 2 h.*

d) Expose the ME EQUIPMENT *to its highest specified environmental operating conditions, but not requiring a water vapour partial pressure greater than 50 hPa, within 5 min (temperature* $^{+4}_{0}$ *°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 confirm that it continues to provide* BASIC SAFETY *and* ESSENTIAL PERFORMANCE *until the* ME EQUIPMENT *reaches* THERMAL STABILITY.

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for at least 2 h. The evaluation of BASIC SAFETY *need not include* LEAKAGE CURRENT *or 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 its* INTENDED USE.

g) Expose the ME EQUIPMENT *to its highest specified environmental operating conditions, but not requiring a water vapour partial pressure greater than 50 hPa, (temperature* $^{+4}_{0}$ *°C ~~and relative humidity ± 3 %~~).*

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

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

i) Expose the ME EQUIPMENT *to its lowest specified environmental operating conditions (temperature* $^{0}_{-4}$ *°C and relative humidity less than or equal to 15 %) within 5 min.*

j) While maintaining the environment of the ME EQUIPMENT *to the conditions in i), evaluate the* ME EQUIPMENT *to its specifications and confirm 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 *or dielectric strength testing.*

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, 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.

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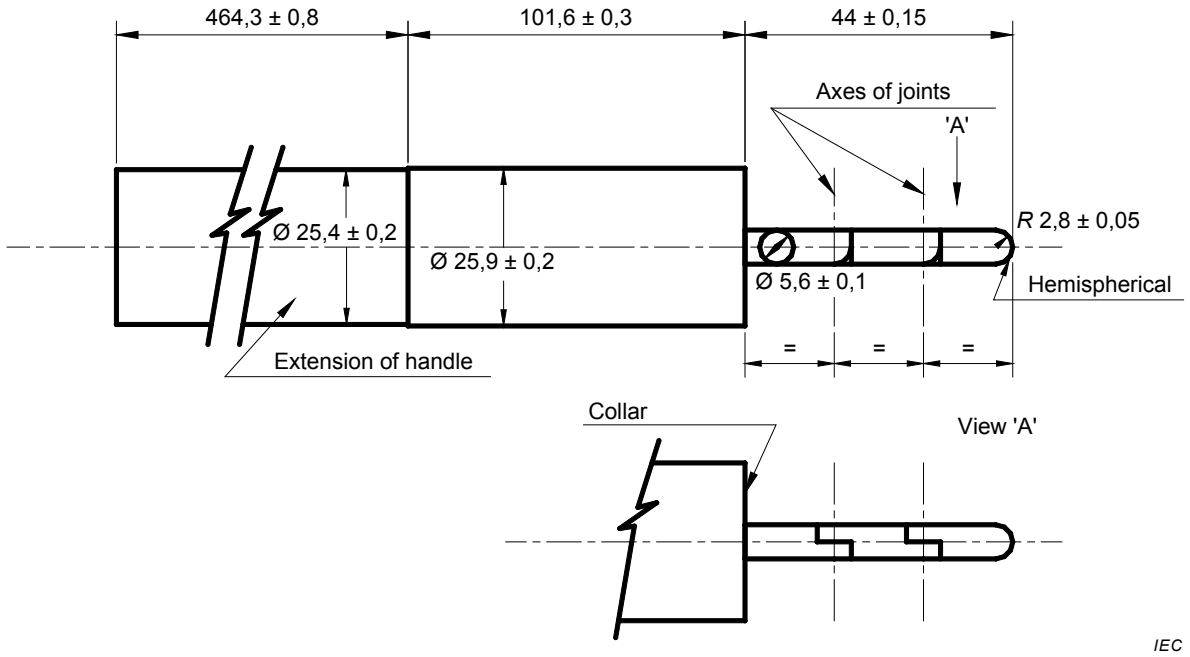
Dimensions in millimetres



– 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 [9], Figure 13]

Figure 1 – Small finger probe Ø 5,6

6 * Classification of ME EQUIPMENT and ME SYSTEMS

In addition to 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 or LAY RESPONSIBLE ORGANIZATION shall be evaluated based on an OPERATOR PROFILE that includes a ~~maximum~~ minimum of eight years of education.

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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 Table C.1 provided by the carrying case shall be marked on the carrying case.~~

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 (2004-01)) (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 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) (seeTable C1, 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 for ME EQUIPMENT that is intended for use by a LAY OPERATOR 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.

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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).

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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 of the INTERNAL ELECTRICAL POWER SOURCE; 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 for ME EQUIPMENT that is intended for use by a LAY OPERATOR 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).
– the time required for the ME EQUIPMENT to warm from the minimum storage temperature between uses (4.2.2) 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 (4.2.2) until the ME EQUIPMENT is ready for its INTENDED USE when the ambient temperature is 20 °C.

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 for ME EQUIPMENT that is intended for use by a LAY OPERATOR 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.;

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– 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, which 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 each TECHNICAL 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:

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– 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.

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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

In addition to 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~~ and IEC 60529:1989/AMD1:1999 + IEC 60529:1989/AMD2:2013 for at least IP22. All other ME EQUIPMENT shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE after undergoing the test of IEC 60529:1989 and IEC 60529:1989/AMD1:1999 + IEC 60529:1989/AMD2:2013 for at least IP21. For PORTABLE ME EQUIPMENT that is only intended to be used~~ with~~ while inside 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 and IEC 60529:1989/AMD1:1999 + IEC 60529:1989/AMD2:2013 with the ME EQUIPMENT placed in the least favourable position of NORMAL USE. Confirm 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. See also 5.1 of the general standard.

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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 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 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 SUPPLY MAINS or near depletion of the INTERNAL ELECTRICAL POWER ~~supply~~ SOURCE. 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 near depletion of INTERNAL ELECTRICAL POWER SOURCES.

If an INTERNAL ELECTRICAL POWER SOURCE is not used, ~~the LIFE-SUPPORTING~~ 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 used, ~~the LIFE-SUPPORTING~~ ME EQUIPMENT or ME SYSTEMS with ESSENTIAL PERFORMANCE intended to actively keep alive or resuscitate a PATIENT 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~~.

NOTE 3 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 LIFE-SUPPORTING~~ 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 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.

8.5 Additional requirements for an INTERNAL ELECTRICAL POWER SOURCE

8.5.1 * Indication of state

If the INTERNAL ELECTRICAL POWER SOURCE is essential to maintain BASIC SAFETY or to maintain ESSENTIAL PERFORMANCE or control the RISKS associated with the loss of ESSENTIAL

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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.

8.5.2 Accessibility of small INTERNAL ELECTRICAL POWER SOURCES

Means other than labelling shall be provided to prevent the RISK of swallowing coin/button cells. A replaceable button cell shall require the use of a TOOL for replacement.

NOTE For the purposes of this standard, a button cell is considered to be an INTERNAL ELECTRICAL POWER SOURCE whose overall height is less than its diameter.

Compliance is checked by inspection.

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 for OPERATOR PROFILES including a LAY OPERATOR 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 environmental conditions specified in this standard;
– 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. The MANUFACTURER shall include the least capable intended LAY OPERATOR or LAY RESPONSIBLE ORGANIZATION in the USABILITY ENGINEERING PROCESS.

EXAMPLES LAY OPERATORS with sensory, cognitive, physical limitations or comorbidities.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

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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.~~ Additions to the mechanical strength applicability of Table 28 of the general standard are indicated in 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 (15.3.4.2)	-
	-	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 (15.3.4.2)	-
	-	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)	-

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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 [7].

– *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).*

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

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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).*

Confirm 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 in the HOME HEALTHCARE ENVIRONMENT.

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 [7].

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

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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).*

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/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).*

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.

Confirm 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.*~~

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10.2 Additional requirements for actuating parts of controls of ME EQUIPMENT

In addition to the requirements of ~~15.4.6.1 b)~~ 15.4.6.2 of the general standard for ME EQUIPMENT that is intended for use by a LAY OPERATOR, 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~~ EMISSIONS of ME EQUIPMENT and ME SYSTEMS

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

~~Addition:~~

~~12.1 Emissions classification~~

In addition to the requirements of ~~6.1.1.1~~ 7.1.1 of IEC 60601-1-2:~~2007~~ 2014, 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'.

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~~**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

In addition to the requirements of 6.3.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 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 intended for confirmed delivery of ALARM CONDITIONS (6.11.2.2.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) that includes the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, each HIGH PRIORITY and MEDIUM PRIORITY ALARM CONDITION shall cause the generation of auditory or verbal ALARM SIGNALS as specified in IEC 60601-1-8:2006 and IEC 60601-1-8:2006/ AMD1:2012.

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13.2 * Additional requirement for ALARM SIGNAL volume

In addition to the requirements of ~~6.3.3.2~~ 6.3.3.3 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 for the ALARM SYSTEM of ME EQUIPMENT and ME SYSTEMS intended to actively keep alive or resuscitate a PATIENT and 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 intended for confirmed delivery of ALARM CONDITIONS (6.11.2.2.1 of IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012) that includes the generation of auditory ALARM SIGNALS as specified in IEC 60601-1-8:2006+IEC 60601-1-8:2006/AMD1:2012.

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.

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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~~ can be used by:

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– 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~~ 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.

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.

This second edition of IEC 60601-1-11 has been harmonized with IEC 60601-1:2005/AMD1:2012.

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.

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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 be used for diagnosis, treatment, or monitoring of a PATIENT; or

– the ME EQUIPMENT be 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 [8], 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 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; and

– 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. Electromagnetic compatibility (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 and is covered by IEC 60601-1-12. The goal of emergency medical services is to either provide treatment to those in need of urgent medical

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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 3.2 – 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 [8], IEC 60335-1 [3] and IEC 60065 [2] have a ± 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 SYSTEMS intended to actively keep alive or resuscitate a PATIENT 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 [11].

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. [13] [14]

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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 [26], 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 [25]. 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 related 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 = $\Delta H/R$

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 shows the saturation water vapour pressure as a 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.

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$$RH = P_V / P_S \quad \text{(A.3)}$$

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.

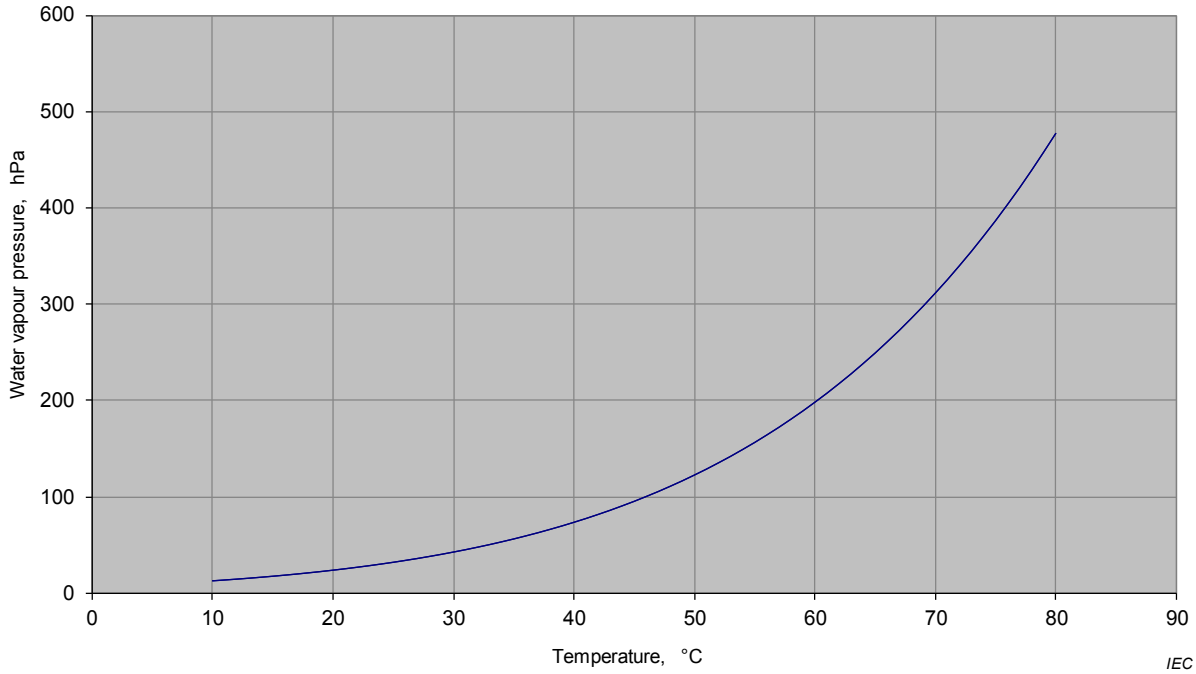

Figure A.1– Saturation water vapour pressure as function of temperature

Subclause 4.2.2 – Environmental conditions of transport and storage between uses

These environmental ranges defined in IEC TR 60721-4-7 [7] 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

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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.

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

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Subclause 4.2.3 – 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 4.2.3.2 – 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 HEALTHCARE 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

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for MEANS OF PATIENT PROTECTION (MOPP). Similarly concerns about integrity of solid insulation are considered minimal because of the 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 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 4.2.3 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 4.2.3, 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, inter alia:

– as degradation or loss of seals (which could be a RISK CONTROL measure for O_2 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 and the 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.

The ME EQUIPMENT is required to maintain ESSENTIAL PERFORMANCE during and following these tests.

For some ME EQUIPMENT, moving between atmospheric pressure extremes might need to be considered. This subclause does not require a test or provide a protocol for this possibility. Such ME EQUIPMENT where concerns about environmental atmospheric pressure shock might need investigating includes air handling systems, such as ventilators and associated ACCESSORIES. However, most ME EQUIPMENT is unlikely to be affected by rapid pressure changes.

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Clause 5 – General requirements for testing ME EQUIPMENT

For purposes of electrical safety, the identification of ACCESSIBLE PARTS using the small test probe defined in Figure 13 of IEC 61032:1997 [9] is appropriate for the HOME HEALTHCARE ENVIRONMENT because this equipment is likely to be around small children who are unsupervised. However, for purposes of ELECTROSTATIC DISCHARGE (ESD) tests, the standard test finger described in Figure 6 of the general standard is deemed adequate. ~~See 12.5.~~

Clause 6 – Classification of ME EQUIPMENT and ME SYSTEMS

Many countries have a standard or code covering electrical installations in buildings that is derived from the IEC or CENELEC standards and is incorporated into building regulations, health and safety regulations or is otherwise legally enforceable. The problem is that these standards are not ~~retroactive~~ retrospective, so many existing buildings and their occupants do not benefit from this level of safety. As a result, the safety means, and in particular the PROTECTIVE EARTH CONNECTION, in older buildings is questionable.

While the standards of safety in most areas of life are constantly improving, the safety of domestic electrical installations in existing buildings has not kept pace. People expect to be at their safest when in their own homes and tend not to be aware of the RISKS that face them there.

For example, the current completion rate for newly built dwellings implies that the average lifetime of a European dwelling is 200 years and the majority (60%) of European housing stock is already over 30 years old [16]. A significant majority of domestic electrical installations in Europe do not meet current electrical codes. The high average age of homes coupled with an intense electricity-based lifestyle and increasing safety standards are factors that require a regular, periodic renovation of electrical installations. Presently, this is not the case. The renovation rate for electrical installations in Europe is low. The above figures are based on the European situation. The experts from the joint working group that prepared this standard were of the opinion that the average situation with regard to the safety of the electrical installation in the HOME HEALTHCARE ENVIRONMENT is not significantly better in other parts of the world, and might be even worse. In some countries, for example Japan and Denmark, a connection for protective earth in homes is not usually available.

The lack of adequate safety measures can have serious consequences. Electrical defects are a common cause of fire. Research has shown that fires caused by electrical defects result in more damage and personal injuries than average fires. Poorly maintained electrical equipment can also cause injuries through electric shock, especially if the safety means of the protective earth is not present or not functioning. These electrical defects can also cause ME EQUIPMENT to malfunction with serious consequences for the people involved and specifically for the PATIENT who might not be able to respond to these defects, e.g. by reflex, which is a major difference compared to other electrical equipment used by healthy persons in the household.

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

– it can be reasonably foreseen that ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT will quite often be used with electrical installations that lack effective PROTECTIVE EARTH CONNECTIONS;
– the typical LAY OPERATOR will not be able to determine the status/safety of the electrical installation; and
– much of the ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT will be installed and used without professional support (i.e. the support of a professional home care provider).

Consequently the RISK CONTROL measures for protection against electrical shock for ME EQUIPMENT intended for the HOME HEALTHCARE 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 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 PERMANENTLY INSTALLED since such equipment is required to be 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 connection is made, which is normally performed by SERVICE PERSONNEL (e.g. a skilled electrical contractor), the adequacy of the PROTECTIVE EARTH CONNECTION can be verified. There are specific disclosure requirements included in 7.5.1 to ensure specifically that the appropriate information is available for this 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 HOME HEALTHCARE ENVIRONMENT:

a) It was felt that ME EQUIPMENT in the HOME HEALTHCARE ENVIRONMENT would likely have NETWORK/DATA COUPLING ports for ACCESSORIES, including connections to the internet, a telecommunication 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 HOME HEALTHCARE ENVIRONMENT this level of supervision is likely 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, 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 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, e.g. haemodialysis equipment. Haemodialysis equipment also represents a class of ME EQUIPMENT where providing an F-TYPE APPLIED PART can be impractical. 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 PERMANENTLY INSTALLED ME EQUIPMENT.

The MANUFACTURER of 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 7.1 – USABILITY of the ACCOMPANYING DOCUMENTS

As required by the general standard and its USABILITY collateral standard, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013, ACCOMPANYING DOCUMENTS for use in the HOME HEALTHCARE ENVIRONMENT should focus on the characteristics of the intended LAY OPERATOR to make the ACCOMPANYING DOCUMENTS most effective for them. A major shortcoming of many

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ACCOMPANYING DOCUMENTS is that they have not been written with the target LAY OPERATORS in mind. Consequently, LAY OPERATORS have often misunderstood or been unable to comprehend the ACCOMPANYING DOCUMENTS.

Because of the wide variation expected in the education and competency of LAY OPERATORS, the committee considers a reading comprehension comparable to the eighth year of education to be reasonable. This is consistent with guidance from the US Food and Drug Administration (FDA) [22] [23] [24]. These references are suggested as useful guidance documents for developing high quality ACCOMPANYING DOCUMENTS for LAY OPERATORS of ME EQUIPMENT for the HOME HEALTHCARE ENVIRONMENT.

User research and the ongoing USABILITY ENGINEERING PROCESS involve the systematic collection of data from members of the intended user group on various characteristics of the ACCOMPANYING DOCUMENTS. User research of ACCOMPANYING DOCUMENTS should focus on one or more of the following areas: LAY OPERATOR comprehension, LAY OPERATOR performance, acceptability, and credibility. User research can identify specific strengths and weaknesses of ACCOMPANYING DOCUMENTS. The findings from user research can improve ACCOMPANYING DOCUMENTS before the ME EQUIPMENT is brought to market. User research methods include focus group interviews, in-depth individual interviews, questionnaires, and readability testing. The use of clear, simple, precise graphics can help any user understand instructions.

Software TOOLS available to estimate the grade level readability of text include:

– Flesch-Kincaid Grade Level – part of standard Microsoft Word word processing program;
– SMOG (Simple Measure of Gobbledygook) Readability Index – commonly used by the U.S. government to measure readability;
– Fry Readability Graph.

These TOOLS measure readability based upon words per sentence and syllables per word.

Most often, some combination of these methods is used to develop a USABILITY SPECIFICATION for the most effective ACCOMPANYING DOCUMENTS possible. The MANUFACTURER VERIFIES that the final ACCOMPANYING DOCUMENTS fulfill the USABILITY SPECIFICATION. VALIDATION includes testing with representative LAY OPERATORS.

The committee reminds designers of ME EQUIPMENT for use in the HOME HEALTHCARE ENVIRONMENT that ideally a RISK CONTROL measure will be intrinsic to the design, and not rely on the ACCOMPANYING DOCUMENT, which particularly in the HOME HEALTHCARE ENVIRONMENT, can be misunderstood and is likely to be lost.

Subclause 7.2 – Additional requirements for marking of IP classification

Subclause 8.3.1 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 LAY persons (such as homecare providers, clinicians or knowledgeable LAY RESPONSIBLE ORGANIZATIONS) can be involved in selecting equipment for the HOME HEALTHCARE 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.

Subclause 7.4.2 – 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 it needs replacing.

ME EQUIPMENT intended for the HOME HEALTHCARE ENVIRONMENT that utilizes an INTERNAL ELECTRICAL POWER SOURCE, that is not periodically or automatically maintained, can usually be

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powered with batteries that are readily available to the general public. For example, a sphygmomanometer designed for use in the HOME HEALTHCARE 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 ~~(primary)~~ INTERNAL ELECTRICAL POWER SOURCE,

  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 ~~(secondary)~~ 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 7.4.7 – Additional requirements for cleaning, disinfection and sterilization

The disclosure is required to reduce the RISK of infection to acceptable levels. See rationale to 8.1.

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

Subclause 8.2 – Additional requirements for sterilization of ME EQUIPMENT and ME SYSTEMS

ME EQUIPMENT, ME SYSTEMS and ACCESSORIES should not be operated or used if their condition could compromise the health or safety of the PATIENT using them or the employees or third parties supplying them. Among other reasons, this means that ME EQUIPMENT, ME SYSTEMS and ACCESSORIES cannot be operated or used if there is a potential RISK of the PATIENT becoming infected from the ME EQUIPMENT, a ME SYSTEM or an ACCESSORY.

ME EQUIPMENT, ME SYSTEMS and ACCESSORIES used in the HOME HEALTHCARE ENVIRONMENT require an appropriate level of disinfection, depending on their use, but rarely need to be sterile. Methods used for the cleaning and disinfection of ME EQUIPMENT, ME SYSTEMS and

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ACCESSORIES need to reduce/eliminate the RISK of infecting a PATIENT with microorganisms while also reducing the RISK to the OPERATOR who performs the cleaning and disinfection PROCESS. The methods also need to be feasible for the HOME HEALTHCARE ENVIRONMENT in which they are intended to be performed.

All ME EQUIPMENT, ME SYSTEMS and ACCESSORIES are a potential source of infection in humans. Any ME EQUIPMENT, ME SYSTEM or ACCESSORY that has been used by a PATIENT is potentially contaminated with reproductive human pathogenic microorganisms until proven otherwise. Appropriate PROCEDURES for handling and PROCESSING are essential to protect the next person handling, or the next PATIENT using, the ME EQUIPMENT, ME SYSTEMS or ACCESSORY. Hence ME EQUIPMENT, ME SYSTEMS and ACCESSORIES that have been used need PROCESSING, following the MANUFACTURER'S instructions, prior to reuse by another PATIENT.

The basic requirements for such PROCESSING of ME EQUIPMENT, ME SYSTEMS or ACCESSORIES are usually determined by:

– the potential degree of contamination of the ME EQUIPMENT, ME SYSTEMS or ACCESSORY; and
– the RISK of infecting another PATIENT or third party or re-infecting a PATIENT resulting from reuse of the ME EQUIPMENT, ME SYSTEM or ACCESSORY and the type of application of the ME EQUIPMENT, ME SYSTEM or ACCESSORY.

Reusable ME EQUIPMENT, ME SYSTEMS and ACCESSORIES that are used in professional healthcare facilities are routinely intended for sequential use with multiple PATIENTS, i.e. moved from one sick PATIENT to another sick PATIENT. This practice creates opportunities for cross contamination by potentially virulent microorganisms. In order to prevent infection caused by cross contamination, professional healthcare facilities vigorously clean and sterilize reusable ME EQUIPMENT, ME SYSTEMS or ACCESSORIES using expensive, elaborate equipment and/or toxic chemicals.

The situation is quite different for ME EQUIPMENT, ME SYSTEMS or ACCESSORIES in the HOME HEALTHCARE ENVIRONMENT:

– Reusable ME EQUIPMENT, ME SYSTEMS or ACCESSORIES for chronic care are not routinely moved from PATIENT to PATIENT so the RISK of cross contamination is low.
– PATIENTS using ME EQUIPMENT and ME SYSTEMS are not always sick and usually not infected with virulent microorganisms.
– It is generally not feasible to purchase and operate elaborate sterilization systems and it is not safe to use toxic chemicals in the HOME HEALTHCARE ENVIRONMENT.

ME EQUIPMENT or ME SYSTEMS in the HOME HEALTHCARE ENVIRONMENT are often used repeatedly on the same PATIENT. ACCESSORIES and components that would typically be either subject to cleaning and high-level disinfection or cleaning and sterilization in the professional healthcare facility should be cleaned and disinfected in a manner that reduces the RISK of infection from common, household- and PATIENT-resident microorganisms.

When selecting and evaluating the cleaning and disinfection or cleaning and sterilization methods the MANUFACTURER has to consider:

– the amount and type of microorganisms expected to be on the ME EQUIPMENT, ME SYSTEM or ACCESSORY used;
– the RISK for the microorganisms to be transmitted; and
– the resistance of the microorganisms to the cleaning and disinfection or cleaning and sterilization methods intended to be used.

The RISKS posed by such PROCESSING of ME EQUIPMENT, ME SYSTEMS or ACCESSORIES are determined by the following factors:

a) undesired effects, which can result from:

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– the previous use of the ME EQUIPMENT, ME SYSTEM or ACCESSORY,
– the previous cleaning and disinfection or cleaning and sterilization PROCEDURES, and
– transportation and storage;

b) the RISKS from the type of subsequent uses, such as:
– residues from the previous use (such as secretions and other bodily components or drugs);
– residues from the previous cleaning and disinfection or cleaning and sterilization PROCEDURES (such as cleaning agents, disinfectants and other substances, including their reaction products);
– changes of physical, chemical or functional properties of the ME EQUIPMENT, ME SYSTEM or ACCESSORY; and
– changes in the condition of the material (such as accelerated wear and tear, embrittlement and changed surface conditions, connectors and adhesive joints);

c) the RISK of transmission of any microorganisms.

When considering the suitability and feasibility of the cleaning and disinfection or cleaning and sterilization PROCEDURE for ME EQUIPMENT, ME SYSTEM or ACCESSORY within the HOME HEALTHCARE ENVIRONMENT, the MANUFACTURER should consider the following:

– the RISKS involved in the PROCESS;
– the cost effectiveness of the PROCESS;
– the practicability of the PROCESS;
– the availability of the cleaning equipment and the cleaning agents specified in the PROCESS;
– the efficiency of the PROCESS;
– the reproducibility of the PROCESS;
– the quality management requirements of the PROCESS; and
– the environmental impact of the PROCESS and the disposal of any supplies (e.g. cleaning agents) utilized.

When in the HOME HEALTHCARE ENVIRONMENT ME EQUIPMENT or an ME SYSTEM is intended to be used on a different PATIENT, it is appropriate to use methods of cleaning and disinfection or cleaning and sterilization that are used in the professional healthcare facility. This might include the need for specific TOOLS or equipment and specific knowledge or training of the persons involved in these PROCEDURES which are usually not available in the HOME HEALTHCARE ENVIRONMENT, i.e. this might include the need to involve professional organizations (e.g. hospitals, homecare providers or MANUFACTURERS) in that PROCESS.

Subclause 8.3.1 – Ingress of water or particulate matter into ME EQUIPMENT

ME EQUIPMENT intended for use in the HOME HEALTHCARE ENVIRONMENT can face many situations which ME EQUIPMENT intended for use only in the professional healthcare facilities is not likely to encounter due to environmental controls and OPERATOR training in professional healthcare facilities.

Therefore, as a minimum requirement, ENCLOSURES of ME EQUIPMENT intended for use in the HOME HEALTHCARE ENVIRONMENT are required to provide protection against ingress of an object of Ø 12,5 mm (an adult's finger). This is in addition to the requirement in Clause 5 for determining ACCESSIBLE PARTS utilizing Ø 5,6 mm (equivalent to a child's finger). All HAND-HELD and BODY-WORN ME EQUIPMENT are required to be protected against the ingress of vertically falling water drops with the ME EQUIPMENT ENCLOSURE tilted at 15º (IPX2). MOBILE and PORTABLE ME EQUIPMENT in non-TRANSIT-OPERABLE use are to be protected against the ingress of vertically falling water drops with the ME EQUIPMENT ENCLOSURE positioned on a turntable (IPX1). These requirements are summarized in Table A.2.

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