



BSI Standards Publication

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

National foreword

This British Standard is the UK implementation of EN 60601-1-11:2010. It is identical to IEC 60601-1-11:2010.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/1, Common aspects of Electrical Equipment used in Medical Practice.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

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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
(IEC 60601-1-11:2010)**

Appareils électromédicaux -
Partie 1-11: Exigences générales
pour la sécurité de base et les
performances essentielles -
Norme collatérale: Exigences
pour les appareils électromédicaux
et les systèmes électromédicaux utilisés
dans l'environnement des soins à domicile
(CEI 60601-1-11:2010)

Medizinische elektrische Geräte -
Teil 1-11: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale -
Ergänzungsnorm: Anforderungen
an medizinische elektrische Geräte
und medizinische elektrische Systeme
für die medizinische Versorgung
in häuslicher Umgebung
(IEC 60601-1-11:2010)

This European Standard was approved by CENELEC on 2010-06-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 62A/693/FDIS, future edition 1 of IEC 60601-1-11, prepared by SC 62A, Common aspects of electrical equipment used in medical practice, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-1-11 on 2010-06-01.

This EN 60601-1-11:2010 constitutes a collateral standard to EN 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* hereafter referred to as the general standard.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN and CENELEC shall not be held responsible for identifying any or all such patent rights.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2011-03-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2013-06-01 |

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

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

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

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

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

In referring to the structure of this standard, the term

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

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

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

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

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

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

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 93/42/EEC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-1-11:2010 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

[2] IEC 60065:2001	NOTE Harmonized as EN 60065:2002 (modified).
[3] IEC 60335-1:2001	NOTE Harmonized as EN 60335-1:2002 (modified).
[4] IEC 60364 series	NOTE Harmonized in HD 60364 series (partially modified).
[5] IEC 60721-3-7:1995	NOTE Harmonized as EN 60721-3-7:1995 (not modified).
[7] IEC 60950-1:2005	NOTE Harmonized as EN 60950-1:2006 (modified).
[8] IEC 61032:1997	NOTE Harmonized as EN 61032:1998 (not modified).
[10] ISO 10651-2:2004	NOTE Harmonized as EN ISO 10651-2:2004 (not modified).

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
IEC 60068-2-27	2008	Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock	EN 60068-2-27	2009
IEC 60068-2-31	2008	Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens	EN 60068-2-31	2008
IEC 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance	EN 60068-2-64	2008
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529 + corr. May	1991 1993
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1 + corr. March	2006 2010
IEC 60601-1-2 (mod)	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2 + corr. March	2007 2010
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
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	EN 60601-1-8 + corr. March	2007 2010
CISPR 11 (mod)	2009	Industrial, scientific and medical equipment - Radio-frequency disturbance characteristics - Limits and methods of measurement	EN 55011	2009

Annex ZZ (informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

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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 3.2). The safety of MEDICAL ELECTRICAL EQUIPMENT in this uncontrolled environment with regard to the electrical installation and its related safety and protection means is a cause for concern.

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

Collateral Standard:

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

1 Scope, object and related standards

1.1 * Scope

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

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

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

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

1.2 Object

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

1.3 Related standards

1.3.1 IEC 60601-1

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

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

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

1.3.2 Particular standards

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

2 Normative references

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

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

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

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

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

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

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

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

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

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

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

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

3 Terms and definitions

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

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

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

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

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

3.1

* BODY-WORN

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

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

3.2

HOME HEALTHCARE ENVIRONMENT

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

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

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

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

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

3.3

* LAY

term referring to nonprofessional or professional without relevant specialized training

EXAMPLES LAY OPERATOR, LAY RESPONSIBLE ORGANIZATION

3.4

LIFE-SUPPORTING ME EQUIPMENT OR ME SYSTEM

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

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

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

3.5

SHELF LIFE

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

3.6

TRANSIT-OPERABLE

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

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

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

3.7

USABILITY ENGINEERING

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

3.8

USABILITY ENGINEERING FILE

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

3.9

USABILITY SPECIFICATION

documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

3.10

VALIDATION

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

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

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

[ISO 9000:2000, definition 3.8.5]

4 General requirements

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

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

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

4.2 Environmental conditions for ME EQUIPMENT

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

4.2.1 * Environmental conditions of transport and storage between uses

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

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

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

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

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

²⁾ Figures in square brackets refer to the Bibliography.

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

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

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

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

EXAMPLES Removal of batteries, emptying fluid reservoirs

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

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

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

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

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

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

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

4.2.2 * Environmental operating conditions

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

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

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

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

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

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

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

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

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

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

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

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

4.2.3 * Environmental shock to TRANSIT-OPERABLE ME EQUIPMENT

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

Compliance is checked by the following test:

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

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

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

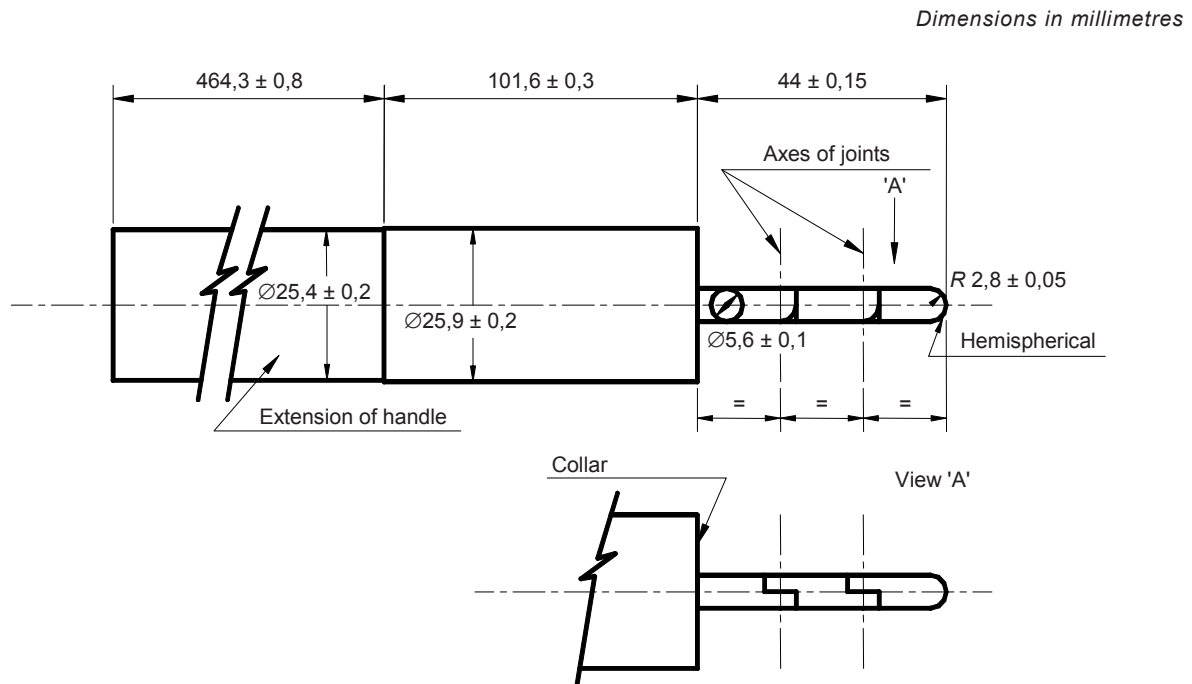
NOTE While the ME EQUIPMENT is warming or cooling, the evaluation of BASIC SAFETY and ESSENTIAL PERFORMANCE is repeated for two hours or until THERMAL STABILITY is reached.

5 * General requirements for testing ME EQUIPMENT

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

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

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



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- Finger: metal material
- Handle: insulating material

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

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

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

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

Figure 1 – Small finger probe Ø 5,6

6 * Classification of ME EQUIPMENT and ME SYSTEMS

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

- shall be CLASS II or INTERNALLY POWERED;
- shall not have a FUNCTIONAL EARTH TERMINAL; and
- if equipped with APPLIED PARTS, shall have either TYPE BF APPLIED PARTS or TYPE CF APPLIED PARTS.

Compliance is checked by inspection.

7 ME EQUIPMENT identification, marking and documents

7.1 * USABILITY of the ACCOMPANYING DOCUMENTS

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

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

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

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

7.2 * Additional requirements for marking of IP classification

Notwithstanding the requirements of 7.2.9 of the general standard, the ENCLOSURE of ME EQUIPMENT shall be marked with the IP classification required by 8.3.1. If some or all of the protection against the ingress of water or particulate matter is provided by a carrying case, then the degree of protection provided by the ENCLOSURE shall be marked on the ENCLOSURE and the degree of protection provided by the carrying case shall be marked on the carrying case. A carrying case that is not intended to provide protection against the ingress of water or particulate matter need not be marked.

EXAMPLE If for TRANSIT-OPERABLE ME EQUIPMENT, the ENCLOSURE provides the protection against the ingress of particulate matter and the carrying case provides the protection against the ingress of water, the ENCLOSURE of the ME EQUIPMENT would be marked IP20 and the carrying case would be marked IP02.

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

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

7.3 ACCOMPANYING DOCUMENTS

7.3.1 Contact information

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

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

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

7.3.2 LAY OPERATOR briefing information

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

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