



Assistive products for persons with disability—General requirements and test methods

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 - Bus and Coach Association of New Zealand
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 - New Zealand Transport Agency
 - Novita Children's Services
 - Occupational Therapy Australia
 - Physical Disability Australia
 - Queensland Health
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Australian Standard[®]

**Assistive products for persons with
disability—General requirements and
test methods**

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PREFACE

This Standard was prepared by the Standards Australia Committee ME-067, Assistive Technology Products for Persons with Disability, to supersede AS EN 12192—2002, *Technical aids for disabled persons—General requirements and test methods*.

The objective of this Standard is to specify requirements and test methods for assistive products for persons with disability.

This Standard is identical with, and has been reproduced from EN 12182:2012, *Assistive products for persons with disability—General requirements and test methods*.

As this Standard is reproduced from a European Standard, the following applies:

- (a) In the source text ‘this European Standard’ should read ‘this Australian Standard’.
- (b) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
EN		AS EN	
556	Sterilization of medical devices— Requirements for medical devices to be designated “STERILE”	556	Sterilization of medical devices— Requirements for medical devices to be designated “STERILE”
556-1	Part 1: Requirements for terminally sterilized medical devices	556.1	Part 1: Requirements for terminally sterilized medical devices
EN ISO		AS/NZS ISO	
11137	Sterilization of health care products— Radiation	11137	Sterilization of health care products— Radiation
11137-1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	11137.1	Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
11137-2	Part 2: Establishing the sterilization dose	11137.2	Part 2: Establishing the sterilization dose
		AS/NZS	
13850	Safety of machinery—Emergency stop—Principles for design	4024	Safety of machinery
		4024.1604	Part 1604: Design of controls, interlocks and guarding—Emergency stop—Principles for design
CISPR		AS/NZS CISPR	
11	Industrial, scientific and medical equipment—Radio-frequency disturbance characteristics—Limits and methods of measurement	11	Industrial, scientific and medical equipment—Radio-frequency disturbance characteristics—Limits and methods of measurement

Only normative references that have been adopted as Australian or Australian/New Zealand Standard have been listed.

The term ‘informative’ has been used in this Standard to define the application of the annex to which it applies. An ‘informative’ annex is only for information and guidance.

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NOTES

AUSTRALIAN STANDARD

Assistive products for persons with disability—General requirements and test methods**1 Scope**

This European Standard specifies general requirements and test methods for assistive products for persons with a disability, which are medical devices according to the definition laid down in the EU Directive 93/42/EEC.

This European Standard does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

Where other European Standards exist for particular types of assistive products then those standards apply. However, some of the requirements of this standard may still apply and may be considered in addition to those in other European standards.

NOTE Not all the items listed in EN ISO 9999 are medical devices. Contracting parties may wish to consider if this standard or parts of this standard can be used for assistive products which are not medical devices as defined in the EU Directive 93/42/EEC.

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.

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source: Smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: Match flame equivalent*

EN 614-1, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1021-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

EN 1021-2, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN ISO 25424, *Sterilization of medical devices - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424)*

EN 60065, *Audio, video and similar electronic apparatus — Safety requirements (IEC 60065)*

EN 60335-1, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1)*

EN 60529, *Degrees of protection provided by enclosures (IP Code) (IEC 60529)*

EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 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 60601-1-2:2007, modified)*

EN 60695-11-10, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods (IEC 60695-11-10)*

EN 60730-1, *Automatic electrical controls for household and similar use — Part 1: General requirements (IEC 60730-1)*

EN 60950-1, *Information technology equipment — Safety — Part 1: General requirements (IEC 60950-1)*

EN 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2)*

EN 61000-3-3, *Electromagnetic compatibility (EMC) — Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection (IEC 61000-3-3)*

EN 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3)*

EN 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test (IEC 61000-4-8)*

EN 62304, *Medical device software — Software life-cycle processes (IEC 62304)*

EN 80601-2-35, *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35)*

EN ISO 3746, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746)*

EN ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1)*

EN ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1)*

EN ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1)*

EN ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2)*

EN ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1)*

EN ISO 12952-1, *Textiles - Assessment of the ignitability of bedding items - Part 1: Ignition source: smouldering cigarette (ISO 12952-1)*

EN ISO 12952-2, *Textiles - Assessment of the ignitability of bedding items - Part 2: Ignition source: match-flame equivalent (ISO 12952-2)*

EN ISO 13732-1, *Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces (ISO 13732-1)*

EN ISO 13850, *Safety of machinery — Emergency stop — Principles for design (ISO 13850)*

EN ISO 14155, *Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971)*

EN ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1)*

EN ISO 24415-1, *Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips (ISO 24415-1)*

ISO 24415-2, *Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches*

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

NOTE Standards which are referred to in the text as informative material are listed in the Bibliography.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

assistant

person who is helping a person with a disability in using the assistive product

Note 1 to entry: Examples of the ways assistants help persons with a disability are; pushing wheelchairs, operating hoists, assisting with entering and leaving seats, beds and wheelchairs.

3.2

assistive product(s)

instrument, equipment or technical system intended by the manufacturer to be used for the prevention, treatment or alleviation of, or compensation for injury, impairment, a disability or handicap of a person with a disability

Note 1 to entry: The definition is not identical to the definition in EN ISO 9999 because EN 12182 is restricted to medical devices.

3.3

bedding

items normally placed on a mattress

Note 1 to entry: Bedding includes; mattress covers, underlays, incontinence sheets and pads, sheets, blankets, electric blankets, quilts (duvets) and their covers, pillows and bolsters, pillow cases.

3.4

class I

referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution so that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

3.5

class II

referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

3.6**clinical evaluation**

means for confirming that an assistive product conforms to the requirements of EU Directive 93/42/EEC when used as intended by the manufacturer

Note 1 to entry: It may include a compilation of clinical data, any scientific literature and the results of any clinical investigations, taking into account any relevant harmonized standards.

3.7**clinical investigation**

systematic study into human subjects, undertaken to verify the safety and performance of a specific medical device, under the manufacturer's intended conditions of use

3.8**disability**

umbrella term for impairments, activity limitations and participation restrictions denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)

[SOURCE: ICF 2001, WHO]

3.9**hand held assistive products**

equipment intended to be supported by the hand during normal use

3.10**impairments**

problems in body function or structure, such as a significant deviation or loss

[SOURCE: ICF 2001, WHO]

3.11**intended use**

use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer

Note 1 to entry: This information includes pre-sale information.

3.12**maximum rated load**

greatest permissible load as specified by the manufacturer

Note 1 to entry: Includes user mass and the mass and loading of the accessories (mattresses, baskets, etc.).

3.13**medical electrical system**

combination, as specified by its manufacturer, of items of equipment, at least one of which is a medical equipment to be inter-connected by functional connection or by use of a multiple socket-outlet

3.14**mobile assistive products**

equipment intended to be moved from one location to another while supported by its own wheels or equivalent means

3.15**normal use**

operation. including routine inspection and adjustments by any operator, and stand-by, according to the instructions for use

Note 1 to entry: Normal use is not to be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc..

3.16

operator

person handling the assistive product

Note 1 to entry: The operator can either be the user or the assistant.

3.17

person with a disability

person with one or more impairments, one or more activity limitations, one or more participation restrictions or a combination thereof

[SOURCE: ICF 2001, WHO]

3.18

portable assistive products

equipment intended to be moved from one location to another while being carried by one or more persons

3.19

single fault condition

condition in which a single means for reducing a risk is defective or a single abnormal condition is present

3.20

technical documentation

manufacturer's data that shows that an assistive product conforms to the requirements of this standard and which may be used as part of the technical documentation required by EU Directive 93/42/EEC for conformity assessment procedures

3.21

user

person with a disability for whom the assistive product is intended

4 General requirements

4.1 Risk analysis

The safety of an assistive product shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in EN ISO 14971.

When using an assistive product in combination with a device that is not a medical device the device shall behave in a safe way regarding the MDD as a system.

NOTE 1 In the case of certain disabilities there may be a need for higher levels of safety for equipment used to offset the effects of that disability.

NOTE 2 Conformity with the requirements of this standard may be used to claim compliance with the requirements of EN ISO 14971 for those hazards and risks identified in this standard.

4.2 Intended performance and technical documentation

- a) An assistive product shall have sufficient strength and durability to sustain all loads expected during its intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and scientific literature in addition to requirements in this standard, strength and/or durability calculations, appropriate test standards and their test results.

- b) The intended performance including, if appropriate, strength, durability and tipping stability of an assistive product shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.
- c) The technical documentation shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, conformity with appropriate test standards and their test results.

4.3 Clinical evaluation and investigation

A clinical evaluation shall be done for all assistive products.

If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN ISO 14155-1 and EN ISO 14155-2. A clinical evaluation shall always be done before performing a clinical investigation.

NOTE Guidance for the evaluation of clinical data is given in MEDDEV 2.7.1.

4.4 Assistive products that can be dismantled

If it is intended that an assistive product can be dismantled for storage or transportation, it shall not be possible to reassemble the assistive product in a manner that presents a hazard.

4.5 Fasteners

If it is intended that an assistive product can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling shall not be single use fasteners.

EXAMPLE Single use fasteners include wood screws and self-tapping screws.

4.6 Mass limits

The user mass limit and maximum rated load shall be declared by the manufacturer.

4.7 Immobilising means

If the movement of an assistive product or of any of its parts constitutes a risk for the user or a nearby person, there shall be immobilising means that provide control of the speed and/or prevent any undesired movement.

4.8 Design requirements in relation to persons with cognitive impairment

- a) Persons with cognitive impairment shall be considered potential users of all assistive products.
- b) Cognitive impairment aspects shall, as far as possible, be considered in the design, performance and use of all assistive products.
- c) The result of such considerations shall be described in the producer's technical documentation.
- d) An assistive product may be used not only by whom it is primarily intended, but also by an assistant. Risk management shall include all involved persons.

NOTE Cognition is the understanding, integrating and processing of information. Cognition involves fundamental mental characteristics such as the capacity to learn, remember, understand, solve problems, plan, keep focused, etc. Cognitive impairment may reduce, more or less, the possibilities to learn how to operate a product, to understand warnings, etc. This increases the risk that persons with cognitive impairment will find themselves in hazardous situations. Cognitive impairment also involves a large and growing number of the population of Europe and other parts of the industrialized world.

For further guidance, see Annex C.

5 Materials

5.1 General

Manufacturers should, wherever possible, use materials that can be recycled for further use.

For guidance, see EN 60601-1-9.

5.2 Flammability

5.2.1 General

Manufacturers shall consider the environments and methods of use to which an assistive product or any materials that are usually used in combination with this assistive product, will be exposed and take appropriate steps to minimize any fire hazard.

The manufacturer shall include a warning in the instructions for use about safe combinations of flame resistant and non flame resistant materials.

NOTE 1 If flammable materials are used it needs to be indicated in the documentation.

Every effort should be made to use products which meet the flammability requirements as it is of particular importance to persons with a disability who may not be able to escape from a fire. The use of non-flame retardant materials should be reviewed regularly, as there is continuous development in this field.

Special attention shall be paid to assistive products where the main purpose is protection from fire.

NOTE 2 For guidance, see B.5.2.

5.2.2 Upholstered parts, mattresses, bed bases and bedding

Upholstered parts, mattresses and bed bases and bedding shall comply with the requirements of 5.2.2 a) or 5.2.2 b).

- a) If the manufacturer claims that an assistive product is resistant to ignition by a cigarette or a small flame it shall comply with the appropriate requirements in 5.2.3, 5.2.4 or 5.2.5;
- b) if the clinical requirements prevent the use of materials which comply with 5.2.2 a), the reasons shall be included in the technical documentation and the assistive product shall be supplied with the following:
 - 1) warning that it is not flame retardant, placed on the product if possible, and included in the instructions for use; and
 - 2) a description of the precautions required to offset the increased risk.

5.2.3 Upholstered parts

If the manufacturer claims that the upholstered parts are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-1 and EN 1021-2.

5.2.4 Mattresses and bed bases

If the manufacturer claims that mattresses and/or bed bases are resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 597-1 and EN 597-2.

5.2.5 Bedding

If the manufacturer claims that bedding is resistant to ignition by a cigarette or a small flame, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN ISO 12952-1 and EN ISO 12952-2.

If the manufacturer claims that bedding is resistant to ignition by small flames, such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN ISO 12952-2.

5.2.6 Moulded parts

If the manufacturer claims that a plastic moulded part is resistant to ignition by cigarettes, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with FV-1 of EN 60695-11-10 or better. If the product is of a type that the user normally (by himself) cannot escape from or detect as a dangerous situation it shall be FV-0.

If the manufacturer claims that plastic moulded parts are resistant to ignition by small flames, such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 60695-11-10.

5.3 Biocompatibility and toxicity

Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1 and shall fulfil the following requirements.

The assessment shall take into account the intended use and contact by those involved in user care or transportation and storage of the product.

The assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The assessment should follow the guidance given in Annex D.

The result of the assessment shall be incorporated in the risk analysis (see 4.1).

NOTE For additional guidance and test methods, see Annex D.

5.4 Contaminants and residues

5.4.1 General

The requirements given in 5.4.2 do not apply to the body fluids which may be collected in an assistive product (e.g. stomacare products) but only to those substances which are an integral part of an assistive product or are needed for its function (e.g. oil and grease).

5.4.2 Substances which may leak from an assistive product in intended use and in fault conditions

Substances which may leak from the assistive product shall either:

- be assessed for biocompatibility in accordance with the guidance given in EN ISO 10993-1; the assessment shall take into account the intended use and contact by those involved in user care, transport and storage; or
- be provided with protection that minimizes the possibility of such substances becoming a biological hazard.

NOTE 1 Substances that can leak include lubricants and hydraulic fluids.

NOTE 2 An example of a method of protection from a hazardous substance is where batteries are placed in a container made from acid resistant material.

5.5 Infection and microbiological contamination

5.5.1 Cleaning and disinfection

If an assistive product is intended to be cleaned, the method and suitable cleaning materials shall be described in the information supplied by the manufacturer.

If an assistive product is intended to be disinfected, the method and suitable materials shall be described in the information supplied by the manufacturer.

NOTE 1 For guidance, see B.5.5.1.

If an assistive product is intended to be cleaned by automatic washing systems or hand held jet stream/steam washing the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the assistive product shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of test of machine washable assistive products in B.5.5.1.

NOTE 2 It is only practicable when the assistive product is of sufficient size.

5.5.2 Animal tissue

Where a device has been manufactured utilising tissues of animal origin or their derivatives, a risk assessment shall be performed and documented according to EN ISO 22442-1.

NOTE For guidance, see B.5.5.2.

5.6 Resistance to corrosion

The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis (see 4.1).

NOTE As a guidance EN ISO 9227 might be used for the assessment of corrosion resistance of metallic materials.

6 Emitted sound and vibration

6.1 Noise and vibration

If noise and vibration are not part of the intended performance of an assistive product, hazards and nuisance from noise and vibration shall be assessed in the risk analysis (see 4.1).

Measurements for noise of power operated assistive products shall be done in accordance with EN ISO 3746, and the result of the measurement shall be recorded in the pre sale information and in the instructions for use.

NOTE For guidance, see B.6.

6.2 Sound levels and frequencies of audible warning devices

The frequency shall be within the range 500 Hz to 16 000 Hz and should be within the range 500 Hz and 3 000 Hz.

Sound levels shall be at least 65 dB(A) for audible alarms, and should be at least 75 dB(A).

The alarm or feedback signal shall be distinguished from the noise of the product itself either by frequency or sound level.

Measurements shall be made in accordance with EN ISO 3746.

6.3 Feedback

All user commands shall have some kind of feedback e.g audible, visible or tactile that clearly indicates that a command has been given and/or effectuated. The feedback shall be accessible for all relevant operators.

The sound level for a feedback or speech system shall be within 50-80 dB(A).

Measurements shall be done in accordance with EN ISO 3746.

7 Electromagnetic compatibility

7.1 General

An assistive product containing electrical or electronic devices/components shall conform to EN 60601-1-2 and shall, in addition, conform to 7.2, 7.3 and 7.4.

7.2 Emissions

When tested in CISPR 11, the equipment shall meet the radiated emissions limits specified in CISPR 11 for group 1, class B equipment specified in CISPR 11.

The requirements in EN 61000-3-2 apply, if applicable, as specified in EN 61000-3-2.

The requirements in EN 61000-3-3 apply, if applicable, as specified in EN 61000-3-3.

7.3 Immunity

Assistive products shall, in addition to the requirements in EN 60601-1-2:2007, subclause 36.202.2.1, also be tested with a field strength of 20 V/m (RMS value of the unmodulated carrier) in the frequency range of 800 MHz to 2,5 GHz. The test shall be performed in accordance with EN 61000-4-3.

If, as a result of the application of this test, the assistive product presents a hazard, or there is any unintentional operation of the assistive product, the assistive product fails the test.

NOTE 1 It may be necessary to assess the risk associated with the assistive product when used in close proximity to (a) mobile telephone(s) or other forms of transmitter. In this case higher field strength values over a broader range of frequency may apply.

NOTE 2 Assistive products are used in a wide range of environments and may be used in the presence of other electronic equipment. The electromagnetic compatibility (EMC) needs to be carefully matched to the intended use of the assistive product.

7.4 Power frequency magnetic field immunity

When the equipment is tested in accordance with EN 61000-4-8 using test level 4, at 50 Hz and 60 Hz:

- a) the equipment shall behave safe in the presence of the applied field;
- b) electrically powered devices or electrically moved functions shall not make any unintentional operation in the presence of the applied field.

Perform the continuous field immunity test specified in EN 61000-4-8 on the equipment as table-top equipment. Test the equipment for not less than one minute for each orientation of the applied field.

For guidance, see B 7.4

8 Electrical safety

8.1 General

Assistive products shall comply for electrical safety to the requirements of applicable standards according to guidance given in Table 1.

Table 1 — Applicable standards for electrical safety

Assistive products that fall within the scope of EN 60601-1 (Medical electrical equipment) are tested according to:	Assistive products that fall within the scope of EN 60335-1 (Household and similar electrical appliances) are tested according to:	Assistive products that fall within the scope of EN 60065 (Audio, video and similar electronic apparatus) are tested according to:	Assistive products that fall within the scope of EN 60950-1 (Information technology equipment) are tested according to:
EN 12182 EN 60601-1 EN 60601-1-2 EN 60601-2-xx	EN 12182 EN 60335-1 EN 60335-2-xx	EN 12182 EN 60065	EN 12182 EN 60950-1

NOTE This list may not be complete and might be updated due to further developments of standards.

Homecare electrical equipments connected to mains shall be of class II (double isolated) except if the use is in wet areas where the requirement shall be class I (earth).

Hospital based electrical equipments connected to mains shall be of class I (earth).

8.2 Electrical systems

An electrical system can consist of several components, each tested to different standards.

For the applicability of standards for components of electrical systems see Table 1.

NOTE In specific cases, there may be other useful standards in addition to those mentioned in Table 1.

EXAMPLE A medical electric system for an electrically operated door opener can consist of three different components, tested to different standards: a hand-control (EN 60601-1), a door-opener (EN 60335-1) and a computer (EN 60950-1).

8.3 Continuity of power supply

If the safety of a person using an assistive product powered from electrical supply mains depends upon the continuity of the power supply, the assistive product shall be provided with a level of protection as follows:

- If the (intended) user is not able to react reasonably or timely, an auxiliary source of power, which – in case of discontinuity of the power supply – is automatically and timely connected to the assistive product and a means to signal to the assistant that a discontinuity of the power supply has occurred; the auxiliary source of power shall provide sufficient power to allow timely reaction;
- If the (intended) user is able to react reasonably and timely, an auxiliary source of power and a means to signal to the user that a discontinuity of the power supply has occurred; the auxiliary power source shall provide sufficient power to allow timely reaction;

- If it is feasible, a method of non-electrical operation that reduces the risk to users to an acceptable level until they can be removed from the assistive product, or power is restored together with a means to signal power failure to the operator who is intended for such emergency operations.

If there is a battery backup when there is a failure in the mains, this should start to function as fast as possible and have a performance time long enough to bring the user to a safe place or position.

NOTE 1 A timely reaction may be providing access to the supply mains without interruption of the continuity of the power supply.

If the safety of a person using an internally powered assistive product depends upon the continuity of the power supply, a means of informing the user of a critical charge of the power supply shall be provided. At the time of reaching the critical charge, either an auxiliary source of sufficient power or a sufficient reserve charge of the internal power supply shall be available to allow timely reaction.

NOTE 2 A timely reaction may be either recharging/replacing an internal power supply without interruption of the continuity of the power supply or by allowing the return to a safe place that provides the possibility to recharge/replace the internal power supply.

8.4 Battery powered assistive products

8.4.1 Battery housings

- a) The need for, and the design of, battery housings shall be based on the risk analysis (see 4.1) and shall identify the hazards and evaluating the risks associated with:
 - 1) leakage of acid and/or other substances from the battery(ies);
 - 2) ventilation of gases generated during charging and/or use;
 - 3) short circuits of the battery(ies);when operated for intended use.
- b) Housings containing batteries from which gases can escape during charging or discharging shall be ventilated.

NOTE The ventilation should minimize the risk of accumulation and ignition of flammable gases.

- c) If a short circuit of a battery could result in a safety hazard, the battery shall be contained in a housing/compartment that prevents the risk of accidentally short circuiting the battery(-ies).
- d) Any battery housing/compartment shall collect and store any fluids and/or substances (other than gases) which may leak from the battery(ies) specified by the manufacturer.
- e) The materials used in the manufacture of battery housings shall be resistant to the substances that might leak from the battery(ies) specified by the manufacturer.

8.4.2 Connection

If a safety hazard can develop from the incorrect connection or replacement of a battery, an assistive product shall be fitted with a means of preventing incorrect polarity.

8.4.3 Charge level indicator

If the safety of a person using an internally powered assistive product depends upon the power supply, a means of informing the user of the state of the charge of the power supply shall be provided. At the time of indicating the critical charge, sufficient reserve charge of the internal power supply shall be available to allow timely reaction.

NOTE A timely reaction may be either recharging or replacing the power supply without interruption of the availability of the power or by allowing the return to a safe place that provides the possibility to re-charge/replace the internal power supply.

There shall be some kind of indication of the status of the battery that is adapted to all kind of users, e.g. persons with a visual or a hearing disability.

For guidance, see CEN/CENELEC Guide 6:2002, Tables 5 and 6.

8.5 Circuit protection

A fuse or over-current release shall be provided in each supply lead for class I equipment and for class II equipment having a functional earth connection, and in at least one supply lead for other single-phase class II equipment, except that:

- For permanently installed equipment, the neutral conductor shall not be fused.
- If examination shows that two means of protection are present between all parts of opposite polarity within the mains part, and between all parts of the mains part and earth, then the fuses or over-current releases may be omitted. These insulation requirements shall be continued up to and within any component. The effect of short-circuit fault conditions in other circuits shall be considered before eliminating fuses or over-current releases.

A protective earth conductor shall not incorporate a fuse or over-current release.

Protective devices shall have adequate breaking capacity to interrupt the maximum fault current (including short-circuit current) which can flow.

If fuses complying with EN 60127 are used and the prospective short-circuit current exceeds 35 A or 10 times the current rating of the fuse, whichever is greater, the fuses should have high breaking capacity (1 500 A).

- a) Thermal cut-outs and over-current releases with automatic resetting shall not be used in assistive products if their use could result in a hazardous situation by such resetting.

Compliance is checked by inspection of the risk management file.

- b) Thermal cut-outs with a safety function that have to be reset by a soldering operation that can affect the operating value shall not be fitted in assistive products.

Compliance is checked by inspection of the design documentation and the risk management file.

- c) In equipment where a failure of a thermostat could constitute a hazard, an independent non-self-resetting thermal cut-out shall additionally be provided. The temperature of operation of the additional device shall be outside that attainable at the extreme setting of the normal control device but shall be within the safe temperature limit for its intended function.

Compliance is checked by inspection of the design documentation and the risk management file.

- d) Loss of function of the equipment caused by operation of a thermal cut-out or over-current release shall not result in a hazardous situation.

Compliance is checked by inspection of the design documentation and the risk management file.

- e) Capacitors or other spark-suppression devices of equipment shall not be connected between the contacts of thermal cut-outs.

Compliance is checked by inspection.

- f) The use of a thermal cut-out or over-current release in the design shall not affect the safety of the equipment.