BS EN 12182:2012

BSI Standards Publication

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



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**National foreword**

This British Standard is the UK implementation of EN 12182:2012. It supersedes BS EN 12182:1999 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/173, Assistive products for persons with disability.

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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EUROPEAN STANDARD

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# EN 12182

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English Version

# Assistive products for persons with disability - General requirements and test methods

Produits d'assistance pour personnes en situation de handicap - Exigences générales et méthodes d'essai

Technische Hilfen für behinderte Menschen - Allgemeine Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 9 March 2012.

CEN 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 CEN-CENELEC Management Centre or to any CEN 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 CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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# Contents

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# Foreword

This document (EN 12182:2012) has been prepared by Technical Committee CEN/TC 293 “Assistive products for persons with a disability”, the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2012, and conflicting national standards shall be withdrawn at the latest by November 2012.

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

This document supersedes EN 12182:1999.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

This standard provides one means to demonstrate that assistive products for persons with a a disability, which are also medical devices, conform to the essential requirements outlined in general terms in Annex I of the EU Directive 93/42/EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with assistive products for persons with a disability. These are as follows, with Level 1 being the highest:

— Level 1: General requirements for assistive products;

— Level 2: Particular requirements for families of assistive products;

— Level 3: Specific requirements for types of assistive products.

Levels 2 and 3 may be combined into one single document.

All European Standards produced or currently being developed by CEN/TC 293 are listed in Annex A.

This standard is a Level 1 standard and contains requirements and recommendations which are generally applicable to assistive products for persons with a disability. For certain types of assistive products, these requirements are to be supplemented, modified or replaced by the special requirements of a standard for a particular assistive product (Level 2 or 3).

The Level 2 standards apply to a more restricted set or family of assistive products such as assistive products for walking. The Level 3 standards apply to specific types of assistive products, e.g. elbow crutches and urine collection bags.

Where standards for particular assistive products or groups of assistive products exist (Level 2 or 3), this general standard should not be used alone. The requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular assistive product, it is necessary to start with standards of the lowest available level.

European and International Standards for other assistive products for persons with a disability are being or may be developed by other technical committees within CEN/CENELEC, ISO/IEC (e.g. assistive products for hearing) and other organisations. For such assistive products, this Level 1 standard is only applicable if explicitly cited as a normative reference in the particular standard, although it may be used for general guidance within the field of assistive products for persons with a disability.

NOTE 1 Special care is required in applying this general standard to assistive products for which no particular standard exists to ensure that all aspects of safety are covered in the particular circumstances of the use of those assistive products. Guidance is given on aspects of the Essential Requirements of EU Directive 93/42/EEC to assist in this process.

NOTE 2 The use of assistive products may involve undesirable side effects and it is necessary to establish a balance between achieving the desired end result and the risk of such side effects. Hence, in exceptional circumstances, provision is made within this standard for clinical needs to override the requirements of this standard so long as adequate warnings are given.

NOTE 3 This standard calls for technical documentation to be prepared which may be used by manufacturers as part of the technical documentation required by EU Directive 93/42/EEC.

NOTE 4 Where this standard does not fully apply to particular assistive products, contracting parties should consider if appropriate parts of the standard can be used.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## 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 possibilites 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:

a) 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

b) 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<br>EN 60601-1<br>EN 60601-1-2<br>EN 60601-2-xx | EN 12182<br>EN 60335-1<br>EN 60335-2-xx | EN 12182<br>EN 60065 | EN 12182<br>EN 60950-1 |

NOTE This list may not be complete and might be updated due to furter 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.

Compliance is checked by inspection and, if applicable, by the following tests.

Verify compliance of Positive Temperature Coefficient devices (PTCs) with EN 60730-1 as applicable.

Thermal cut-outs and over-current releases shall be tested by operating the equipment.

Self-resetting thermal cut-out and self-resetting over-current releases including circuits that perform equivalent functions (other than PTCs) shall be caused to operate 200 times unless approved to the appropriate IEC component standard.

Manual reset thermal cut-outs and over-current releases shall be caused to operate 10 times if they are not approved to the appropriate IEC component standard.

Thermal protection devices shall comply with the appropriate IEC component standards or the manufacturer shall provide adequate data to demonstrate the reliability of the component to perform its safety-related function.

Thermal protection devices can be tested separately from medical electrical equipment where engineering judgement indicates that doing so would not impact the test results.

g) Equipment that incorporates a fluid filled container having heating facilities shall be provided with a protection device to safeguard against overheating in the event of the heater being switched on with the container empty. An unacceptable risk shall not occur from overheating.

   Compliance is checked by operating the relevant equipment with an empty container until the protection device activates.

h) Equipment that incorporates tubular heating elements shall have protection against overheating in both leads where a conductive connection to earth could result in overheating.

An internal electrical power source in equipment shall be provided with an appropriately rated device for protection against fire hazard caused by excessive currents if the cross-sectional area and layout of the internal wiring or the rating of connected components may give rise to a fire hazard in case of a short circuit.

## 8.6 Electronic programmable systems

Assistive products which are required to comply with the requirements of EN 60601-1 and which have an electronic programmable system shall also comply with the requirements of EN 62304.

## 8.7 Electrically heated blankets, pads and similar flexible heating appliances

An electrically heated blanket, pad or similar flexible heating appliances shall fulfil the requirements in EN 80601-2-35.

## 8.8 Assistive products with skin contact electrodes

Assistive products with skin contact electrodes shall comply with the requirements of EN 60601-1 for continuous leakage currents and patient auxiliary currents.

NOTE European standards exist for some types of medical assistive products with skin contact electrodes. In such cases this standard may not apply.

## 8.9 Ingress of liquids

Enclosures shall be classified according to the degree of protection against harmful ingress of water as detailed in EN 60529.

Compliance is checked by tests in EN 60529 placed in the least favourable position for normal use.

For equipment not in contact with water or body fluids, it shall be protected to IP X1.

For equipment that is in contact with water or body fluids it shall at least be protected to IP X4.

# 9 Overflow, spillage, leakage, and ingress of liquids

## 9.1 Overflow

### 9.1.1 Requirements

If an assistive product incorporates a reservoir or liquid storage chamber that may be overfilled or may overflow in the manufacturer's intended use, liquid overflowing from the reservoir or chamber shall not wet electrical insulation and live parts which are liable to be adversely affected by such a liquid, nor shall a safety hazard be created. Unless restricted by a marking or by the instructions for use, no safety hazards shall develop if assistive products are tilted through an angle that is 15º greater then the maximum inclination that can occur during intended use.

### 9.1.2 Test method

Fill the reservoir to the maximum level specified by the manufacturer and, if possible, add further liquid equal to 15% of the capacity of the reservoir or until the reservoir is full.

Tilt the assistive product through an angle of $15^{\circ}\ ^{+1^{\circ}}_{-0^{\circ}}$ in each direction(s) starting from the position of the manufacturer's intended use or the maximum angle of intended use, whichever is the most severe. If necessary, refill the reservoir between tests.

If the working position is a specified range the $15^{\circ}\ ^{+1^{\circ}}_{-0^{\circ}}$ shall add to the extreme position of this range.

These procedures shall not wet parts of the assistive product that will cause a hazard. In particular, an assistive product shall show no signs of wetting of un-insulated live parts or electrical insulation of parts which may cause a safety hazard. For electrical insulation, in case of doubt, the assistive product shall be subjected to the dielectric strength test as described in EN 60601-1.

## 9.2 Spillage

### 9.2.1 Requirements

Assistive products requiring the use of liquids for the manufacturer's intended use shall be so constructed that spillage does not wet parts which may cause a safety hazard in the product.

### 9.2.2 Test method

Position the equipment as in the manufacturer's intended use. Pour 200 ml $^{+5}_{-0}$ of water steadily on an arbitrary point on the top surface of the assistive product.

After the test, the assistive product shall function as specified by the manufacturer.

## 9.3 Leakage

Assistive products shall be so constructed that liquid which might escape in single fault condition does not cause a safety hazard.

## 9.4 Ingress of liquids

### 9.4.1 Requirements

If liquid unintentionally can come into an enclosure there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any harm.

The hazards that can be caused by the ingress of liquids to non-electrically powered assistive products shall be assessed in the risk analysis (see 4.1).

NOTE 1 See B.9.4.

NOTE 2 For requirements for electrically powered assistive products see 8.9.

#### 9.4.2 Test method

Test if the liquid can get out of the enclosure by tilting it 10 degrees to each direction. If there still is liquid in the enclosure test the equipment to check if it fails to work, or if the liquid is likely to cause any harm.

## 10 Surface temperature

The risk analysis (see 4.1) shall identify hazards and evaluate the risks associated with the surface temperature of parts which can come into contact with human skin during the intended conditions of use.

The risk analysis shall take account of:

a) the range of ambient temperatures to be expected during the intended use and foreseeable misuse;

NOTE These temperatures could include direct exposure to sunshine, extreme cold, saunas, etc.

b) temperatures that may result from single fault conditions;

c) the ergonomic data on acceptable temperatures of touchable surfaces in EN ISO 13732-1;

d) the use of assistive products by people with insensitive skin (i.e. cannot feel heat) and/or damaged skin: in this case the maximum temperature shall not exceed 41° C when measured by the methods of test in EN ISO 13732-1; except that:

   1) if a manufacturer cannot meet this requirement without impairing the intended performance of the assistive product, each assistive product should be supplied with a warning identifying which surfaces may reach a higher temperature than that specified and a description of the precautions necessary to offset the increased risk; and

   2) if a manufacturer cannot meet the surface temperature requirement the reasons shall be set out in the technical documentation (see 4.2).

## 11 Sterility

### 11.1 Sterility requirements

If the assistive product is intended to be sterilised, the method shall be described in the information supplied by the manufacturer.

An assistive product which is labelled "STERILE" shall conform to the requirements of EN 556-1.

### 11.2 Sterilization processes

Sterilization processes shall be validated and routinely controlled.

If an assistive product is sterilized by ethylene oxide the process shall conform to the requirements of EN ISO 11135-1.

If an assistive product is sterilized by steam the process shall conform to the requirements of EN ISO 25424.

If an assistive product is sterilized by radiation the process shall conform to the requirements of EN ISO 11137-1 and EN ISO 11137-2.

### 11.3 Maintenance of sterility in transit

The packaging shall conform to the requirements of EN ISO 11607-1.

## 12 Safety of moving parts

### 12.1 Squeezing

Unless the intended purpose of an assistive product, or part of an assistive product, is to grip, cut, squeeze etc., or if the intended use cannot be achieved without a hazard such as risk of squeezing (e.g. the elbow or knee flexion of a limb prosthesis):

a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed by the use of a tool; or

b) the gap between exposed parts of an assistive product that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in Table 2:

**Table 2 — Safe distances between moving parts**

| To avoid | Safe distances for adults | Safe distances for children |
|---|---|---|
| Finger traps | Less than 8 mm or more than 25 mm | Less than 4 mm or more than 25 mm |
| Foot traps | Less than 35 mm or more than 120 mm | Less than 25 mm or more than 120 mm |
| Head traps | Less than 120 mm or more than 300 mm | Less than 60 mm or more than 300 mm |
| Genitalia traps | Less than 8 mm or more than 75 mm | Less than 8 mm or more than 75 mm |

or

c) if cords (ropes), chains and drive belts are used, they shall either be confined so that they cannot run off or jump out of their guiding devices, or a safety hazard shall be prevented by other means. Mechanical means applied for this purpose shall be removable only by the use of a tool; or

d) the assistive product shall incorporate a control device which initiates the movement when it is operated and stops the movement when it is released (e.g. a spring loaded control device that returns to the stop position when released); or

e) the assistive product shall incorporate a means for detecting that a person is in danger of being trapped and automatically activating a means of preventing injury (e.g. by stopping the movement).

For moving parts that can cause squeezing, manufacturers shall take into consideration what part/parts of the body that are at risk. The user/user group has to be specified, so that correct safety distances can be applied.

NOTE A product intended to be used by a child may also be operated by an adult.

### 12.2 Mechanical wear

Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection.

### 12.3 Emergency stopping functions

If there is a risk for the user to be squeezed or a single fault appearing that might create a safety hazard there shall be an emergency stop as specified in EN ISO 13850 together with the following requirements:

— The assistive product shall be designed to prevent accidental damage or stopping movements.

— The user shall be able to reach the emergency stop easily, and stop the dangerous situation within one action.

— The stopping device shall maintain the equipment in a safe position, but not interfere with other critical functions.

— The emergency stopping device shall maintain the assistive product in a stopped position until it is realesed by a designated procedure

— The designated procedure for the release of the emergency stop shall require two independent actions.

— A safe stopping distance shall be considered in the risk analyses.

## 13 Prevention of traps for parts of the human body

### 13.1 Holes and clearances

Holes in, and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of an assistive product shall be as specified in Table 3.

**Table 3 — Safe distances between stationary parts**

| To avoid | Safe distances for adults | Safe distances for children |
|---|---|---|
| Finger traps | Less than 8 mm or<br>more than 25 mm | Less than 5 mm or<br>more than 12 mm |
| Foot traps | Less than 35 mm or<br>more than 100 mm | Less than 25 mm<br>or more than 45 mm |
| Head traps | Less than 120 mm or<br>more than 250 mm | Less than 60 mm or<br>more than 250 mm |
| Genitalia traps | Less than 8 mm or<br>more than 75 mm | Less than 8 mm or<br>more than 75 mm |

If the intended purpose of an assistive product cannot be met without a hazard caused by the size of holes and the clearance between stationary parts, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.

For stationary parts that can cause a trap, manufacturers shall take in consideration what part/parts of the body that are at risk. The user/user group has to be specified, so that correct safety distances can be applied.

NOTE 1 A product intended to be used by a child may also be operated by an adult.

The design of parts that confine a hole or clearance shall take into consideration the forces that can be applied in normal use.

NOTE 2 A force might cause a hole/clearance to widen. This can then cause a failure, as specified in Table 3.

On holes with the shape of a keyhole or V-shaped openings the lower limit shall not apply. When inspecting the assistive product for traps for body parts any flexibility/elasticity of adjacent parts shall be taken into account.

### 13.2 V-shaped openings

The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. Particular guidance can be found in B.13.2.

## 14 Folding and adjusting mechanisms

### 14.1 General

Folding and adjusting mechanisms may cause a hazard if parts of the body can enter a gap between parts and be trapped when the gap is closed.

If an assistive product incorporates folding and/or adjusting mechanisms it shall conform to 14.2 and 14.3.

### 14.2 Locking mechanisms

The mechanisms shall be capable of being securely locked when the assistive product is in any fixed working configuration. It shall also be capable of being securely locked when folded if it constitutes a risk for the user or assistant. The product shall fold in a safe manner.

### 14.3 Guards

Either:

a) the assistive product shall incorporate means to protect the user from trap and/or squeeze hazards; or

b) the gap between exposed parts of an assistive product that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in Table 2; or

c) if the intended purpose of an assistive product cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.

The design of a guard shall take into consideration the forces that can be applied in normal use.

## 15 Carrying handles

### 15.1 General

Manufacturers should note that national and other requirements may demand test loads in excess of the following.

If an assistive product is intended by the manufacturer to be portable and it has a mass of more than 10 kg, it shall have one or more carrying-handles suitably placed which enable the assistive product to be carried by two or more persons. If an assistive product or parts of an assistive product have a mass of more than 10 kg and need to be handled in the manufacturer's intended use, they shall either:

a) be provided with suitable handling devices (e.g. handles, lifting eyes); or

b) the instructions for use shall indicate the points where assistive products can be lifted safely and describe how they should be handled during lifting, assembly and/or carrying; if practical, the component parts shall be labelled to indicate where the assistive product can be lifted safely and/or how it can be handled during assembly and/or carrying.

### 15.2 Requirement

If an assistive product incorporates carrying handles or grips, they shall not become detached from the assistive product and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in 15.3.

After the completion of the test the assistive product shall operate as intended by the manufacturer.

### 15.3 Test method

If an assistive product has one handle or grip, or if an assistive product can be readily carried or lifted by one of a number of handles or grips, determine the force on each handle or grip when it is carried or lifted.

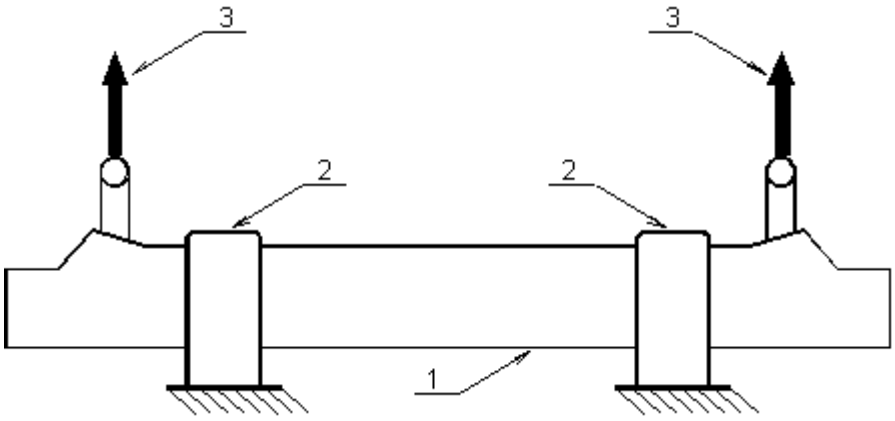
If an assistive product has more than one handle or grip, determine the force on each handle or grip when the assistive product is carried or lifted in the intended manner.

On each handle or grip determine the force necessary to carry the assistive product in the intended manner with a tolerance of $^{+5\,\%}_{-0\,\%}$. If there is more than one intended manner determine the highest force.

Restrain the assistive product from being lifted or moved during the following test. Apply a force to each handle or grip, equal to twice that determined above with a tolerance of $^{+5\,\%}_{-0\,\%}$, uniformly distributed over a 70 mm ± 5 mm length in the centre of the handle or grip, avoiding shock (see Figure 1).

Maintain the force for between 60 s and 70 s.

Remove the force and the restraints and inspect the assistive product for damage and satisfactory operation.




**Key**
1 assistive product
2 restraints
3 test force

**Figure 1 — Carrying handle test (example)**

## 16 Assistive products which support or suspend users

### 16.1 General

If an assistive product is intended to support or suspend a person with a disability and/or an assistant or load, no part of the assistive product shall become detached, exhibit cracking, permanent deformation, loss of stability or any other failure when tested as specified in 16.2 and 16.3. After the test, the assistive product shall operate as intended by the manufacturer.

If an assistive product is intended to fold for transport and/or storage, it shall not fold when tested as specified in 16.2 and 16.3.

## 16.2 Static forces

Position the support or suspend system in the least favourable position of intended use.

Apply a test load to the support surface in the worst case position and in a manner that ensures that there is negligible dynamic loading. The test load is equal to the maximum rated load, including any accessories, specified by the manufacturer, with a tolerance of $^{+5\,\%}_{-0\,\%}$, multiplied by a safety factor. The safety factor is equal to 1,5 for a supported system. For a suspended system, the safety factor is as specified in Table 4.

Maintain the test load for between 60 s and 70 s.

Remove the test load and inspect the assistive product for damage. The product shall still function normally.

**Table 4 — Loads on suspended systems**

| Lifting accessories | Loads |
|---|---|
| Wire-rope | 5 times |
| Chains | 4 times |
| Textile ropes or slings | 7 times |
| Metallic components | 4 times |
| Manually operated machinery | 1.5 times |

## 16.3 Dynamic forces

Apply a test load equal to the maximum rated load intended by the manufacturer for a supported and suspended system (including any accessories) with a tolerance of $^{+5\,\%}_{-0\,\%}$, to the support surface in the worst case position (in a manner that ensures that there is negligible dynamic loading). The test cycle shall be calculated from normal use and life time of the product.

## 16.4 Requirements and test method for tips

### 16.4.1 General

If the assistive product is provided with a tip that carries or supports the user, it shall be safe in its use and environment.

EXAMPLES A shower chair, a crutch.

### 16.4.2 Friction of tips

For safety of friction of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the relevant parts of EN ISO 24415-1 shall be used.

### 16.4.3 Durability of tips

For durability of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the relevant parts of ISO 24415-2 shall be used.

# 17 Portable and mobile assistive products

A portable assistive product or any of its parts that is portable shall withstand the stresses caused by a free fall from the height indicated in Table 5 onto a hard surface.

Compliance is checked by the following test:

The sample to be tested, with the maximum recommended rated load in place, is lifted to a height as indicated in Table 5 above a 50 mm ± 5 mm thick hardwood board (for example, > 600 kg/m$^3$) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board shall be at least those of the footprint of the sample tested. The sample is dropped three times from each orientation in which it may be placed during the intended use.

**Table 5 — Drop height**

| **Mass (*m*) of portable assistive product or its parts** kg | **Drop height** cm |
|---|---|
| $m \leq 0{,}2$ | 100 |
| $0{,}2 < m \leq 1$ | 20 |
| $1 < m \leq 10$ | 5 |
| $10 < m \leq 50$ | 3 |
| $m > 50$ | 2 |

After the test, the equipment shall be inspected for any damage, which results in an unacceptable risk or loss of function. Any such damage constitutes a failure.

A mobile assistive product and any of its parts that is mobile shall withstand the stresses caused by rough handling and movement and shall not result in an unacceptable risk or loss of function.

Compliance is checked by the following tests.

The sample is tested in the intended transport position with maximum rated load in place and in the most adverse condition permitted for the intended use.

a) Ascending step shock:

The sample is pushed three times in its intended direction of travel at a speed of 0,4 m/s ± 0,1 m/s or, for motor driven mobile assistive product, the maximum speed capable of being maintained, against an ascending hardwood step obstruction with vertical face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample does not need to go over the 40 mm obstruction.

b) Descending step shock:

The sample is pushed three times in its intended direction of travel at a speed of 0,4 m/s ± 0,1 m/s or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, in order to fall over a descending vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete). The direction of movement is perpendicular to the face of the descending step.

During performance of the descending step shock test, if a part other than a wheel comes in contact with the obstruction before one of the wheels touches the ground, the equipment continues to be pushed until it has fully descended.

c) Door frame shock:

The sample is moved three times in its normal direction of travel at a speed of 0,4 m/s ± 0,1 m/s, or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, against a hardwood vertical obstacle having suitable dimensions that is affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle must be at the height of the equipment's contact point(s). The direction of movement is perpendicular to the face of the obstacle.

After each test, the sample shall be inspected for any damage, which results in an unacceptable risk or loss of function. Any such damage constitutes a failure.

## 18 Surfaces, corners, edges and protruding parts

If not required for the intended function of an assistive product, all accessible edges, corners and surfaces shall be smooth and be free from burrs and sharp edges.

If not required for the intended function, assistive products shall not have protruding parts. Where possible, necessary protruding parts shall have protection to prevent injury and/or damage.

NOTE For guidance, see B.18.

## 19 Hand held assistive products

An assistive product and any of its parts that is hand-held during its intended use shall not result in an unacceptable risk or loss of function as a result of a free fall.

Compliance is checked by the following tests:

The sample to be tested, with the maximum rated load in place, is allowed to fall freely once from each of three different starting orientations encountered during the intended use from the height at which the assistive product is used (as defined by the manufacturer specified in the accompanying documents), or from a height of 1 m, whichever is greater, onto a 50 mm ± 5 mm thick hardwood board (hardwood > 600 kg/m$^3$) lying flat on a concrete or a similar rigid base.

After the test, the hand-held assistive product and any of its parts that are hand-held during their intended use shall not result in an unacceptable risk or loss of function.

NOTE 1 There may be a hand-held assistive product that might need more drops due to its intended use or user group.

NOTE 2 For guidance, see B.19.

## 20 Small parts

Assistive products and their parts intended to be used by small children shall not be of a size where they can create a danger to small children being choked.

NOTE For guidance, see B.20.

## 21 Stability

For safety of stability of any assistive product, other than fixed or handheld, intended to be placed on a floor, table or on the ground, the relevant parts of EN 60601-1:2006 including parts 9.4.1, 9.4.2, 9.4.3 shall be used.

NOTE Relevant parts are dependent on the intended use of the product.

## 22 Forces in soft tissues of the human body

The hazards that can be caused by forces applied to the soft tissues of the body shall be assessed in the risk analysis (see 4.1).

NOTE For guidance, see B.22.

## 23 Ergonomic principles

An assistive product shall be designed to the ergonomic principles set out in EN 614-1 taking into account the special needs of the person with a disability for whom the assistive product is intended.

An assistive product may be used not only by whom it is primarily intended for, but also by an assisting person. The ergonomic principles set out in EN 614-1 shall apply to all involved persons.

Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:

a) the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm;

b) the distance between any upper surface of a pedal (in its operating position) and any other part of the assistive product shall have a vertical toe clearance of not less than 75 mm;

c) the diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between19 mm and 43 mm;

d) for assistive products operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor;

e) for assistive products operated from a standing position, hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the surface of the floor;

f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.

NOTE 1 For guidance on operating forces, see B.23.

NOTE 2 Some operating controls may need other positions depending of the use of the assistive product.

## 24 Requirements for information supplied by the manufacturer

### 24.1 General

The information supplied by the manufacturer comprises the data in the instructions for use and the details on the label.

The information applied to, and supplied with, assistive products shall conform to EN 1041.

Assistive products covered by the scope of a specific standard shall also, in addition to EN 12182, conform to the requirements according to the clause dealing with information regarding electrical aspects of the product.

Any means of provision of information with assistive products shall take into account the intended users, the conditions of use and any issues specific to individual assistive product types that are necessary for the safe and effective use of the product.

Special attention shall be paid to the user information, particulary the instructions on operation and the design of labels and the design and presentation of warnings.

Further guidance on requirements for persons with different type of impairments can be found in CEN/CENELEC Guide 6:2002, Tables 1, 2, 4 and 6, and in Annex C, Cognitive impairment.

In addition, the manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information as specified in 24.2.1, 24.2.2 and 24.2.3. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.

Further guidance on the preparation of instructions can be found in EN 62079.

If the manufacturer is not located in the European Community, the manufacturer is required to designate an 'EC authorised representative' established in the European Community. In such cases and to comply fully with the Essential Requirements of EU Directive 93/42/EEC on medical devices, the name and address of the authorised representative are required.

## 24.2 Instructions for use

### 24.2.1 Pre-sale information

In addition to the requirements of 24.1, pre-sale information shall include the following:

a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities;

b) all information shall as far as possible be available in Pictogram;

c) a description of the intended use and the intended environment;

d) maintenance instructions, if applicable;

e) if an assistive product is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable;

f) if an assistive product is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable;

g) the overall dimensions (width, length and height) of the assistive product, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled;

h) the mass expressed in kilograms if the assistive product can be dismantled or has any removable parts that has a mass which is heavier than 10 kg;

i) if the assistive product is supposed to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way;

j) warning about dangerous combinations of devices (e.g. cushions for the prevention of decubitus ulcers often only work on correct seat surface) and combinations of flame resistant and non-flame resistant material;

k) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product;

l) if a programmable controller is fitted, information on the method of programming, the competence required to carry out the programming and the effects on performance;

m) operator control adjustments;

n) whether and how the assistive product can be folded or dismantled to assist in storage or transport;

o) instructions regarding transport of the assistive product (e.g. in a car or aeroplane);

p) measured sound power level.

### 24.2.2 User information

User information shall be provided by the manufacturer with each assistive product. Information shall contain all pre-sale warnings and informations and the following as applicable for each assistive product:

a) the location and the type of identification number/word on the assistive product shall be given for the unique identification number of the assistive product;

b) the intended user;

c) any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product;

d) information on adjustment possibilities and the competence required to carry out these adjustments;

e) instructions on operation of all controls;

f) the battery type and nominal voltage;

g) instructions for battery maintenance;

h) instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area);

i) instructions on dismantling and re-assembly of the assistive product or any removable parts;

j) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;

k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);

l) a warning if the assistive product might disturb the operation of devices in its environment that emit electromagnetic fields (e.g. alarm systems of shops, automatic doors, etc.);

m) a warning if the performance of the assistive product can be influenced by electromagnetic fields (e.g. those emitted by portable telephones, electricity generators or high power sources);

n) if the intended purpose of an assistive product cannot be met without a hazard (e.g. holes, V-shaped opening), a warning and instructions on how to operate the assistive product safely;

o) if the intended purpose of an assistive product cannot be met without a hazard due to moving parts such as squeezing, a warning and instructions on how to operate the assistive product safely;

p) the level of resistance to ignition of materials and assemblies;

q) information on the recycling of used batteries and other parts of the assistive product;

r) expected lifetime of the assistive product.

It is recommended to include instructions on how to solve simple problems for the ease of use.

#### 24.2.3 Service information

The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the assistive product and for the replacement of parts.

The service information shall contain all the pre-sale information and the user information.

The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.

The service information shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the assistive product.

Additionally, the service information shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the periods to be applied and details about the actual performance of such maintenance.

### 24.3 Labelling

In addition to the requirements of 24.1, the manufacturer shall apply permanent labels for the year of production for the product;

Detachable parts of an assistive product with a mass of more than 10 kilograms shall be marked with the actual mass on the part.

Symbols for use in the labelling of medical devices shall be in accordance with EN 980.

## 25 Packaging

The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 4.1).

NOTE For guidance, see B.25.

## 26 Test report

The test report shall at least contain the following information:

a) unique report number;

b) the name and address of the testing institution;

c) the date of issue of the test report;

d) a reference to this edition of this European Standard, i.e. EN 12182:2012;

e) the name and address of the manufacturer of the assistive product;

f) a description of the sample including the manufacturer's or vendor's trade mark, model or type, serial number and any variations or accessories fitted;

g) the source of the sample;

h) the ambient temperature at which each test was carried out;

i) where the controller is programmable, the settings used while testing;

j) a photograph of the sample equipped as during the test;

k) the results of the tests;

l) a statement of whether or not the tested sample met all of the applicable requirements of this European Standard and a list of all the failed requirements.

# Annex A
(informative)

## European standards for assistive products for persons with a disability produced or currently being developed by CEN/TC 293

EN 1985, *Walking aids — General requirements and test methods*

EN 12182, *Technical aids for disabled persons - General requirements and test methods*

EN 12183, *Manual wheelchairs — Requirements and test methods*

EN 12184, *Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods*

EN ISO 8669-2, *Urine collection bags — Part 2: Requirements and test methods (ISO 8669-2)*

EN ISO 8670-2, *Ostomy collection bags — Part 2: Requirements and test methods (ISO 8670-2)*

EN ISO 9999, *Assistive products for persons with disability — Classification and terminology (ISO 9999)*

EN ISO 10328, *Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328)*

EN ISO 10535, *Hoists for the transfer of disabled persons — Requirements and test methods (ISO 10535)*

EN ISO 11199-1, *Walking aids manipulated by both arms — Requirements and test methods — Part 1: Walking frames (ISO 11199-1)*

EN ISO 11199-2, *Walking aids manipulated by both arms — Requirements and test methods — Part 2: Rollators (ISO 11199-2)*

EN ISO 11199-3, *Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables (ISO 11199-3)*

EN ISO 11334-1, *Assistive products for walking manipulated by one arm — Requirements and test methods — Part 1: Elbow crutches (ISO 11334-1)*

EN ISO 11334-4, *Walking aids manipulated by one arm — Requirements and test methods — Part 4: Walking sticks with three or more legs (ISO 11334-4)*

EN ISO 16021, *Urine-absorbing aids — Basic principles for evaluation of single-use adult-incontinence-absorbing-aids from the perspective of users and caregivers (ISO 16021)*

EN ISO 16201, *Technical aids for disabled persons — Environmental control systems for daily living (ISO 16201)*

EN ISO 22523, *External limb prostheses and external orthoses — Requirements and test methods (ISO 22523)*

EN ISO 22675, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods (ISO 22675)*

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

EN 60601-2-52, *Medical electrical equipment — Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52)*

Details of standards containing further requirements for particular products and groups of products can be obtained from national standards bodies.

NOTE European and International Standards for other assistive products for persons with a disability are being or may be developed by other technical committees within CEN/CENELEC, ISO/IEC (e.g. hearing aids) and other organisations. For such assistive products, this Level 1 standard is only applicable if explicitly cited as a normative reference in the particular standard, although it may be used for general guidance within the field of assistive products for persons with a disability.

# Annex B
(informative)

# General recommendations

The numbering of the clauses in this Annex corresponds to the numbers of the clauses and subclauses in the main text to which the guidance applies (e.g. B.5.2 refers to 5.2 in the main text).

## B.5.2 Flammability

When considering the flame resistance of assistive products, manufacturers should note that persons with a disability may be at greater risk than able-bodied persons as they may be unable to escape from fire.

Hazards which should be considered include:

— smoker´s materials;

— stoves, ovens and other cooking devices;

— fires and other space heaters;

— electrostatic charges.

Particular care is needed if an assistive product may be used near or in conjunction with flammable substances.

### B.5.5.1 Cleaning and disinfection

An assistive product should be easy to clean and should not incorporate features which will retain dust, liquid and/or contaminated material, except where the intended function of the assistive product is to retain such material.

An assistive product, other than single use assistive products, which may come into contact with body fluids should be able to be disinfected repeatedly by readily available disinfectants without damage to the assistive product.

An example of marking for machine washable assistive products by an automatic washing system is shown in Figure B.1.

**Figure B.1 — Example of marking for machine washable assistive product**

An example of marking for assistive products intended to be cleaned by hand held jet stream/steam cleaning is shown in Figure B.2.

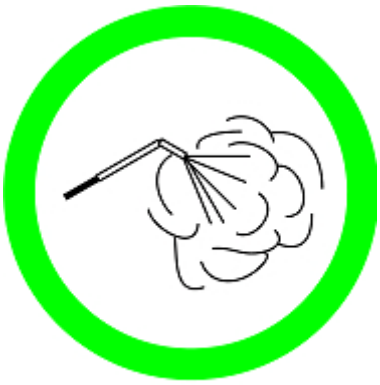


**Figure B.2 — Example of marking for assistive products intended to be cleaned by hand held jet stream/steam cleaning**

An assistive product specified by the manufacturer to be machine washable by an automatic washing system should function normally after the test.

Variations to the test procedure regarding test-cycle, temperature, time and cleaning fluids should be covered in the risk management file of the manufacturer.

The present test method is representing a basic procedure for disinfection of an assistive product in a washing machine.

Compliance is checked by the following tests:

a) parts and access covers which can be detached/opened without the use of a tool should be detached/opened:

   1) temperature preconditioning treatment of 10 days at 65 °C ± 2 °C or at maximum value of the rated storage temperature, if higher, is carried out;

   2) the assistive product should then be kept at room temperature for not less than 16 hours;

b) 50 test cycles according to the procedure the manufacturer described in the instruction for use or consisting of:

   1) 2 minutes wash with 70 °C water at a ph-value 5-8, 0,5 % cleaning and disinfectant solution as specified by the manufacturer;

   2) 20 seconds rinse with 85 °C water at a ph-value 5-8, and 0,2 % clear rinsing solution according to the data of the manufacturer;

   3) 10 minutes cooling at 20 °C ambient temperature.

Acceptance criteria:

   4) Immediately after the test cycles, the assistive product is connected to mains; no unintentional movements should arise;

   5) The assistive product should function as specified by the intended use at the following intervals:

      i) immediately after the test cycles;

ii) 5 min (± 1 min) after the test cycles;

iii) 60 min (± 5 min) after the test cycles;

iv) 24 h (± 30 min) after the test cycles;

6) Perform dielectric strength and leakage current tests according to EN 60601-1 at the following intervals:

i) immediately after the test cycles;

ii) 24 h (± 30 min) after the test cycles;

7) Perform a visual inspection for ingress of water that may result in an unacceptable risk (i.e. shorting of isolation barriers and violation of creepage distances).

NOTE For some assistive products not all acceptance criteria apply (i.e. for manually operated assistive products, electrical acceptance criteria would not apply).

#### B.5.5.2 Animal tissue

Manufacturers should be aware that such products can carry infection and microbial contamination and should examine them for signs of disease or contamination. This is of particular important when there is a possibility of contact with damaged skin.

Typical materials and products affected are:

— leather (shoes, thigh cuffs, prosthetic sockets);

— sheepskin (seating assistive products);

— pig bristle (brushes);

— human hair (wigs).

### B.6.1 Noise and vibration

Manufacturers should evaluate any noise and vibration from powered assistive products in the intended environment(s) of use. Care should be taken of the possible sensitivity of pets.

Where specific standards are not available, manufacturers should determine what appropriate methods of test are available in other standards and supplement these with a panel consisting of disabled users, carers and appropriate professionals to assess the acceptability of noise and vibration.

Noise levels should be related to the circumstances in which an assistive product is used.

Noise should be reduced as much as possible at its source.

Manufacturers should consider the following standards relating to the effects of vibration:

— ISO 2631-1;

— EN ISO 5349-1;

— EN ISO 5349-2.

### B.7.4 Power frequency magnetic field immunity

When specifying the EMC performance of an assistive product, manufacturers are recommended to consider the already widely established environments:

— residential, commercial and light industrial;

— industrial;

— other (typically meaning more harsh environments and some specific places such as surgical theatres or near specific machinery, e.g. transmitters).

A user should be able to use an assistive product in all the manufacturer's intended environments of use for the assistive product with the minimum of limitation. The manufacturer should make it clear in simple language when limitations exist by describing the circumstances that must be avoided and should explain the consequences of exposing the assistive product to a potentially dangerous environment, e.g. radio transmitters. If possible, any appropriate actions that will offset any hazard should be described.

### B.8.5 Circuit protection

If an assistive product may be overloaded in use, and operation of a circuit protection device may leave the person with a disability at risk, consideration should be given to the use of resettable circuit breakers located within the reach of the user or automatic resetting circuit breakers.

If an assistive product incorporates independent circuits with significantly different current levels, each circuit or group of circuits should have separate circuit protection (e.g. separation of drive and lighting circuits on a wheelchair).

### B.9.4 Ingress of liquids

Assistive products, such as bath assistive products, which are intended to be repeatedly immersed in water or other liquids should be constructed to withstand repeated immersion without causing a safety hazard.

### B.13.2 V-shaped openings

A V-shaped opening should be at least 75 degrees.

This will reduce the risk for a user to be trapped by the head or other parts of the body at any position.

## B.18 Surfaces, corners, edges and protruding parts

The requirements set in EN 1888:2003, 6.1.3, should be applied.

For guidance on test methods for protruding parts see EN 716-2:2008, 5.9.

## B.19 Hand held assistive products

Hand-held control devices for a powered assistive product should be capable of withstanding being dropped 50 times onto a hard surface from a height of 1 m without damage.

Manufacturers should consider the suitability of the appropriate tests in EN 60068-2-32.

The risk analysis (see 4.1) should consider all the conditions of use, misuse and abuse and the manufacturer should ensure that the assistive products will operate satisfactorily in service.

Manufacturers are recommended to inform users of any tests that have been performed.

## B.20 Small parts

Regarding assistive products for children, any part that can be detached without the use of a tool should not fit wholly within the cylinder as specified in EN 716-2:2008, 5.4.

NOTE Small children are considered to be under the age of 5.

## B.22 Forces in soft tissues of the human body

People with disabilities resulting in sensory loss in soft tissues and impaired mobility are particularly susceptible to develop pressure ulcers. In general, there is a high prevalence of pressure ulcers among hospital patients, nursing home patients and home care residents.

Pressures ulcers can cause acute discomfort and suffering and result in a severely reduced quality of life. They also add a heavy economical burden to health services and society as a whole.

**1) Overview of causes**

In general, pressure ulcers are caused by the sustained deformation of soft tissues to impede arterial and venous blood flow, eventually causing tissue necrosis (death).

There are many contributory factors external to the body which contribute to the development of pressure ulcers. Pressure, shear and friction have been identified as major contributors, along with temperature, humidity and moisture of the environment immediately next to the tissues. The time these conditions are maintained also influences the occurrence and severity of the pressure ulcer.

The design of assistive technology devices requires to take into account their effects primarily on the severity of the external factors causing pressure ulcers as follows:

**2) Effects of posture**

Pressure ulcers occur most frequently where pressures are highest – that is over the bony prominences of the body which carry body weight. This corresponds, during lying, to the sacrum, greater trochanters, heels and elbows; and during sitting, to the sacrum and ischial tuberosities.

**3) Pressure**

Gravity is the major contributor to pressure on body tissues. It is usually considered to act perpendicular to the plane of the tissues.

One way of reducing the pressure over certain parts of the body is to distribute it over as large an area as possible. Typically, this involves using soft conforming materials which allow the body to sink into the material. Foams, or fluid filled flexible pads are frequently used for this purpose. Alternatively, forces may be redistributed to tissues which may be more resistant to pressure, for example in cushion designs which cut away areas under the ischial tuberosities and build up surfaces under the thighs.

NOTE Because pressure ulcers are caused by a wide variety of factors, there is no one threshold of pressure below which pressure ulcers will not occur.

**4) Time**

The time forces are applied to tissues is routinely limited by ensuring that people carry out regular changes of posture and move between different support surfaces at regular intervals. Some support surfaces change their surface profile to limit the time forces are applied to specific tissues. Other support surfaces alter the pressure on parts of the body within short time intervals, e.g. alternating air mattresses.

**5) Shear forces**

Shear forces are also considered to be a major contributor to the causes of pressure ulcers and in combination with pressure the risk will increase. They act parallel to the planes of the tissues and can cause severe deformation. This can occur when the skin remains stationary on the supporting surface whilst the underlying body structure moves, such as when a person slides down a tilted bed or chair

One way of reducing shear forces is to keep the patient in a 180° horizontal lying position. However, this position may not be tolerated by people with breathing difficulties.

By restricting the elevation of a head/back section support of the assistive technology to less than 20° the shear forces will be reduced. However, in positions with the head/back section elevated more than 20° it will be neccessary to elevate the knees (upper leg section) to a position of at least 10° above horizontal in order to reduce the effect of the shear forces from the back elevation and displacement of the body.

Allowing the knees to bend at the same time by lowering the lower leg section will reduce pressure at the heels and give a more comfortable sitting position (relaxing the hamstring muscles and tendons).

Similarly, wheelchair seating systems should be designed to have cushions which inhibit the tendency to continuously slide down the seat. Care should be taken when increasing the angle of backrest recline as this will increase the tendency for shear forces to occur due to sliding.

**6) Friction**

Skin injuries similar to pressure ulcers can occur when people are slid over support surfaces, e.g. bed linens. Typically, this occurs when transferring from one support surface to another. Most friction injuries can be avoided by using appropriate techniques when moving individuals so that their skin is lifted clear of the surfaces and never dragged across them.

Voluntary and involuntary movements by the individuals themselves can lead to friction injuries, especially on elbows and heels. Assistive products can be designed with materials that reduce this contact or that decreases the friction between the skin and the support surface.

**7) Temperature**

Higher temperatures cause the metabolic rate of tissues to increase along with a corresponding increase in demand for blood supply. They also increase sweating and raise risks from humidity and moisture.

Ideally support surfaces should conduct heat away from the body to minimise this risk. Unfortunately, many materials such as foams which are good pressure distributors tend to be good insulators and cause increased temperatures.

**8) Humidity and moisture**

Humidity and moisture in the environment are thought to increase risk of pressure ulcers through their effect on the mechanical strength of tissues. These conditions can be exacerbated by sweating caused by high temperatures or by the presence of incontinence.

**9) Risk assessment**

The provision and design of any assistive products which are intended to support the body or cause forces to be applied to the body should consider the risks of causing pressure ulcers. They should minimise these risks appropriately for the susceptibility of the individuals for whom they are intended and balance them against the risks of other adverse effects of use of the device.

## B.23 Ergonomic principles

Guidance on the design and location of control actuators for able people in industry is given in EN 894-3. This guidance should be used with caution as persons with a disability may need special features to suit their disability. In most cases control forces should not exceed the following:

- the operating force for levers used to activate or release a feature by hand should not exceed 60 N;
- the operating force for levers used to hold or move a feature for a significant time should not exceed 13 N (e.g. the joystick of a wheelchair);
- the operating force for levers used to activate or release a feature by foot should not exceed 60 N in a "pulling direction" and 100 N in a "pushing direction";
- the operating force for devices used to activate or release a feature by finger action should not exceed 5 N.

Persons with a disability are likely to suffer from weakness and lack of control in their limbs. In order to facilitate the operation of a particular feature and also to avoid accidental operations certain ergonomic criteria should be considered: a minimum threshold for the operating force to be applied by the user is advisable; size, position and spacing between control mechanisms should be appropriate. The user should receive feedback from the mechanism (i.e. by light, click, noise, etc.) to make certain that it has actually been operated.

## B.25 Packaging

The packaging of an assistive product is intended to provide appropriate protection against damage, deterioration or contamination during storage and transportation to the point of use. The various forms of storage and the types of transportation that might be encountered therefore should be considered, and the effectiveness of the packaging checked.

# Annex C
(informative)

# Cognitive impairment

## C.1 Introduction

The concept of cognitive impairment is complex and involves a large number of different mental characteristics that may be relevant when designing assistive products - reduced understanding, planning or attention capacity etc - due to traumatic brain injury, dementia, Alzheimer's disease, ADHD or other mental disorders.

As persons become elderly they will often be affected by cognitive limitations or impairments, for example reduced memory and learning capacity, and they will also need more assistive products and services. As most users of assistive products and services are elderly, the demographic development in many parts of the world is of significant importance to the providers of assistive products and services.

A cognitive impairment is not visible and can therefore be easily overlooked. It is not obvious to others what kind of problems these people meet. As more and more daily life activities in our information society are related to cognitive abilities, this impairment can lead to severe problems. Furthermore, there is little awareness of well-designed products and services that can enhance life and increase independence in daily life. The sooner this insight is well acknowledged, the sonner business opportunities can be more fully exploited to the benefit of both producers and potential users with cognitive impairments.

When designing products and services it is crucial that cognitive aspects are being dealt with from the very beginning in order to ensure that their products can be used by as many persons as possible without the need for adaptation or specialised design (accessible design approach). Products that are well designed for persons with cognitive impairment are likely to be equally beneficial to other potential users.

Annex C gives an overview of the concept of cognitive impairment and identifies factors to consider in the design process in relation to cognitive limitations. The factors presented are not exhaustive, they merely present some of the more important principles, which subsequently need to be studied in more detail.

Annex C is based on CEN/CENELEC Guide 6 "Guidelines for standards developers to address the needs of older persons and persons with disabilities". Relevant parts of Guide 6 have been referred to in Annex C.

NOTE 1 This annex covers not only products exclusively addressed to persons with cognitive impairment, but all possible assistive products.

NOTE 2 CEN/CENELEC Guide 6 is identical to ISO/IEC Guide 71.

NOTE 3 European Telecommunications Standards Institute, ETSI, has published a Special Report providing a listing of standardization documents relevant to telecommunications on the subjects of Human Factors and disability. This report can be downloaded from http://www.etsi.org .

## C.2 The concept of cognitive impairment

Cognition is the understanding, integrating and processing of information. The information includes the abstraction and organisation of ideas and time-management. Persons with cognitive impairment may have trouble learning new things, making generalisations and associations, and expressing themselves through spoken and written language. These impairments can produce anxiety, loneliness, depression, delusions, obsessions and compulsions. Such disorders may result in reduced ability to concentrate on a task. Impairment leads to perception problems, which include difficulty taking in, attending to, and discriminating sensory information. Difficulties in problem solving include; recognising the problem, identifying, choosing and

implementing solutions, and evaluating the outcome.[1)]

ICF, the International Classification of Functioning, Disability and Health (WHO, 2001), is a guide for the understanding of cognitive impairment.

## C.3 Important factors to be considered in the design process

### C.3.1 General

A product should be designed so that it can be used by as many persons as possible, without the need for adaptation or specialized design (*accessible design*). This may be achieved by designing products that are readily usable by most users without any modification, by making them adaptable to different users and by having standardized interfaces to be compatible with special products for persons with impairments.[2)]

The accessible design approach also implies that an assistive product should, as far as possible, look similar to other comparable products. If the assistive features are too obvious, potential users may avoid it.

The design of a product should be simple, clear and unambiguous. The use and performance should be easily and "intuitively" understood. Distinct shapes, easily recognised and easily operated controls, few and easily understood logical steps, simple and clear displays, alarms that cannot be misunderstood, etc. are fundamental design features. This also includes information such as user manuals, symbols, warnings, etc.

Operations or sequences of operations should, as far as possible, be automatically performed.

It is important to consider whether persons with cognitive impairment require special training in order to learn how to use the product in the intended way. The skills and learning capacity can be limited and special training program and pedagogic methods may be required. Assistants, family members and others involved may need corresponding training. This also calls for an increased attention to the need for "fail-safe" systems, alarms, reminders and similar safety-related features.

NOTE Accessible design equals terms like design for all, universal design, barrier-free design, inclusive design and transgenerational design.

### C.3.2 Checklists

The lists below may serve as checklists aiming to identify possible hazards and need for special design features or actions and assist in eliminating non-relevant aspects.

The skills of the potential users should, as far as possible, be identified.

Factors that are particularly important to consider in the design process are:

— user information and user interface - instructions for use, warnings, displays, etc.;

— ease of handling, inclusive logical process - controls, operation, etc.;

— the need for "fail-safe" systems - backup functions, alarms, etc.

Cognitive impairment may imply limitations or difficulties with:

— memory (especially the working memory, i.e. the capacity to memorize a small amount of information and simultanously use it in thinking);

— learning;

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1) With reference to CEN/CENELEC Guide 6:2002, 9.4.1.1, 9.4.1.2 and 9.4.2.3.

2) With reference to CEN/CENELEC Guide 6:2002, 3.2.

— understanding;

— abstract thinking, generalisation;

— orientation (physical or mental);

— problem-solving;

— communication;

— time-management;

— impulse control;

— planning;

— organisation, structuring;

— decision-making;

— attention;

— initiative;

— motivation;

— perseverance;

— stress-management;

— reading, linguistic, mathematical, visual and verbal comprehension.

## C.4 User information and user interface

### C.4.1 General

The best designed products or services avoid the need for any explanatory information, signalling the way they should be used by form and appearance. Some users may not pay attention to any information provided. Nevertheless, where information is supplied, in particular safety warnings, it needs to be available to all users of a product or service. [3)]

### C.4.2 Alternative format

An alternative format describes a different presentation or representation intended to make products and services accessible through a different modality or sensory ability, e.g. voice, vibration, tactile markings, script and symbols/illustrations. When products offer input and output in alternative formats, people with different limitations (sight, hearing, cognition, etc.) have a greater opportunity to use the product.

Wherever feasible, visual information which is presented on electronic products should be available from the product in audio or other sensory stimuli, icons/symbols, etc. for those who have difficulty with reading or are unable to read. Printed visual information should be available in alternative formats (electronic audio, etc.).

Wherever feasible, sound signals should be supported by visual or other sensory stimuli, e.g. communication in writing, graphical symbols, vibration or sign language.

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3) With reference to CEN/CENELEC Guide 6:2002, Table 1.

Considerations should be given as to whether audible warnings should also activate an alternative warning, for example visual stimuli such as flashing lights to make the warnings more understandable. On the other hand, using many different stimuli at the same time may be puzzling for some persons with cognitive impairment and thereby create hazardous situations.[4)]

Pictograms may serve as an effective means of communication for some persons with cognitive impairment.

Regardless of format, the position of information on a product should be prominent. Visible information needs to be viewed from different positions, e.g. from the angle of view of someone standing and seated in a wheelchair.

### C.4.3 Colour, contrast and lighting level

Choice of colour is important for ease of recognition and ease of seeing. The use of colours may be an effective complementary means for communicating with persons who have a cognitive impairment. Colours can, for example, signal special functions of a product (controls, assembly points, etc.) and facilitate the understanding for use, assembly and maintenance of a product.

The best colour combinations depend on the purpose of information, whether it is for guidance or a hazard warning, and the lighting conditions under which it is most likely to be viewed. For example, black on yellow or light grey are general purpose combinations which provide strong definition without too much glare, pastel shades on pastel backgrounds or red lettering or symbols on light grey are difficult to see and should normally be avoided.

All information conveyed with colour should also be available without the perception of colour. Colour coding should not be used as the only means for conveying information, indicating a response or distinguishing a visual element.

The visibility (lighting level, glare, etc.) may affect the possibilities for persons with, for example, a reading or an attention impairment to make use of the information presented.

Flicker rates, or flashing or blinking text, objects or video screens should avoid frequencies that are most likely to trigger visually induced seizures.

NOTE With reference to CEN/CENELEC Guide 6:2002, 8.4 and 8.5.

### C.4.4 Complexity of information

Instructions or operations which are too complex will often deter persons with limited intellect or other cognitive impairments from using a product. Persons with reading or attention difficulties may loose focus and stop picking up the information. Complexity may also lead to misunderstandings. This kind of information failure can create dangerous situations when using the product.

The information should always be presented in a simple way, irrespective of the format chosen (written text, speech, pictograms etc). This implies that only the necessary information be given. Too much information distracts and a too rapidly or disrupted presentation may in the worst case be experienced as chaotic. Simple written or spoken messages are also clearer to understand by someone with a visual or hearing impairment.

Background noises or images may distract and should be avoided.

NOTE With reference to CEN/CENELEC Guide 6:2002, 8.7.2.

4) With reference to CEN/CENELEC Guide 6:2002, 8.2.

### C.4.5 Clear language in written or spoken information

The language should be as clear and simple as possible. The context should always be given to ensure that information is meaningful and instructions should be given in logical order. Key points should be reinforced by repetition. (Rules for spoken information are similar to those for printed information.)

Information should be made available in text format wherever possible, in addition to other forms, to facilitate recognition and translation into speech and other languages for those who have trouble recognizing or deciphering non-text information presentations.

Printed instructions should use short sentences of simple, straightforward and non-technical language and may include simple illustrations.

NOTE With reference to CEN/CENELEC Guide 6:2002, 8.7.

### C.4.6 Graphical symbols and illustrations

Supplemental media such as symbols and illustrations have indeed the potential to greatly enhance the possibilities to use a product. The use of meaningful graphical symbols, icons or other illustrations, in addition to text, should be considered in instructions and also on a product, for ease of use, assembly and maintenance. [5)]

Further guidance can be found in the documents listed below (examples):

ISO 9186-1:2007, *Graphical symbols — Test methods — Part 1: Methods for testing comprehensibility*

ISO/IEC TR 19765, *Information technology – Survey of icons and symbols that provide access to functions and facilities to improve the use of information technology products by the elderly and persons with disabilities*

ISO/IEC TR 19766, *Information technology — Guidelines for the design of icons and symbols accessible to all users, including the elderly and persons with disabilities*

ITU - *Operations and quality of service human factors: Procedures for designing, evaluating and selecting symbols, pictograms and icons.* ITU-T F910 (1995)

ETSI - *Human factors: The Multiple Index Approach for the evaluation of pictograms.* ETSI ETR 070 (1993)

### C.4.7 Slow pace of information presentation

Announcements presented at a slow measured pace allow receivers to have time to think about and understand and act on the message. If a message is delivered too rapidly, it is difficult to assimilate by someone with a learning impairment or other cognitive difficulties. Consideration should be given to the length of time information remains in view when presented on moving displays, or when information is temporarily displayed and then removed.[6)]

Important information should, as far as possible, be repeated.

## C.5 Ease of handling

### C.5.1 Controls

Pre-programmable operation and personal preferred settings can be particularly effective for persons with cognitive impairment.

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5) With reference to CEN/CENELEC Guide 6:2002, 8.8.

6) With reference to CEN/CENELEC Guide 6:2002, 8.10.

The position of controls should be prominent and they should be easily identified by a familiar or distinctive form. The use of colours may be helpful.

It should be easy to distinguish between different controls (by form, colour, etc). Controls should be spaced to avoid interference when another one is being operated.

Controls should be easily accessed by seated or standing users without bending and stretching. This may mean that the positioning needs to be flexible or adjustable or duplicated.

Easily understood feedback should be provided on the status of controls.

The force required to twist, turn, push or pull controls or fastenings is significant for people with various impairments. Operating controls should allow comfortable grip, avoid twisting of the wrist, avoid the need for simultaneous actions and offer minimal resistance. Textured surfaces, to increase friction, assist the application of force. Provision of alternative controls offering greater leverage or power-assistance should be considered.

Operating forces should be as low as reasonably attainable, compatible with security of contents.[7)]

NOTE Persons with cognitive impairments can use most well designed controls and displays, but it may take longer to learn to use them and may need error protection.

### C.5.2 Duration of actions and timed responses

Products should not need a long handling time. Unnecessary repetition of operations should normally be avoided, but sometimes repetition can be helpful because it makes learning easier.

Whenever possible, users should be able to control any limits on the amount of time available to them to read or respond.

NOTE With reference to CEN/CENELEC Guide 6:2002, 8.12.5 and 8.12.6.

### C.5.3 Logical process

All functionality should be as predictable as possible and any deviations from predictability should be preceded by warnings and/or explained to users after the changes occur.

The number of steps in a logical sequence should be as few as possible. Each step should be easily recognized and it should always be possible to stop and reverse in an operative process.

Appropriate feedback should be given when a step in a sequence of actions is successfully completed.

Operations such as the opening of packaging and assembling, installing or operating a product, should follow simple, straightforward and logical sequences.

NOTE With reference to CEN/CENELEC Guide 6:2002, 8.17.

### C.5.4 Fail-safe

Product or system design should ensure that even when incorrectly assembled or installed or there is mistaken use of controls, the product or system will fail in a safe manner without hazard to the user. [8)]

Special attention should be paid to the need for backup systems, alarms, reminders and other necessary safety details.

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7) With reference to CEN/CENELEC Guide 6:2002, 8.12.3.

8) With reference to CEN/CENELEC Guide 6:2002, 8.21.

## C.6 User participation

The field of cognitive impairment is characterized by large individual variations. The wide range of different needs and skills of the users often makes it difficult to predict how a particular product will be handled by persons with cognitive impairment. Experience shows that an efficient way to deal with this problem is to engage potential users with different kind of cognitive impairments as early as possible in the design process. This may occasionally be valid also for assistants, family members and others involved.

It is strongly recommended that producers engage potential users as early as possible in the development work.

# Annex D
(informative)

# Environmental and consumer related requirements

## D.1 Assesment of hazardous substances in assistive products for persons with a disability – general aspects

This annex provides some general guidance to minimize hazardous chemicals in assistive products for persons with a disability. It is intended to complement legal obligations by providing some practical recommendations keeping in mind but going beyond legal minimum requirements.

D.2 of the annex focuses on classes of chemicals which are of very high concern from a human health or environmental perspective (CMR, PBT, vPvB, and substances of equivalent concern) which may be found in all materials and products.

D.3 to D.6 contain recommendations for textiles, plastics, metals and wood.

## D.2 Hazardous substances in all materials or products

### D.2.1 Substances of very high concern (SVHC): the European approach on chemicals

#### D.2.1.1 General

In 2006, the new EU regulatory framework concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH, 1907/2006) was adopted. REACH requires an authorisation for substances of “very high concern” (other substances just require a registration). These are CMR chemicals (carcinogenic, mutagenic and toxic for reproduction), PBTs/vPvBs (persistent, bio accumulating and toxic/very persistent and very bio accumulating substances) and substances identified as causing serious and irreversible effects to humans or the environment equivalent to the effects mentioned on a case-by-case basis. All these substances will be identified in co-operation with the Member States. They are incorporated in a so-called “candidate list” which is published and periodically updated by the European Chemicals Agency (ECHA). Finally, substances requiring authorisation will be taken up in Annex XIV.

#### D.2.1.2 CMR chemicals

CMR chemicals may belong to one of three different categories. For carcinogenic substances this is described as follows:

a) Category 1: substances known to be carcinogenic to man. There is sufficient evidence to establish a causal association between human exposure to a substance and the development of cancer.

b) Category 2: substances which should be regarded as if they are carcinogenic to man. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development of cancer, generally on the basis of:

   1) appropriate long-term animal studies,

   2) other relevant information.

c) Category 3: substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment. There is some evidence from appropriate animal studies, but this is insufficient to place the substance in Category 2.

For mutagenic substances and substances toxic to reproduction the categories 1, 2 and 3 are described in a similar way (Annex VI of Directive 67/548/EEC).

The applicable risk phrases (R-phrases) for CMR chemicals are listed in Table D.1.

**Table D.1 — R-phrases covering CMR chemicals (Annex VI of Directive 67/548/EEC)**

| **CARCINOGENIC SUBSTANCES** | **SUBSTANCES TOXIC FOR REPRODUCTION** |
|---|---|
| R40 Limited evidence of carcinogenic effects (category 3) | R60 May impair fertility (category 1 & 2) |
| R45 May cause cancer (category 1 & 2) | R61 May cause harm to the unborn child (category 1 & 2) |
| R49 May cause cancer by inhalation (category 1 & 2) | R62 Possible risk of impaired fertility (category 3) |
| | R63 Possible risk of harm to the unborn child (category 3) |
| **MUTAGENIC SUBSTANCES** | |
| R46 May cause heritable genetic damage (category 1 & 2) | |
| R68 Possible risk of irreversible effects (category 3) | |

In 2008, the European Union adopted the “Globally Harmonised System of Classification and Labelling of Chemicals (GHS, 1272/2008). It will gradually replace the current classification and labelling scheme mentioned above in the forthcoming years.

For CMR chemicals, categories 1, 2 and 3 will be replaced by categories 1A, 1B and 2 with broadly the same meaning. R-phrases will be replaced by new H-phrases.

The applicable Risk phrases (R-phrases) for CMR chemicals are listed in Table D.2.

**Table D.2 — H-phrases covering CMR chemicals (Annex I of regulation 1272/2008)**

| **CARCINOGENIC SUBSTANCES** | **SUBSTANCES TOXIC FOR REPRODUCTION** |
|---|---|
| H350 May cause cancer (category 1A & 1B) | H360 May damage fertility or the unborn child (category 1A & 1B) |
| H351 Suspected of causing cancer (category 2) | H361 Suspected of damaging fertility or the unborn child (category 2) |
| | H362 May cause harm to breast-fed children (additional category for effects on or via lactation) |
| **MUTAGENIC SUBSTANCES** | |
| H340 May cause genetic defects (category 1A & 1B) | |
| H341 Suspected of causing genetic defects (category 2) | |

### D.2.1.3 PBT and vPvB substances

Criteria for the identification of PBT (persistent, bio accumulating and toxic) and vPvB (very persistent and very bio accumulating) substances are included in Annex XIII of the REACH document. A substance that fulfils certain given criteria on persistence, bioaccumulation and toxicity is a PBT substance. A substance that fulfils certain given criteria on persistence and bioaccumulation is a vPvB substance.

#### D.2.1.4 Substances of equivalent concern

Substances such as those having endocrine disrupting properties or those having persistent, bio accumulative and toxic properties or very persistent and very bio accumulative properties, which do not fulfil the criteria set out in Annex XIII for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern as CMR, PBT and vPvB substances are identified on a case-by-case basis.

### D.2.2 Recommendations

#### D.2.2.1 General

Whilst the implementation of REACH including the authorisation of SVHS will take many years, it is advisable, as a matter of prudence, to eliminate such substances wherever possible as soon as practicable. Safety data sheets of substances used in the production of assistive products will provide the necessary information. It is also recommended to regularly check the “candidate list” on the website of ECHA to identify any new entry: http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp .

#### D.2.2.2 CMR chemicals

It is proposed to avoid CMR chemicals from all three categories. A threshold of 0.1 % by weight can be used here as a starting point. However, some CMR substances are of concern at much lower levels. It is therefore recommended to reduce the levels of CMR substances as far as technically feasible using a precautionary approach.

#### D.2.2.3 PBT and vPvB substances

The product should not contain any PBT and vPvB substances based on the criteria listed in Annex XIII of REACH in amounts exceeding 0.1 % by weight.

#### D.2.2.4 Substances of equivalent concern

As these substances are identified on a case-by-case basis it is recommended to avoid using substances once included in the candidate list in amounts exceeding 0.1 % by weight unless lower levels seem to be warranted.

## D.3 Hazardous substances in textiles

### D.3.1 Relevant substances

For textiles, several ecolabel criteria exist at European and national levels that should be considered when establishing requirements for textile components of assistive products for persons with disabily.

The Oekotex 100 standard for textile end-products has received broad recognition on the market place as representing the state-of-the-art. About 5000 companies in the world have an Oekotex 100 label which makes the Oekotex 100 label the most widespread label of all textile eco-labels.

Limit values are included for:

- formaldehyde;
- heavy metals;
- pesticides;
- chlorinated phenols;
- phthalates;

— organic tin compounds;

— other chemical residues;

— colorants;

— chlorinated benzenes and toluenes;

— biological active products;

— flame retardant products;

— colour fastness;

— emission of volatiles;

— odours.

The Oeko-Tex Association has developed different criteria for textile products: for babies, for products with and without direct skin contact and for decoration materials. More details can be found on the website: http://www.oekotex.com .

### D.3.2 Recommendations

Textile products or components should comply with the relevant Oeko-Tex 100 requirements. Other ecolabels may contain more ambitious requirements (e.g. for organic textiles) and should be also considered.

## D.4 Hazardous substances in plastic materials

### D.4.1 Relevant substances

Various national and European specifications contain criteria for plastic materials or components which can be taken as a basis when establishing requirements for plastic components of assistive products for persons with a disability. Key criteria include:

— substances based on lead, cadmium, mercury and their compounds;

— halogenated organic materials;

— phthalates.

### D.4.2 Recommendations

#### D.4.2.1 Substances based on lead, cadmium, mercury and their compounds or tin organic compounds

The European Council Directive on packaging and packaging waste (94/62/EC) has set a limit of 100 ppm for the sum of lead, cadmium, mercury and hexavalent chromium in plastic packaging. In order to set a limit to heavy metal content of plastic used in assistive products for persons with a disability, it is proposed to comply with the limit as used in the European Packaging Directive.

#### D.4.2.2 Organic halogenated compounds

Organic halogenated compounds as flame retardants can be added to plastic parts. Some of the halogenated flame retardants show hazardous impacts to health and environment, are persistent and bio-accumulative. Polybrominated biphenyls (PBB), polybrominated diphenylether (PBDE) and short-chained chloroparaffins (all are organic halogenated compounds) can be added to plastic part(s). PBB and PBDE belong to the group of brominated flame retardants and show hazardous effects on health and the environment. Many chlorinated

paraffins are persistent and bio accumulative. It is recommended to avoid the use of PBBs, PBDEs or chlorinated paraffin.

#### D.4.2.3 Phthalates

These substances are used as plasticizers in PVC and may have reprotoxic effects. It is therefore preferable to exclude phthalates. For medical devices, there are alternatives for phthalates on the market. However, phthalate substitutes may reduce the functionality of the device or, when used in blood bags, may even have health impacts on patients. It is therefore proposed that plastic parts of assistive products for persons with a disability should not contain phthalates in quantities higher than 0,1 ppm unless there is evidence that phthalates are necessary on technical grounds and cannot be substituted by other plasticizers or the product cannot be produced using other plastic materials.

## D.5 Metals

### D.5.1 Relevant substances

Of particular importance are criteria for metal coatings including:

— cadmium;

— chromium;

— nickel

and their compounds. Such coatings are necessary only where heavy physical wear can be anticipated or in the case of parts that require particularly tight connections. For parts that are intended to come into frequent contact with skin, such coatings should be avoided. Cadmium should not be used at all.

### D.5.2 Recommendations

Metal parts should not be coated with cadmium, chromium, nickel and their compounds. In exceptional cases, metal surfaces may be treated with chromium or nickel where this is necessary on the grounds of heavy physical wear or in the case of parts that require particularly tight connections. This exemption does not include parts that are intended to come into frequent contact with skin and the treated parts must be recyclable.

NOTE Criteria for other coatings such as paints will be considered in the next revision of this standard.

## D.6 Wood

### D.6.1 Relevant substances

Various national and European specifications contain criteria for formaldehyde, an irritating and carcinogenic substance, in wood based panels.

### D.6.2 Recommendations

One of the two following requirements should be fulfilled:

a) The content of free formaldehyde measured in accordance with EN 120 using the perforator method should be:

   1) Single values: ≤ 8 mg formaldehyde/100 g product;

   2) Half year mean value: ≤ 6.5 mg formaldehyde/100 g product.

b) Formaldehyde emission measured in a test chamber in accordance with EN 717-1 should be < 0,13 mg formaldehyde/$m^3$ air.

NOTE Criteria for other substances contained in coatings or wood preservatives will be considered in the next revision of this standard.

# Annex ZA
(informative)

## Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC**

| Clauses/subclauses of this EN | Essential Requirements (ERs) of Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| All | 1 | Partially covered. Each device needs to be considered against its intended user, and its intended usage to establish the potential hazards and risks. |
| All | 2 | Partially covered. Each device needs to be considered against its intended user and its intended usage to establish the potential hazards and risks and to consider if the solutions are appropriate. |
| All | 3 | Partially covered. Each device needs to be considered against its intended user and its intended use. |
| All | 4 | Partially covered. The tests are based on stresses that can occur during the lifetime of the device under general conditions of use. Test results may require further interpretation to fully cover the intended user and the intended usage of an individual device.<br>The lifetime of the device is not covered. |
| All | 5 | Fully covered |
| 4 | 6 | Fully covered |
| 4 | 6a | Fully covered |

| | | |
|---|---|---|
| 4, 5 | 7.1 | Fully covered as regards toxicity, biocompatibility and flammability. |
| 5 | 7.2 | Not covered as regards packaging.<br><br>Fully covered as regards risks from contaminants and residues. |
| 5, 8.4, 9 | 7.5 | Not covered regarding treatment as this is not in the scope of this standard. |
| 8, 9 | 7.6 | Fully covered |
| 5.4 | 8.1 | Fully covered regarding how to deal with cleaning and disinfection.<br><br>Not covered regarding requirements on design and manufacturing. |
| 5.5.2 | 8.2 | Fully covered as to risk assessment shall be performed and documented according to EN ISO 22442-1.<br><br>Not covered as to requirements on handling. |
| 11 | 8.3 | Fully covered |
| 11 | 8.4 | Fully covered |
| 24 | 9.1 | Fully covered as regards restrictions on use.<br><br>Not covered as regards all other aspects of this Essential Requirement. |
| 7, 8, 10, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23. | 9.2 | Fully covered as regards<br>- magnetic fields,<br>- external electrical influences,<br>- electrostatic discharge,<br>- dimensions,<br>- ergonomic features,<br>- temperature<br><br>Not covered as regards all other aspects of this Essential Requirement. |
| 5.1, 8, 25 | 9.3 | Fully covered |
| | 10 | Not covered<br><br>This requirement applies when |

| | | |
|---|---|---|
| | | the measuring function is one of the principal functions of the assistive product. e.g. some hoists incorporate a weighing function. When the measuring function is not fundamental to the intended use this requirement does not apply. e.g. the battery charge indicator fitted to an electric wheelchair. |
| 8.6 | 12.1 | Fully covered |
| 8.6 | 12.1a | Fully covered |
| 8.4 | 12.2 | Fully covered |
| 8.3 | 12.3 | Fully covered |
| 7 | 12.5 | Fully covered |
| 8 | 12.6 | Fully covered |
| 12 to 21 | 12.7.1 | Fully covered |
| | 12.7.2 | Not covered. Guidance is given in Annex B. |
| 6.1 | 12.7 3 | Fully covered as regards to testing and risk analysis and sound level where it is important to hear the alarm.<br><br>Not covered regarding specific requirements for safe level. |
| 8 | 12.7.4 | Fully covered as regards electrical connectors and terminals.<br><br>Not covered for all other aspects of this Essential Requirement. |
| 10, 24 | 12.7.5 | Fully covered |
| 8 | 12.8.1 | Partially covered as regards electrically heated blankets, pads and similar flexible heating appliances.<br><br>Fully covered as regards electrical devices.<br><br>Not covered for all other aspects of this Essential Requirement. |
| 8 | 12.8.2 | Not covered for non-electrical devices. |

| | | |
|---|---|---|
| | | Fully covered as regards electrical devices. |
| 8, 24 | 12.9 | Partially covered. Each device needs to be considered against its intended use. |
| 24 | 13 | Fully covered |

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following table ZA.2 details the relevant essential health and safety requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus do not provide presumption of conformity for the machinery directive.

**Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are not addressed or only partly covered by this European Standard**
(according to article 3 of amended Directive 93/42/EEC)

| Clauses/subclauses of this EN | Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC | Qualifying remarks / Notes |
|---|---|---|
| - | 1.1.4 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.1.8 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.3.3 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| 4.4, 4.5 | 1.5.4 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Partially covered by Clause 4 of this standard. |
| - | 1.5.15 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.6.1 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.6.2 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |

| | | |
|---|---|---|
| - | 1.6.3 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.6.4 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 1.6.5 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| 24 | 1.7.4.1 | If a relevant hazard exists, the manufacturer has to cover this EHSR.<br>Partially covered by Clause 24. |
| 24 | 1.7.4.2 | If a relevant hazard exists, the manufacturer has to cover this EHSR.<br>Partially covered by Clause 24. |
| - | 3.2.1 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 3.2.2 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 3.2.3 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 3.6.1 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |
| - | 3.6.2 | If a relevant hazard exists, the manufacturer has to cover this EHSR. Not covered by this standard. |

**WARNING —** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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