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External limb prostheses and external orthoses — Requirements and test methods

Prothèses de membre externes et orthèses externes — Exigences et méthodes d'essai

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 22523 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics.*

Introduction

This International Standard has been prepared in close collaboration with Technical Committee CEN/TC 293 *Technical aids for disabled persons*.

This International Standard represents the revised version of the Harmonized European Standard EN 12523:1999 already implemented by the member countries of the European Union and the European Free Trade Association in accordance with the CEN/CENELEC Internal Regulations. Consequently, these regulations apply accordingly.

This International Standard 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 International Standard.

This International Standard provides one means to demonstrate that external limb prostheses and external orthoses, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42/EEC on medical devices.

This International Standard also provides means to demonstrate that external limb prostheses and external orthoses with radio equipment according to definition 3.8 conform to the essential requirements of the EU Directive 99/5/EC on radio equipment and telecommunications terminal equipment.

This standard is not intended to provide a means of showing conformity with the requirements of any other directive.

There are three levels of European Standard dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

Level 1: General requirements for technical aids

Level 2: Particular requirements for families of technical aids

Level 3: Specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower-level standards take precedence over higher-level standards. Therefore, to address all requirements for a particular aid, it is necessary to consult first, standards of the lowest available level.

This is a combined level 2- and 3-standard (lowest possible) for external limb prostheses and external orthoses, as specified in the scope.

In this International Standard, in addition to the reference to existing test standards, test methods for several types of prostheses and orthoses are specified in separate annexes A to D.

Annex ZA is included to show the parts of this European Standard which address the essential requirements of EU Directives 93/42/EEC and 99/5/EC.

NOTE Although this International Standard does not contain references to the level 1-standard EN 12182 *Technical aids for disabled persons — General requirements and test methods*, it is recommended that EN 12182 be consulted.

External limb prostheses and external orthoses — Requirements and test methods

1 Scope

This International Standard specifies requirements and test methods for external limb prostheses and external orthoses, including the following classifications from ISO 9999:

06 03 - 06 15 Orthoses

06 18 - 06 27 Limb prostheses

It covers strength, materials, restrictions on use, risk and the provision of information associated with the normal conditions of use of both components and assemblies of components.

This International Standard does not cover special seating as it is not classified as an orthosis in ISO 9999 and it is not normally body worn.

NOTE 1 It is intended to cover orthopaedic footwear (classification 06 33) in the future.

NOTE 2 The application of Quality Systems as described or referred to in ISO 13485 and ISO 13488 may be appropriate.

2 Normative references

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

ISO 8548-1, *Prosthetics and orthotics — Limb deficiencies — Part 1: Method of describing limb deficiencies present at birth*

ISO 8548-2, *Prosthetics and orthotics — Limb deficiencies — Part 2: Method of describing lower limb amputation stumps*

ISO 8548-3, *Prosthetics and orthotics — Limb deficiencies — Part 3: Method of describing upper-limb amputation stumps*

ISO 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 8549-2, *Prosthetics and orthotics — Vocabulary — Part 2: Terms relating to external limb prostheses and wearers of these prostheses*

ISO 8549-3, *Prosthetics and orthotics — Vocabulary — Part 3: Terms relating to external orthoses*

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

ISO 13404:2005, *Prosthetics and orthotics — Classification and description of external orthoses and orthotic components*

ISO 13405-1, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 1: Classification of prosthetic components*

ISO 13405-2, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 2: Description of lower-limb prosthetic components*

ISO 13405-3, *Prosthetics and orthotics — Classification and description of prosthetic components — Part 3: Description of upper-limb prosthetic components*

ISO 15032, *Prosthetics — Structural testing of hip units*

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

IEC 60335-2-17 *Household and similar electrical appliances — Safety — Part 2-17: Particular requirements for blankets, pads and similar flexible heating appliances*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests*

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

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

EN 50082-2, *Electromagnetic compatibility (EMC) — Generic immunity — Part 2: Industrial environment*

3 Terms and definitions

For the purposes of this document, the definitions of ISO 8548 Parts 1 to 3, ISO 8549 Parts 1 to 3 (except the definitions for the terms “(external limb) prosthetic device” and “(external) orthotic device”, ISO 13404 (except the definitions for the terms “side member” and 'joint assembly') and ISO 13405 Parts 1 to 3 together with the following terms and definitions apply. The definitions are listed in the order of citation.

3.1
(external limb) prosthetic device
external limb prosthesis
externally applied device consisting of a single component or an assembly of components used to replace wholly, or in part, an absent or deficient lower or upper-limb segment

NOTE In this International Standard the term “prosthetic device” is used.

3.2
(external) orthotic device
external orthosis
externally applied device consisting of a single component or an assembly of components applied to the whole or part of the lower limb, upper-limb, trunk, head or neck and their intermediate joints to assist the neuro-muscular and skeletal systems

NOTE In this International Standard the term “orthotic device” is used.

3.3
user
person using (wearing) the prosthetic or orthotic device

3.4
attendant
person who assists the user

3.5
technical documentation
manufacturer's record of data showing conformity of a prosthetic or orthotic device with the requirements of this International Standard and which is intended to be used as part of the technical documentation required by the Medical Devices Directive for conformity assessment procedures

3.6
clinical evaluation
means for confirming that a prosthetic or orthotic device conforms to the requirements of the Medical Devices Directive by a compilation of clinical data that includes any scientific literature and the results of any clinical investigations, taking into account any relevant Harmonized Standards

3.7
clinical investigation
any systematic study in human subjects, undertaken to verify the safety and performance of a specific medical device, under normal conditions of use

[ISO 14155-1]

3.8
radio equipment
product or relevant component thereof, capable of communication by means of the emission and/or reception of radio waves utilizing the spectrum allocated to terrestrial/space radio communication

NOTE The definitions of 3.9 to 3.19 below primarily apply to Annex B.

3.9
knee joint
joint in the side member of a lower limb orthosis that allows movement in the principal plane of flexion of the anatomical knee joint

3.10
side member
medial or lateral component of either one-piece or compound construction and including side pieces (uprights), end pieces, joints or adjustment devices

3.11
joint assembly
knee joint with integral side members or with side members attached

3.12
parallel side member
side member whose individual above-knee and below-knee components have cross sections of essentially constant dimensions

3.13
stepped side member
side member whose cross section, at a distance of more than 75 mm from either side of the axis of flexion, is reduced to a smaller cross section of constant dimensions

3.14
bending deformation
angular deflection (**3.15**) of a joint assembly (**3.11**) upon application of a bending moment by a four-point loading system (see Figures B.1, B.2 and B.3)

3.15
angular deflection
measure of the bending deformation (**3.14**) (see Figures B.1, B.5 and B.6), angular deflection to be the sum of the numerical values of angular rotation α_1 and α_2 of the two shafts which carry the mountings of the two pairs of rollers acting on the ends of the test sample

3.16
limit of proportionality
point in a bending moment/angular deflection (**3.15**) relationship beyond which there is deviation from the initial linear behaviour (see Figures B.5 and B.6)

3.17
bending stiffness
ratio of change of bending moment to corresponding change of angular deflection (**3.15**) within the region of linear proportionality

3.18
maximum bending moment
M_{max}
bending moment at fracture or at which a further increase in the bending deformation of the test sample results in either a decrease of the bending moment (see Figure B.5) or an increase in the rate of change of the bending moment (see Figure B.6)

NOTE If, during a test, the bending moment is constant or decreases as the bending deformation increases, but a secondary structure subsequently carries the load so that the bending moment and the bending deformation resume increasing together, then the maximum bending moment is the first maximum that is observed in the test and the contribution of any secondary structure is ignored (see Figure B.6)

3.19
bending deformation at the maximum bending moment
amount of the bending deformation (**3.14**) when the value of the bending moment is M_{max}

4 General requirements

4.1 Risk management

Possible hazards associated with a prosthetic or an orthotic device can endanger the user. For this reason the manufacturer shall establish and maintain a process for identifying those hazards and evaluating the associated risks, controlling these risks and monitoring the effectiveness of the control. This risk management process shall include the following elements:

— risk analysis;

— risk evaluation;

— risk control;

— post-production information.

NOTE 1 ISO 14971 can be used as guidance.

NOTE 2 Application of ISO 14971, as guidance, does not require that the manufacturer has a formal quality system in place. However, risk management can be an integral part of a quality system (see, for example, Table G.1 of ISO 14971:2000).

NOTE 3 The results of the risk management process may be used to select from this International Standard the requirements which apply.

4.2 Intended performance and technical documentation

The intended performance including, where appropriate, strength and durability of a prosthetic or orthotic device shall be described in the technical documentation which sets out its functional characteristics, its application(s) and conditions of use.

The technical documentation shall include, where appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, appropriate standards and test results.

4.3 Clinical evaluation

The extent and nature of any clinical evaluation shall be governed by the novelty of the design, materials, method of manufacture and/or application in the judgement of a qualified person/body.

The prosthetic or orthotic device under evaluation shall be found to be acceptable in the judgement of a qualified person/body.

The identity of the qualified person/body and the basis of the judgement shall be recorded in the manufacturer's technical documentation (see 4.2).

NOTE Clinical evaluation can require clinical investigation, which can be conducted using ISO 14155-1 and ISO 14155-2 as guidance.

4.4 Strength and related conditions of use

4.4.1 A prosthetic or orthotic device shall have the strength to sustain the loads occurring during use by amputees, or other persons with a physical handicap, in the manner intended by the manufacturer for that device according to his written instructions on its intended use.

NOTE For further information see 5.4 and NOTE in 5.2.2.

4.4.2 In order to comply with the requirement(s) of 4.4.1, the appropriate/relevant requirements of 4.4.3 to 4.4.7 shall be met.

4.4.3 The strength of a lower-limb prosthetic device shall be determined by application of the relevant tests specified in ISO 10328 (see NOTES 1 and 2), ISO 22675 (see NOTE 2) and/or ISO 15032 at a specific test loading level.

NOTE 1 ISO 10328 does not include test methods for flexion testing of knee units with stance phase control mechanisms.

NOTE 2 In order to allow continuity of testing by checking the test methods for ankle-foot devices and foot units specified in ISO 22675 against those specified in ISO 10328, a transition period will be established, during which both test methods are valid. For practical reasons this transition period will be adapted to the period of time after which the systematic review of ISO 10328 and ISO 22675 is indicated. The systematic review of both standards is expected to result, among other outcomes, in the finding on whether the test methods specified in ISO 22675 have demonstrated their suitability.

4.4.4 The strength of all other prosthetic and orthotic devices shall be determined in the manner specified in a) to d).

The justification for the manufacturer's selections in a) to d) shall be recorded in the technical documentation (see 4.2).

a) The manufacturer shall specify which of the following category/categories of strength is/are considered to be appropriate:

   1) fatigue strength: the cyclic load which can be sustained for a prescribed number of cycles;

2) proof strength: the static load representing an occasional severe event, which can be sustained and still allow the prosthetic or orthotic device to function as intended;

3) ultimate strength: the static load representing a gross single event, which can be sustained but which might render the prosthetic or orthotic device thereafter unusable.

a) The manufacturer shall specify the strength level(s) considered to be appropriate.

b) The manufacturer shall specify the method(s) of test to be applied, with the exception described in 4.4.5.

NOTE An upper-limb prosthetic device can be tested, if appropriate, using the methods specified in Annex A as guidance.

c) The manufacturer shall specify the test loading condition(s) and/or the test loading level(s) at which the test(s) shall be conducted.

4.4.5 An orthotic knee joint assembly shall be tested, if appropriate, in accordance with the procedures specified in Annex B.

NOTE These procedures are not intended for the testing of complete lower-limb orthotic devices.

4.4.6 Details of the category/categories of strength and strength level(s) specified and details of the tests, test loading conditions and/or test loading levels applied to the prosthetic or orthotic device shall be given in the information supplied by the manufacturer (see Clause 13).

4.4.7 The manufacturer shall specify the loading conditions for a prosthetic or orthotic device to comply with the requirements of 4.4.1. Reference shall be made to loading parameters and/or other conditions of the intended use that can be quantified or that are known to be interpreted in a uniform way.

NOTE For lower-limb prosthetic devices, the body mass is the quantifiable loading parameter commonly referred to.

The specification of these loading parameters and/or other relevant conditions of use shall take account of the safety factors corresponding to the particular use of the prosthetic or orthotic device intended by the manufacturer, which are determined by the ratio between the test loading conditions and/or test loading levels applied to the device and the corresponding loads expected to be exerted on the device during use by amputees or other persons with a physical handicap in the manner intended by the manufacturer.

4.4.8 Details of the loading conditions for a prosthetic or orthotic device, specified by the manufacturer in accordance with 4.4.7, shall be stated in the information supplied by the manufacturer with the device (see Clause 13).

4.4.9 Details of the specific loading parameters and/or other relevant conditions of use according to 4.4.7, required to comply with the requirements of 4.4.1 for a prosthetic or orthotic device, shall be stated in the written instructions on the intended use of that device, supplied by the manufacturer with the device (see Clause 13).

5 Requirements for materials

5.1 Flammability of materials and toxicity of combustion products

5.1.1 In prosthetic or orthotic devices every effort shall be made to use materials which minimize the risk of propagation of flames or production of toxic gases, as it is of particular importance to disabled persons who may not be able to escape from a fire. The use of non-flame-retardant materials shall be regularly reviewed as there is continuous development in this field.

NOTE To test materials used in lower-limb prosthetic devices, the methods specified in Annex C can be used as guidance.

5.1.2 If the clinical requirements for a prosthetic or orthotic device prevent the use of materials which minimize the risk of propagation of flames or the production of toxic gases, the requirements in 5.1.3 and 5.1.4 shall be met.

5.1.3 The device shall be supplied with a warning and a description of the precautions necessary to reduce the risk (see Clause 13).

5.1.4 The reasons not to use materials such as those referred to in 5.1.2 shall be stated in the manufacturer's technical documentation (see 4.2).

5.2 Biocompatibility, contaminants and residues

5.2.1 General

This subclause shall not apply to materials which have been in use in prosthetic or orthotic devices for several years prior to the publication of this International Standard and which are known to be suitable for the application.

Materials that come into contact with the human body shall be assessed for biocompatibility, taking into account the intended use and contact by those involved in user care or transportation and storage of the product.

NOTE Guidance on the selection of appropriate tests is given in ISO 10993-1.

5.2.2 Contaminants and residues

All materials used in prosthetic or orthotic devices shall not cause the user to be exposed to cytotoxicity, irritation and sensitization when that device is being used in the intended manner.

NOTE Structural materials used in a prosthetic or orthotic device should retain their strength characteristics in the presence of fluids and other substances found in their normal environment.

5.3 Infection and microbiological contamination

The manufacturer shall specify the means by which a prosthetic or orthotic device and/or the body surface to which it applies can be cleaned and, if appropriate, disinfected (see Clause 10).

Animal tissue products can carry infection and microbiological contamination, and manufacturers should examine them for signs of disease or contamination.

For more information see ISO 22442-1.

5.4 Resistance to corrosion and degradation

If the strength of a prosthetic or orthotic device, or the safety of the user or an attendant, may be affected by corrosion and/or degradation, risk analysis shall be used to determine the most appropriate protective measures.

6 Noise and vibration

There are no specific requirements for prosthetic and orthotic devices.