

External limb prostheses and external orthoses — Requirements and test methods

The European Standard EN ISO 22523:2006 has the status of a
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National foreword

This British Standard was published by BSI. It is the UK implementation of EN ISO 22523:2006. It supersedes BS EN 12523:1999 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/168, Prosthetics and orthotics.

A list of organizations represented on CH/168 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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This European Standard was approved by CEN on 13 April 2006.

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 Central Secretariat or to any CEN member.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 22523:2006) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products for persons with 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of an identical text or by endorsement, at the latest by April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 and United Kingdom.

Endorsement notice

The text of ISO 22523:2006 has been approved by CEN as EN ISO 22523:2006 without any modifications.

INTERNATIONAL STANDARD

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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.

7 Electromagnetic compatibility (EMC)

Where relevant, a prosthetic or orthotic device shall satisfy the EMC requirements by complying with IEC 60601-1-2.

Where relevant, a prosthetic or orthotic device shall in particular satisfy the following requirement of radiated immunity: The device shall function in a normal way in the presence of radio frequency (RF) fields up to a level of 12 V/m, from 26 MHz to 1 GHz.

Compliance shall be checked by subjecting the device to a radiated immunity test, carried out in accordance with IEC 61000-4-3 at a test level of 12 V/m, from 26 MHz to 1 GHz.

NOTE The requirement of radiated immunity and the method of checking compliance has been adopted from standards for electrically powered wheelchairs and motorized scooters (see EN 12184:2004 and ISO 7176-21:2003).

Manufacturers should consider the electromagnetic environments in which their products are likely to be used and the possible consequences of malfunction.

Where relevant, prosthetic and orthotic devices may be used in the presence of other electronic equipment. The electromagnetic compatibility (EMC) should be carefully matched to the environment in which the device is intended to be used.

When specifying the EMC performance of the device, manufacturers should recognize the already widely accepted environments of

- residential, commercial and light industrial;
- industrial;
- other (typically meaning more harsh environments and some specific places such as hospitals or near specific machinery, e.g. transmitters and security scanners in public and other places).

If a prosthetic or orthotic device is intended for use in an industrial environment, it shall comply with EN 50082-2.

8 Electrical safety

NOTE IEC 60601-1 and IEC 60601-1-1 can be used as guidance.

8.1 Battery-powered prosthetic and orthotic devices

8.1.1 Battery housings and connections

Battery housings and connections incorporated in a prosthetic or orthotic device shall comply with the requirements of 56.7 of IEC 60601-1:1988.

8.1.2 Charge level indicators

If the safety of the user depends upon the internal power supply of a prosthetic or orthotic device, that device shall be equipped with a means of indicating the state of the power supply prior to the critical state at which safety is no longer guaranteed.

Compliance shall be checked by inspection.

8.2 Circuit protection

If the power supply of a prosthetic or orthotic device can be overloaded in use and the overload can cause a risk to the user, that device shall be protected against the overload.

Compliance shall be checked by inspecting the device in an overload condition.

8.3 Electronic programmable systems

A prosthetic or orthotic device incorporating electronic programmable systems shall be designed to ensure the repeatability, reliability and performance of the systems according to their intended use.

NOTE IEC 60601-1-4 can be used as guidance.

8.4 Electrically heated blankets, pads and similar flexible heating appliances

A prosthetic or orthotic device which incorporates flexible heating appliances should conform to the requirements of IEC 60335-2-17.

8.5 Prosthetic and orthotic devices with skin contact electrodes ¹⁾

The manufacturer shall conduct a risk analysis to assess the safety risks related to the use of skin contact electrodes incorporated in a prosthetic or orthotic device used for nerve and muscle stimulation.

NOTE Guidance on the selection of appropriate tests is given in IEC 60601-1.

8.6 Prosthetic and orthotic devices with radio equipment

8.6.1 General

Radio equipment incorporated in and/or used together with a prosthetic or orthotic device shall comply with the relevant requirements of Clause 7 and 8.1 to 8.3.

In addition, it shall satisfy the requirements of 8.6.2 and 8.6.3.

8.6.2 Frequency spectrum of radio equipment

Radio equipment incorporated in and/or used together with a prosthetic or orthotic device shall be so constructed that the frequency spectrum used does not cause harmful interference, i.e. interference which endangers the functioning of radio navigation service or of other safety services or which otherwise seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with the applicable community or national regulations.

NOTE Due to the lack of uniform regulations applicable worldwide, for the time being this requirement can only be satisfied by demonstrating that the frequency spectrum used by the device complies with the legal frequency spectrum according to national or international regulations applicable to each of the countries in which the device is intended to be placed on the market.

8.6.3 Operation of radio equipment by the user

The manufacturer shall assess the particular conditions of operation of radio equipment incorporated in and/or used together with a prosthetic or orthotic device with respect to the capabilities of the intended user and regard the results in his decision on the appropriate design of control units or elements.

NOTE For further information ISO 16201 may be used as a guidance.

¹⁾ Further guidance on requirements and test methods for prosthetic and orthotic devices with skin contact electrodes for nerve and muscle stimulation is given in [17] (see Bibliography).

9 Surface temperature

A prosthetic or orthotic device may contain units which absorb energy and therefore rise in temperature during normal intended use resulting in the risk of injury to the user touching the device.

The possibility of a temperature rise which may impair comfort should be investigated.

Wherever possible a device such as that referred to in the first paragraph shall be provided with a means of protection to remove or minimize the risk.

If means of protection cannot be incorporated in such a device, clear warnings shall be given either on the device or with the instructions for use (see Clause 13).

10 Sterility

Prosthetic and orthotic devices are not usually supplied or used in a sterile condition. If specific devices require to be sterilized for particular applications, the manufacturer shall provide advice as to which sterilization processes can be applied.

11 Design requirements

11.1 Safety of moving parts

NOTE Due to the nature of its intended purpose, some parts of a prosthetic or orthotic device can be required to move relative to each other and as a result can trap and damage parts of the body or clothing of users or other persons.

Wherever possible such a device shall be provided with means of protection to remove or minimize the risk during normal intended use.

If a means of protection cannot be incorporated in such a device, clear warnings shall be given either on the device or with the instructions for use (see Clause 13).

11.2 Safety of connections

The terminals and connectors to the electric and/or fluid energy supplies or other connections of a prosthetic or orthotic device which the user requires to handle shall be designed and constructed in such a way as to minimize risk to the user.

Compliance shall be checked by inspection.

12 Mechanical requirements

12.1 Restrictions on use

12.1.1 If a prosthetic or orthotic device can be produced by combining components or assemblies of components from different manufacturers, the combination shall satisfy the requirements in 12.1.2 and 12.1.3.

12.1.2 The manufacturer of a component and/or assembly of components shall provide information on the other components which are known to be suitable for use in combination (see Clause 13).

12.1.3 The manufacturer of a prosthetic or orthotic device consisting of components and/or assemblies of components from different manufacturers shall prepare a declaration that the components and/or assemblies of components are mutually compatible and that the intended use of that device is within the safe limits of use of each component and/or assembly of components (see Clause 13).

12.1.4 The manufacturer of a component and/or assembly of components shall provide information on any limitation on the use of a prosthetic or orthotic device to any specific parameter such as loading (see Clause 13).

12.2 Forces in soft tissues of the human body

Prosthetic and orthotic devices by the nature of their functions require to apply forces to the body segments to which they are attached. The interface components of devices should be designed to avoid unacceptable pressure on and stress levels in body tissues.

Mechanically based risks to tissue can include

- cell necrosis due to restricted nutrition and oxygen supply;
- tissue breakdown due to mechanical overload;
- tissue breakdown due to fatigue;
- tissue wear due to abrasion;
- cell destruction due to thermal coagulation.

12.3 Ergonomic principles

If the operation of a prosthetic or orthotic device requires the user to apply a force or moment to an actuator, the manufacturer shall ensure that the magnitude of the required force or moment is suitable for the user.

Prosthetic and orthotic devices should be designed on ergonomic principles taking into account the special needs of the intended user. If a device or one of its components or assemblies of components requires adjustment or operation by the user, the means of adjustment or operation should be easily accessible and ergonomically practicable for the user.

NOTE 1 Annex D describes methods of establishing the force or moment required to operate the control and actuating mechanisms on prosthetic and orthotic devices and can be used as guidance.

It has been found in practice that the minimum value of the operating force or moment to be applied by the user to the actuator of the control or actuating mechanism of a complete prosthetic or orthotic device should be at least 5 N or 0,1 N·m in order to avoid accidental operation of that control or actuating mechanism.

NOTE 2 For further information on ranges of operating force or moment measured on samples of orthotic knee and elbow joints, prosthetic knee and elbow units and prosthetic terminal devices see Clause D.6.

13 Information supplied by the manufacturer

13.1 General

13.1.1 The information supplied with a prosthetic or orthotic device shall conform to the requirements of EN 1041.

13.1.2 The information supplied with a prosthetic or orthotic device shall include those of the items addressed or specified in 4.4.6, 4.4.8, 4.4.9, 5.1.3, 5.3, 9, 11.1, 12.1.2, 12.1.3 and 12.1.4, which are relevant to that device.

NOTE If appropriate, the user should be advised that the safety and lifetime of the prosthetic or orthotic device depends upon the level of his/her activity while using the device.

13.1.3 If a prosthetic or orthotic device uses visual, audible or other sensible (sensory) signals to indicate operating or adjusting parameters, the manufacturer shall ensure that the meaning of these signals is understandable to the user and other involved persons.

13.2 Labelling

13.2.1 Each prosthetic or orthotic device, for which the manufacturer claims compliance with the relevant requirements of one or more standards and/or specifications listed in 4.4.3 and addressed in 4.4.4 and 4.4.5, shall be labelled. The label shall refer to the relevant standard(s) and/or specification(s) and state the test(s), test loading condition(s) and/or test loading level(s) applied (see 4.4.6). If appropriate, the label shall also provide information on the ranges or limits of the intended use of the prosthetic or orthotic device, for example by specifying the permissible maximum values of relevant parameters [see 4.4.7, 4.4.8, 4.4.9 and also 13.3.1 a)].

The statements on the label shall be given independent of any specific information on the intended use of the prosthetic or orthotic device supplied by the manufacturer with the device.

13.2.2 If specific requirements for labelling are included in the relevant standard(s) and/or specification(s) listed in 4.4.3 and addressed in 4.4.4 and 4.4.5, these shall apply.

13.3 Intended use

13.3.1 The written instructions on the intended use of a prosthetic or orthotic device, supplied by the manufacturer with the device, shall comprise at least

- a) specification of the permissible maximum values of principal loading parameters or permissible threshold values of other relevant conditions of use, which limit the loads allowed to be exerted on the prosthetic or orthotic device during use by amputees or other persons with a physical handicap, who are intended to be fitted with this device (see 4.4.7, 4.4.8 and 4.4.9);
- b) statement of the assemblies and/or alignments in which the prosthetic or orthotic device can be used (see 12.1).

13.3.2 If specific requirements for the instructions on the intended use are included in the relevant standard(s) and/or specification(s) listed in 4.4.3 and addressed in 4.4.4 and 4.4.5, these shall apply.

14 Packaging

Manufacturers are strongly recommended to address the need for protective packaging.

NOTE The packaging of a prosthetic or orthotic device 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 A (informative)

Guidance on methods of determining the strength of upper-limb prosthetic devices

A.1 General

The evaluation of upper-limb prosthetic devices described in this annex concentrates on structural strength. The test instructions specify which properties are to be tested and measured and the manner in which tests are to be carried out.

NOTE Either complete prostheses or sub-assemblies or single components can be tested.

This annex does not cover associated requirements for field trials, wear, environmental and functional tests.

This annex does not cover cosmetic devices.

The laboratory tests and field trials shall be repeated when significant design changes are made to load-bearing parts of an upper-limb prosthetic device.

A.2 Principle

The method of evaluating the strength of upper-limb prosthetic devices is based on a series of laboratory tests consisting of a static tensile test, and static and cyclic downward and upward bending tests.

The static tensile test is intended to be applied to test samples of upper-limb prosthetic devices of any composition, aligned in full extension.

The static and cyclic downward and upward bending tests are intended to be applied to test samples of upper-limb prosthetic devices, incorporating an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of flexion/extension and adduction/abduction which allow(s) their alignment as close as possible to the following situation (see also A.3.4):

- shoulder unit in neutral position of flexion/extension and adduction/abduction;
- elbow unit in flexed position with forearm at right angles to the upper arm.

A.3 Test samples

A.3.1 General

The manufacturer/submitter shall prepare a test sample description in accordance with ISO 13405-3, to be submitted together with the test submission document (see clause A.6).

A.3.2 Selection of test samples

The test samples of upper-limb prosthetic devices selected for test shall be taken from normal production. Details of the selection shall be recorded in the test submission document. If the manufacturer/submitter supplies a certificate stating that the test sample has been taken from the normal production, this certificate shall be included in the test submission document, together with details of the sampling method.

NOTE Test samples of prosthetic structures may also be submitted for specific tests by any interested party.

A.3.3 Preparation of test samples

All sub-assemblies and single components submitted for test shall have the manufacturer's/submitter's recommended wrist face centre, elbow joint centre and elbow joint centre line, humeral face centre and shoulder joint centre clearly defined, in order to allow their correct positioning in the test sample set-up as specified in this subclause and in A.3.4.

Omit cosmetic fairings from the sample unless they contribute to the structural strength, or are subject of a requirement of a specific test.

Ensure that the test sample is provided with an upper (proximal) end attachment, required for the fixation of the test sample within the test equipment, and with a lower (distal) end attachment or a special grip device for a terminal device (see below), required for the application of the distal test force to the test sample.

Prepare the location of the point of load application P of the distal test force to the test sample as follows.

- a) If the test force is to be applied to a distal end attachment, point P shall be located on the long axis of the lower arm at a distance, c , from the elbow centre (see Figure A.1.)
- b) If the test force is to be applied to the special grip device described, point P shall be located as specified in 1) and 2).
 - 1) For the distal tensile test (A.8.2) point P should be the connecting point of the attachment cable/cord of the grip device, as illustrated in Figure A.2.
 - 2) For the static and cyclic downward and upward bending tests (A.8.3, A.8.4, A.9.2 and A.9.3) point P shall be the centre of the outer surface of the circular plate of the grip device on the side of load application, as illustrated in Figures A.3 and A.4.

Ensure that the end attachments, as far as possible, match the physical characteristics of the adjacent components used in the prosthetic device so that representative loads are applied.

NOTE This may be achieved by use of the intended adjacent components with the sample for test (see Figure A.5).

Representative loads may also be applied by the special grip devices, addressed in the above and specified below.

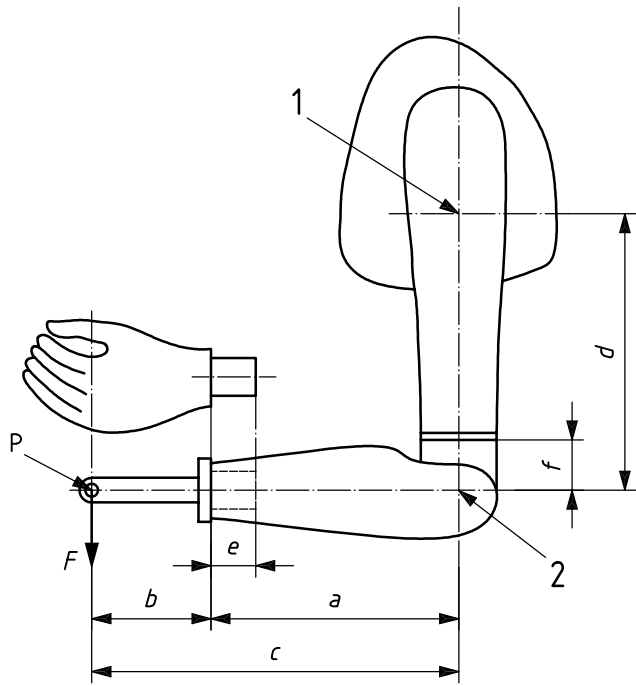
Unless otherwise specified by the test laboratory/facility, the preferred grip device for a terminal device shall be a rod of 19 mm diameter, 100 mm length and a surface roughness R_a of 1,6 μm .

For the distal tensile test specified in A.8.2 the rod shall be configured as illustrated in Figure A.2.

For the bending tests specified in A.8.3, A.8.4, A.9.2 and A.9.3 circular plates of 70 mm diameter and 5 mm thickness should be placed at each end of the cylinder, one of the plates providing means of load application.

If appropriate, a socket may be used and may be partially filled to provide an upper (proximal) end attachment. Ensure that the distal 15 mm (minimum) of the internal length of the socket is maintained void or filled with soft cushioning material.

The representative test sample segment lengths, c and d , are specified in the table in Figure A.1, together with further dimensions for orientation.

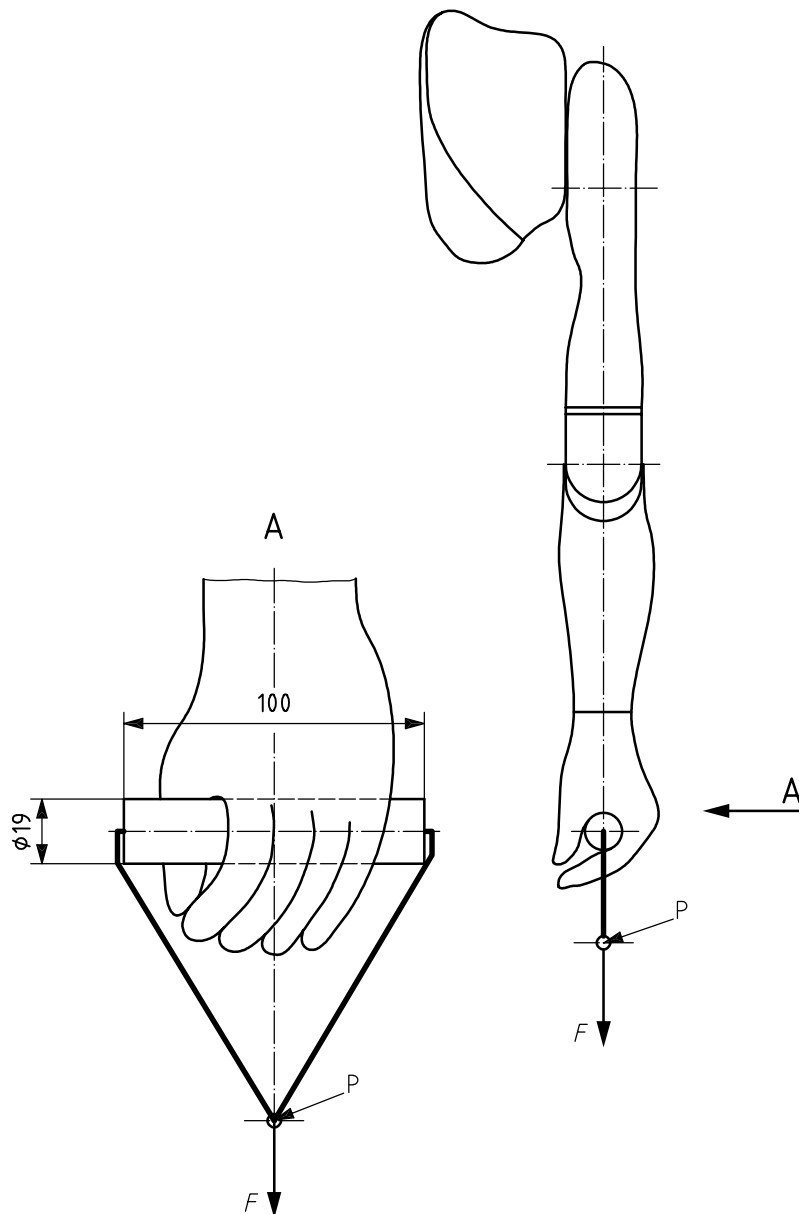


- Key**
- 1 shoulder joint
 - 2 elbow joint
 - F* test force
 - P load application point

Segment length	Dimension (mm)		Comments
	Child	Adult	
<i>a</i>	(≈150)	(≈250)	For orientation only
<i>b</i>	(≈60)	(≈100)	For orientation only
$c = a + b$	210	350	Representative
<i>d</i>	150	250	Representative
<i>e</i>	—	—	Dependent on individual design
<i>f</i>	—	—	Dependent on individual design

Figure A.1 — Test sample segment lengths

Dimensions in millimetres

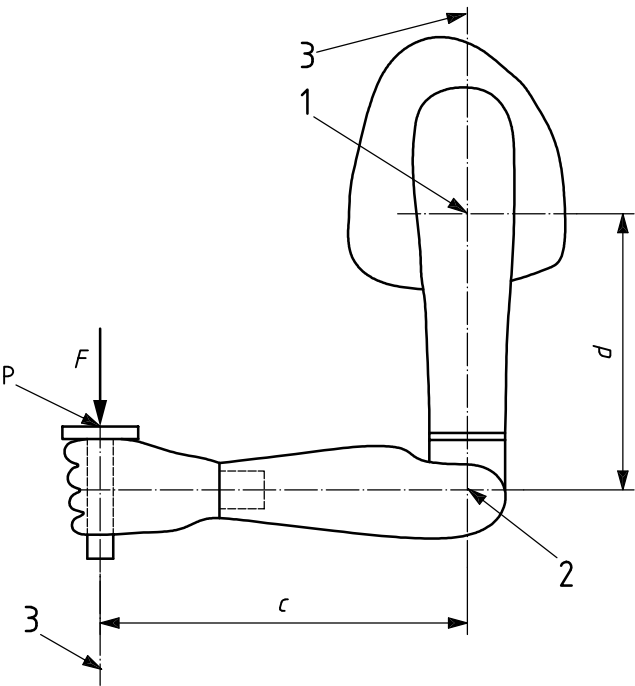


Key

F test force

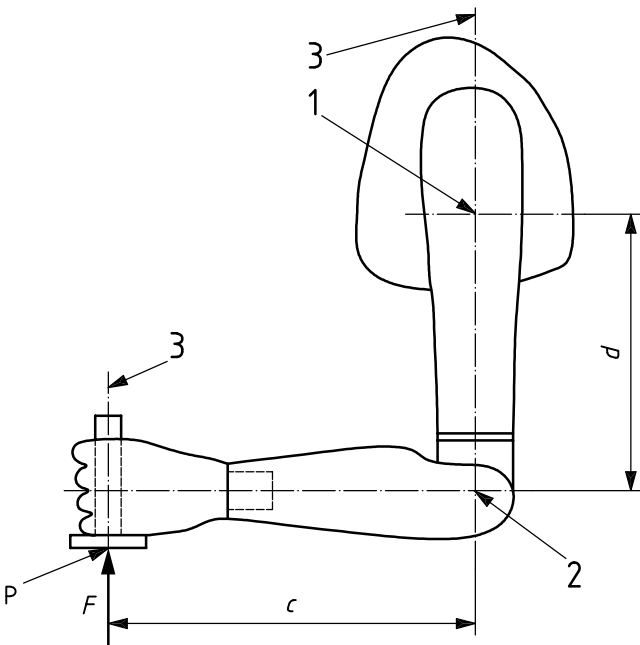
P load application point

Figure A.2 — Configuration of test 1



- Key**
- 1 shoulder joint
 - 2 elbow joint
 - 3 parallel
 - F* test force
 - P* load application point

Figure A.3 — Configuration of test 2 and test 4



- Key**
- 1 shoulder joint
 - 2 elbow joint
 - 3 parallel
 - F* test force
 - P* load application point

Figure A.4 — Configuration of test 3 and test 5

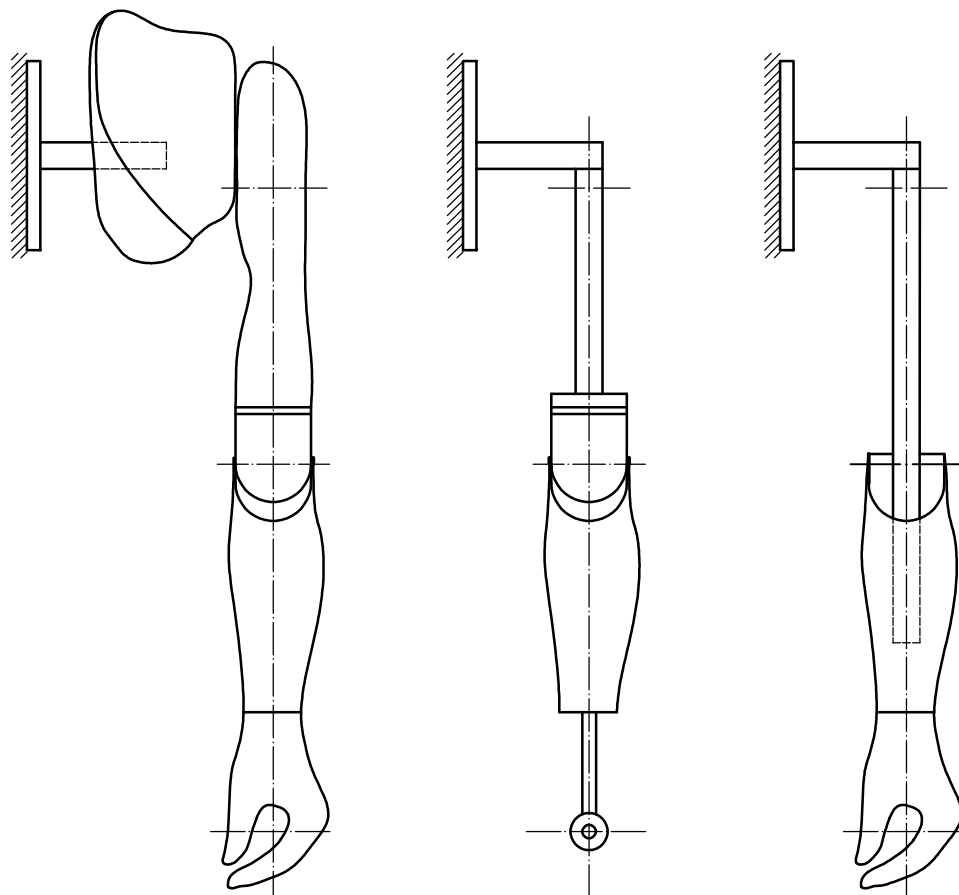


Figure A.5 — Examples of test sample configurations

A.3.4 Alignment of test samples

The alignment of test samples shall be carried out using the long axes of the upper and the lower arm, determined as follows:

- the longitudinal axis of the upper arm passes through the centres of the shoulder unit and the elbow unit;
- the longitudinal axis of the lower arm passes through the centres of the elbow unit and the wrist unit.

For the distal tensile test the long axes of the upper and the lower arm shall be aligned closest to coincidence.

For the downward and upward bending tests the shoulder unit shall be locked closest to its neutral position of flexion/extension and adduction/abduction and the elbow unit shall be locked at a flexion angle, at which the long axes of the upper and the lower arm are closest at right angles.

For all tests the elbow joint centre line shall be aligned perpendicular to the long axes of the upper and lower arm.

All tests shall be conducted in the worst-case alignment position of the test sample.

The structurally worst alignment position shall, if possible, be defined by the manufacturer/submitter in the test submission document. It shall lie within the limitations of the manufacturer's written instructions for the alignment of the limb, as supplied with every component of that type.