SLOVENSKI STANDARD
SIST EN 12523:2000

01-januar-2000

Zunanje proteze za ude in zunanje ortoze - Zahteve in preskusne metode

External limb prostheses and external orthoses - Requirements and test methods

Externe Gliedmaßenprothesen und externe Orthesen - Anforderungen und Prüfverfahren

Protheses de membre externes et ortheses externes - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 12523:1999**

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
11.180.10	Pripomočki in prilagoditve za gibanje	Aids and adaptation for moving

SIST EN 12523:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 12523

January 1999

ICS 11.180

Descriptors: medical equipment, surgical implants, prosthetic devices, orthotics, definitions, specifications, materials, toxicity, cntamination, flammability, safety, design, mechanical strength, operating requirements, ergonomics, tests, information

English version

External limb prostheses and external orthoses - Requirements and test methods

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

Externe Gliedmaßenprothesen und externe Orthesen - Anforderungen und Prüfverfahren

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", 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of an identical text or by endorsement, at the latest by July 1999, and conflicting national standards shall be withdrawn at the latest by July 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European 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 Z, which is an integral part of this standard.

This 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. 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 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 start with 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 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-D.

Annex Z (informative) is included to show the parts of this European Standard which address the essential requirements of EU Directive 93/43/EEC.

Note 1: The test methods specified in Annexes A and C require further work on evaluation of practicality and/or amendment/completion and/or verification/validation to establish the basis from which to decide on a change of their status. In order to allow their use as guidance, for the purposes of this edition of EN 12523, they are included as informative parts.

The test methods specified in Annex D have primarily been developed and applied to establish a data base from which to decide on the applicability of ranges of operating force specified in EN 614-1 and/or other standards referred to therein such as EN 894-3. As these test methods are considered to be also suitable for the purposes of this standard, Annex D is included as informative part.

Note 2: At the time of publication of this combined level 2- and 3-standard, the level 1-standard prEN 12182 "Technical aids for disabled persons - general requirements and test methods" has still been in the final draft stage prior to formal vote. In consideration of the possibility of unknown changes in prEN 12182:1998 after formal vote and before publication, this edition of EN 12523 does not contain references to it. Specific clauses of prEN 12182:1997 originally referred to as being applicable have been adopted as regular parts of the main body of this standard. It is, however, recommended to pay attention to EN 12182 once it is published.

1 Scope

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

06 03 - 06 15Orthoses
06 18 - 06 27Limb 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 European Standard does not cover special seating as it is not classified as an orthosis in EN ISO 9999 and it is not normally body worn.

NOTE 1: It is intended to cover orthopaedic foot-wear (classification 06 33) in the future.

NOTE 2: The application of Quality Systems as described or referred to in EN 46001 and EN 46002 may be appropriate.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1041	Information supplied by the manufacturer with medical devices
EN ISO 9999:1998	Technical aids for disabled persons - Classification (ISO 9999:1998)
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)
EN 50082-2	Electromagnetic compatibility (EMC) - Generic immunitiy - Part 2: Industrial environment
EN 60601-1:1987	Safety of medical electrical equipment - Part 1: General requirements
EN 60601-1-2	Medical electrical equipment - Part 1: General requirements for safety - 2. Collateral standard: Electromagnetic compatibility - Requirements and test methods
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 10328-1	Prosthetics - Structural testing of lower-limb prostheses - Part 1: Test configurations
ISO 10328-2	Prosthetics - Structural testing of lower-limb prostheses - Part 2: Test samples
ISO 10328-3	Prosthetics - Structural testing of lower-limb prostheses - Part 3: Principal structural tests
ISO 10328-4	Prosthetics - Structural testing of lower-limb prostheses - Part 4: Loading parameters of principal structural tests
ISO 10328-5	Prosthetics - Structural testing of lower-limb prostheses - Part 5: Supplementary structural tests
ISO 10328-6	Prosthetics - Structural testing of lower-limb prostheses - Part 6: Loading parameters of supplementary structural tests
ISO 10328-7	Prosthetics - Structural testing of lower-limb prostheses - Part 7: Test submission document
ISO 10328-8	Prosthetics - Structural testing of lower-limb prostheses - Part 8: Test report
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/DIS 15032	Prosthetics - Structural testing of hip units

3 Definitions

For the purposes of this standard the definitions of ISO 8548 Parts 1 to 3, ISO 8549 Parts 1 to 3 (except the definitions for the terms '(external limb) prosthic device' and '(external) orthotic device') and ISO 13405 Parts 1 to 3 together with the following definitions apply (definitions listed in the order of use/application).

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 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 modify the neuro-muscular and skeletal systems.

NOTE: In this 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:** Manufacturers record of data showing conformity of a prosthetic or orthotic device with the requirements of this standard and 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 (EN 540).

NOTE: The definitions of 3.8 to 3.18 below primarily apply to Annex B.

3.8 **knee joint:** A joint in the side member of a lower limb orthosis that allows movement in the principal plane of flexion of the anatomical knee joint.

3.9 **side member:** A medial or lateral component of either one-piece or compound construction and including side pieces, end pieces, joints or adjustment devices.

3.10 **joint assembly:** A knee joint with integral side members or with side members attached.

3.11 **parallel side member:** A side member whose individual above-knee and below-knee components have cross sections of essentially constant dimensions.

3.12 **stepped side member:** A 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.

3.13 **bending deformation:** The angular deflection (see 3.14) of a joint assembly (see 3.10) upon application of a bending moment by a four-point loading system (see figures B.3 and B.4 of Annex B).

3.14 **angular deflection:** Measure of the bending deformation (see 3.13, and figures B.1 and B.2 of Annex B), assuming the amount of angular rotation $\Delta\alpha$ of the links, joining adjacent loading rollers at each end of the test specimen, with respect to each other.

NOTE: The values of α at each end of the test specimen may be different.

3.15 **limit of proportionality:** Point in a bending moment/angular deflection (see 3.14) relationship beyond which there is deviation from the initial linear behavior (see figures B.1 and B.2 of Annex B).

3.16 **stiffness:** The bending moment divided by the angular deflection (see 3.14) within the area of linear proportionality (see 3.15).

3.17 **maximum bending moment (M_{max}):** The bending moment at which a further increase in the bending deformation of the specimen results in either a decrease of the bending moment (see figure B.1 of Annex B) or an increase in the rate of change of the bending moment (see figure B.2 of Annex B).

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.2).

3.18 **bending deformation at the maximum bending moment:** The amount of the bending deformation (see 3.13) when the value of the bending moment is M_{max}.

4 General requirements

4.1 Risk analysis

The safety of a prosthetic or orthotic device shall be assessed by risk analysis. A prosthetic or orthotic device whose failure would endanger the user shall be identified.

NOTE 1: EN 1441 should be used as guidance.

NOTE 2: The results of this assessment may be used to select from this 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 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.

NOTE: Clinical evaluation can require clinical investigation, which can be conducted using EN 540 as guidance.

4.4 Strength

4.4.1 A prosthetic or orthotic device shall have sufficient strength to sustain the loads and/or, if appropriate, deformations expected during normal use.

NOTE: For further information see notes in 5.2.2 and 5.4.

4.4.2 In order to claim sufficient strength, the appropriate/relevant requirements in 4.4.3 to 4.4.8 shall be met.

4.4.3 A lower limb prosthetic device shall be tested, if appropriate, in accordance with ISO 10328 and/or ISO/DIS 15032.

NOTE: ISO 10328-5 does not currently include knee units with stance phase control mechanisms.

4.4.4 For all other prosthetic and orthotic devices the requirements in 4.4.5 to 4.4.8 shall be met.

4.4.5 The manufacturer shall determine which of the following types of strength(s) is/are considered to be appropriate.

a) Fatigue strength: The cyclic load and/or, if appropriate, deformation range which can be sustained for a given number of cycles.

b) Proof strength: The static load and/or, if appropriate, deformation (including the resulting amount of permanent deformation), representing an occasional severe event, which can be sustained and still allow the prosthetic or orthotic device to function as intended.

c) Ultimate strength: The static load and/or, if appropriate, deformation, representing a gross single event, which can be sustained but which would render the prosthetic or orthotic device thereafter unusable together with the failure mode, if appropriate, i.e. brittle, ductile, delamination etc.

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

4.4.7 With the exception described in 4.4.8 the manufacturer shall determine the method of test.

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

4.4.8 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.

5 Requirements for materials

5.1 Flammability of materials and toxicity of combustion products

NOTE 1: In prosthetic or orthotic devices every effort should be made to use materials which minimize the risk for the propagation of flames or the 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 should be regularly reviewed as there is continuous development in this field.

NOTE 2: To test materials used in lower limb prostetic devices the methods specified in Annec C can be used as guidance.

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

5.1.2 The device shall be supplied with a warning and a description of the precautions necessary to offset the risk (see clause 13).

5.1.3 The reasons for the prevention of the use of such materials shall be recorded in the manufacturer's technical documentation.

5.2 Biocompatibility, contaminants and residues

5.2.1 General

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

Taking into account the intended use and contact by those involved in user care or transportation and storage of the product, materials which come into contact with the human body shall be assessed for biocompatibility using the guidance given in EN 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 13).

NOTE: Animal tissue products can carry infection and microbiological contamination and manufacturers should examine them for signs of disease or contamination. For more information see prEN 12442-1.

5.4 Resistance to corrosion

Manufacturers are strongly recommended to address resistance to corrosion.

NOTE: If the strength of a prosthetic or orthotic device, or the safety of the user or an attendant, may be affected by corrosion, the risk analysis should 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)

A prosthetic or orthotic device shall satisfy the EMC requirements by complying with EN 60601-1-2.

NOTE 1: Manufacturers should consider the electromagnetic environments in which their products are likely to be used and the possible consequences of malfunction.

NOTE 2: 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 hospital operating theatres or near specific machinery, e.g. transmitters).

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

8 Electrical safety

8.1 General

NOTE: EN 60601-1 and EN 60601-1-1 can be used as guidance.

8.2 Battery powered prosthetic and orthotic devices

8.2.1 Battery housings

Battery housings incorporated in a prosthetic or orthotic device shall comply with clause 56.7 of EN 60601-1.

8.2.2 Connections

Connections incorporated in a prosthetic or orthotic device shall comply with clause 56.7 of EN 60601-1.

8.2.3 Charge level indicator

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.

8.3 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.

8.4 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: EN 60601-1-4 can be used as guidance.

8.5 Electrically heated blankets, pads and similar flexible heating appliances

NOTE: A prosthetic or orthotic device which incorporates flexible, heatable appliances should conform to the requirements of EN 60967.

8.6 Prosthetic and orthotic devices with skin contact electrodes

Skin contact electrodes incorporated in a prosthetic or orthotic device used for nerve and muscle stimulation shall satisfy the requirements specified in EN 60601-1.

9 Surface temperature

NOTE 1: 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.

NOTE 2: Temperature rise should be addressed when comfort is impaired. Discomfort due to high temperature may indicate potential safety hazard.

9.1 Wherever possible such a device shall be provided with a means of protection to remove or minimize the risk.

9.2 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

NOTE: Prosthetic and orthotic devices are not usually supplied or used in sterile condition.

If sterile condition of specific devices is required for particular applications, the manufacturer should 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.

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

11.1.2 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).

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 has 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 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 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

NOTE 1: 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.

NOTE 2: Mechanically based tissue risks can include:

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

12.3 Ergonomic principles

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

NOTE 1: Prosthetic and orthotic devices should be designed on ergonomic principles taking into account the special needs of the intended user. If the 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 2: Annex D describes methods of establishing the force required to operate the controls on prosthetic and orthotic devices and can be used as guidance.

NOTE 3: It has been found in practice that the minimum value of the operating force to be applied by the user to the actuator of the control mechanism of a complete prosthetic or orthotic device should be at least 5 N in order to avoid accidental operation of that control mechanism.

NOTE 4: For further information on ranges of operating force measured on samples of orthotic knee and elbow joints, prosthetic knee and elbow units and prosthetic terminal devices see clause D.6 of Annex D.

13 Information supplied by the manufacturer

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

It shall include those of the informations specified in clauses 5.1.2, 5.3, 9.2, 11.1.2, 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 his/her activity while using the device.

13.2 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.

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 tranportation 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

Introduction

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 order in which tests are to be carried out.

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 should be repeated when significant design changes are made to load-bearing parts of an upper limb prosthetic device.

A.1 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 which incorporate an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of extension/flexion which allows their alignment with the flexion angle of the elbow unit set to the position closest to 90° and with the angle of the shoulder unit set to the position closest to 0°.

A.2 Test samples

A.2.1 General

The manufacturer/submitter shall submit a test sample description in accordance with ISO 13405, Part 3.

A test submission document and a test report shall be prepared in accordance with ISO 10328, Parts 7 and 8.

A.2.2 Selection of test samples

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

Select the test samples in accordance with clause 5.1 of ISO 10328, Part 2.

Assemble combinations of sub-assemblies or components submitted for testing in accordance with the manufacturer's/submitter's recommendations.

A.2.3 Preparation of test samples

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

Ensure that the test sample is provided with an upper (proximal) end attachment and with a lower (distal) end attachment or a special grip device for a terminal device, specified by the test laboratory/facility.

Ensure that 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.