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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.

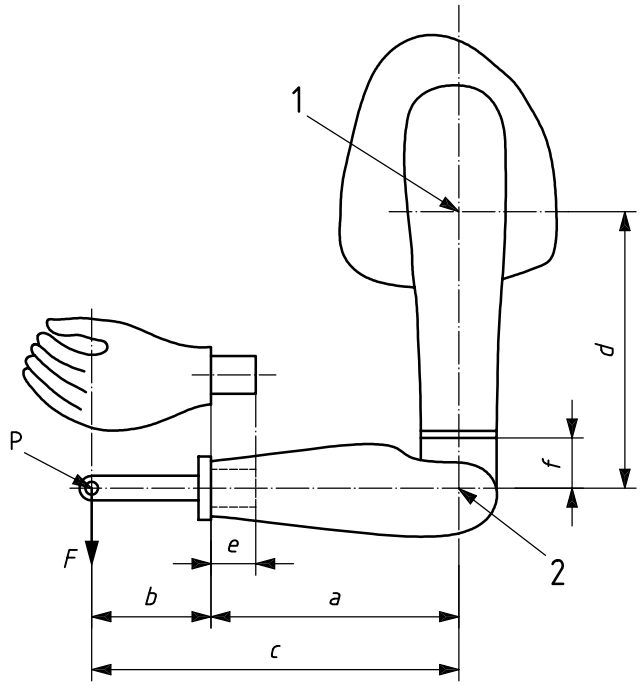
Unless otherwise specified by the test laboratory/facility, the preferred grip device for a terminal device shall be a rod of 19 mm diameter, 100 mm length and a surface roughness Ra of 1,6 µm.

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.



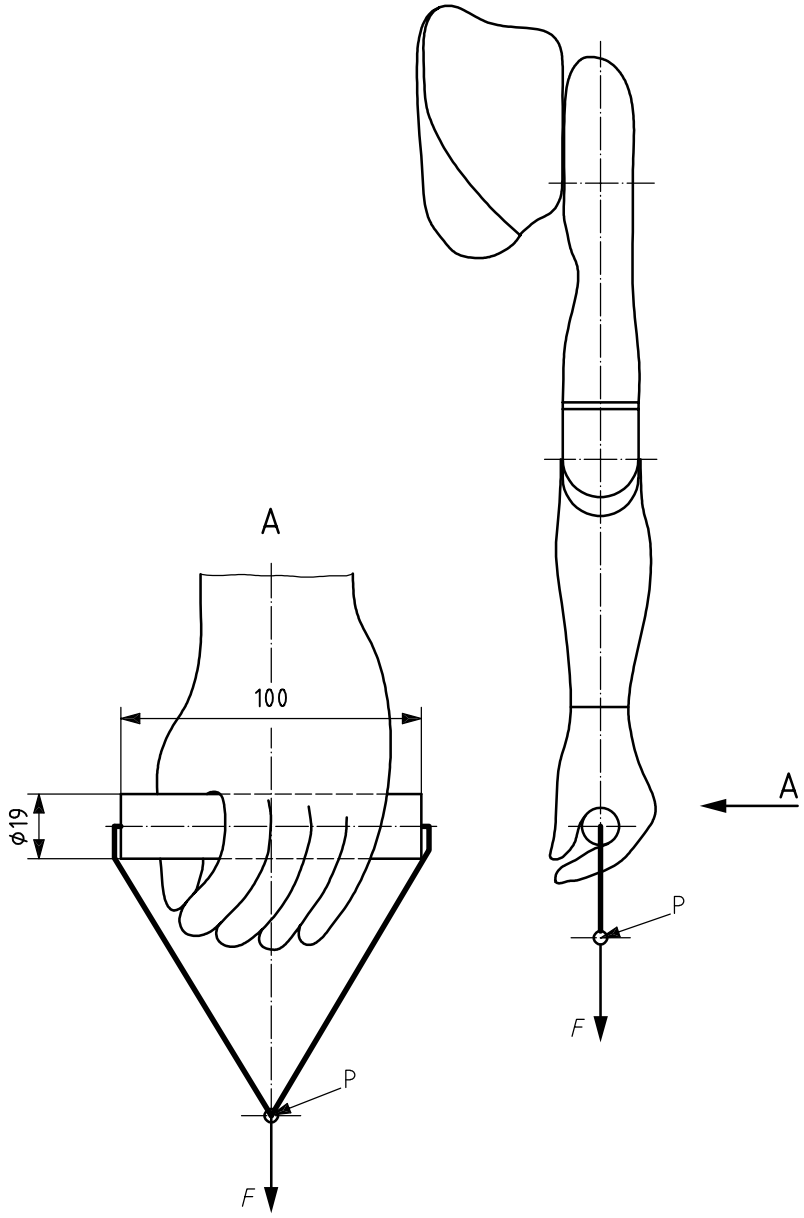
Key

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

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

Figure A.1 — Test sample segment lengths

Dimensions in millimetres

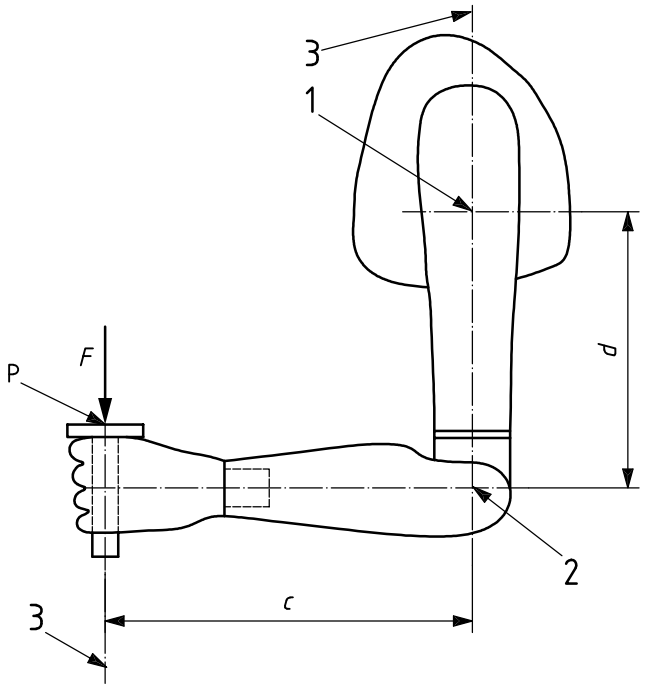


Key

F test force

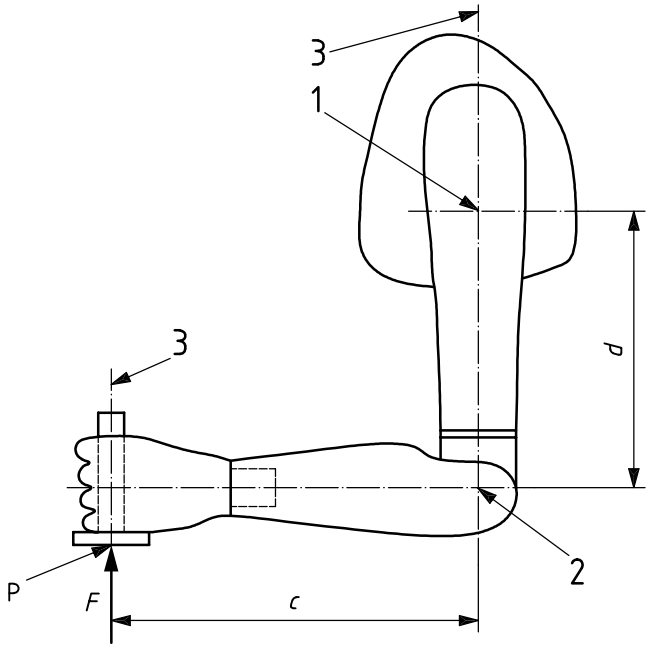
P load application point

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

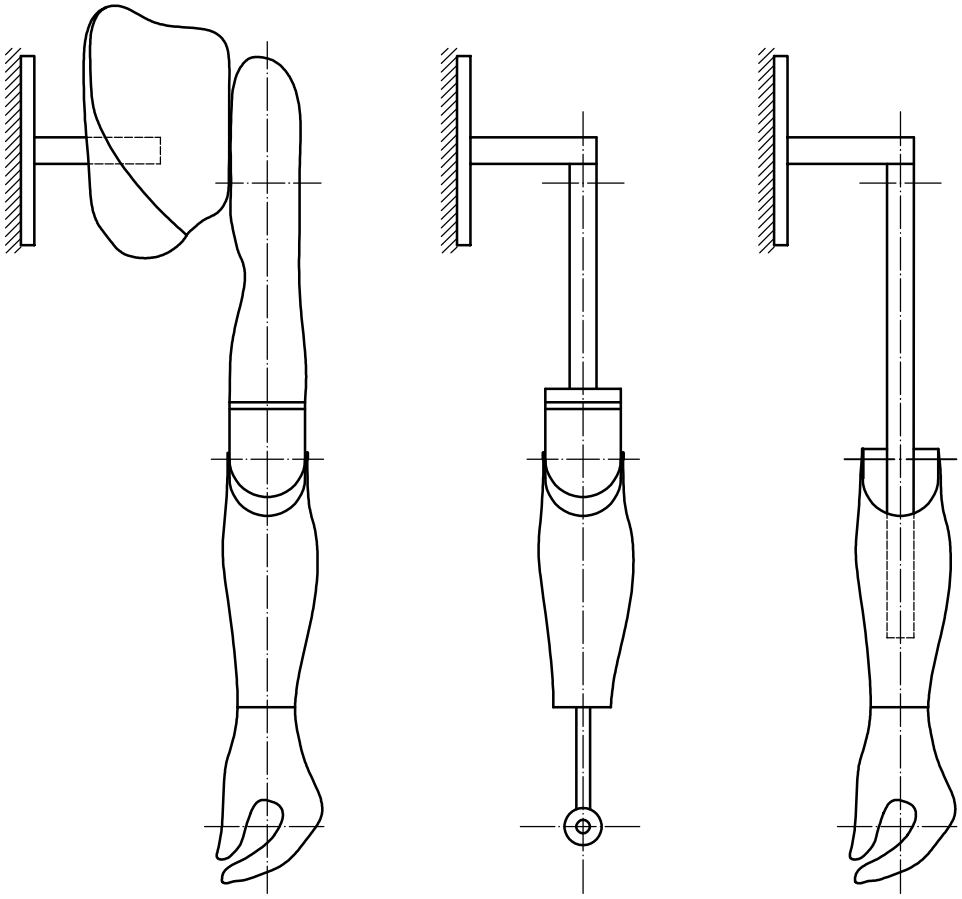


Figure A.5 — Examples of test sample configurations

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.

A.3.5 Orientation marks on test samples

Ensure that samples submitted for test bear marks to indicate “front/anterior”, “outside/lateral”, “upper/proximal”, to correspond with the intended orientation of the prosthesis, when fitted to the user.

Any marks on the test sample shall not affect its strength.

A.4 Number of tests and test samples required

The minimum number of tests and test samples required is listed in Table A.1.

Table A.1 — Number of tests and test samples required

Type of test		Reference	Minimum number of tests [a]	Batch of test samples allowed for each test	
				Regular test samples	Possible substitute test samples [b]
Static tests					
- distal tensile test	(Test 1)	A.8.2	2	2	1
- downward bending test	(Test 2)	A.8.3	2	2	1
- upward bending test	(Test 3)	A.8.4	2	2	1
Cyclic tests					
- downward bending test	(Test 4)	A.9.2	1	1	1
- upward bending test	(Test 5)	A.9.3	1	1	1

[a] The term “minimum” indicates that the repetition of tests on permitted substitute test samples may be necessary.

[b] The number of possible substitute test samples is related to each single test.

A.5 Multiple use of test samples

A.5.1 General

Test samples that have completed, without failing, any of the tests specified in this annex may be subjected to other tests of this annex, except as stated in A.5.2.

Any decision on the multiple use of test samples should be based on a corresponding indication in the test submission document (see Clause A.6) and/or the agreement between the manufacturer/submitter and the test laboratory/facility.

As a general rule, any failure occurring during a test on a test sample that has been subjected to another test justifies the repetition of the failed test on a substitute test sample (see Table A.1).

A.5.2 Restriction

Compliance of any test sample with the requirements of the cyclic tests of this annex cannot be claimed if the test sample has previously been subjected to any of the static tests of this annex at a load level required to determine the ultimate strength [see 4.4.4 a) 3)].

A.6 Test submission document

A.6.1 General requirements

The manufacturer/submitter shall prepare the test submission document with any associated information and shall provide at least one copy with the batch of test samples of every upper-limb prosthetic device submitted for test.

The manufacturer/submitter shall, if appropriate, state in the test submission document which of the information to be recorded in the test log in accordance with this annex shall be included in the test report in addition to the information required to be included according to Clause A.10.

The manufacturer/submitter shall clearly indicate a name and address for communication purposes. If appropriate, the identity of the original equipment manufacturer shall be provided.

The manufacturer/submitter shall provide a unique and traceable identification for the test submission document which shall also be indelibly marked on the test sample. The manufacturer/submitter shall maintain a record of such identification.

The manufacturer/submitter shall clearly indicate the test laboratory/facility required to conduct the test.

The manufacturer/submitter shall clearly indicate the date of submission or dispatch to the test laboratory/facility.

A.6.2 Information required for test samples

The following information, attributable to a fully traceable identification for each test sample, shall be included in the test submission document:

a) manufacturer's name and model identification and/or number or other means of identification;

b) any certification from the manufacturer, which states that the test sample has been taken from normal production and which gives details of the method of selection in accordance with A.3.2;

c) identification of centres and centre lines in accordance with A.3.3;

d) record of any end attachments (including a socket) or special grip devices in accordance with A.3.3;

e) any special assembly instructions in accordance with A.3.3;

f) identification of the worst-case alignment position in accordance with A.3.4;

g) if appropriate, information on the marks indicating “front/anterior”, “outside/lateral”, “upper/proximal” on each test sample in accordance with A.3.5;

h) if appropriate, information on the multiple use of test samples in accordance with A.5.1.

A.6.3 Information required for tests

The following information for each test sample shall be included in the test submission document:

The particular test requested (Clauses A.8 and A.9), together with the test load level to be applied (Clause A.8) or the cyclic range of the pulsating test force and the frequency of test to be applied (Clause A.9), respectively.

The following information for each test sample shall be included in the test submission document:

a) the particular test requested (Clauses A.8 and A.9);

b) the relevant loading parameter(s) to be applied, which is/are

   1) the test load level for the static tests according to Clause A.8;

   2) the cyclic range F_{cr} of the pulsating test force $F_c(t)$, the preferred frequency of test and the endurance (required number of cycles) for the cyclic test according to Clause A.9.

A.7 Accuracy

A.7.1 General

Details of methods used to measure accuracy shall be recorded.

Test equipment shall be calibrated at least annually and when any part is replaced. Records of the calibration should be maintained.

A.7.2 Accuracy of equipment

In order to meet the accuracy of procedure specified in A.7.3, the test equipment is recommended to measure:

a) linear dimensions to an accuracy of ± 0,2 mm;

b) angular dimensions to an accuracy of ± 0,2°;

c) the load to be applied to an accuracy of ± 1 % of the highest value required in the test;

d) the frequency of test to an accuracy of ± 1 % of the test frequency used.

A.7.3 Accuracy of procedure

a) Linear dimensions shall be set with a tolerance of ± 1 mm.

b) Angular dimensions shall be set with a tolerance of ± 1°.

c) Static test forces shall be applied with a tolerance of ± 2 % of the highest value prescribed for the test.

d) Pulsating test forces shall be applied at the instant of F_{cmin} with a tolerance of ± 5 N and at the instant of F_{cmax} with a tolerance of ± 3 % of the highest value prescribed for F_{cmax}.

e) The frequency of test shall be controlled with a tolerance of ± 10 % of the test frequency used.

A.8 Static tests

A.8.1 General

The static tests comprise the distal tensile test specified in A.8.2, the static downward bending test specified in A.8.3 and the static upward bending test specified in A.8.4. The order in which the tests are described is not mandatory for their application.

Keep a log with the test machine during testing and record the test number, the machine reference, the test loads and the dimensions according to the table in Figure A.1, together with the records specifically called for in A.8.2, A.8.3 and A.8.4.

This log forms the basis from which to select the information to be included in the test report (see Clause A.10) in accordance with the test submission document (see A.6.1).

A.8.2 Distal tensile test (Test 1)

Prepare and align the test sample in accordance with A.3.3 and A.3.4.

If a test sample that has already completed, without failing, any of the other tests specified in this annex is used for this test in accordance with Clause A.5 (see also last paragraph of this subclause), realign it in accordance with A.3.4. Record the re-use of the test sample.

Record the test load level to be applied, specified by the manufacturer/submitter in the test submission document (see A.6.3).

Mount the test sample in the test equipment in accordance with the test configuration illustrated in Figure A.2.

Ensure that any locking mechanisms at the shoulder and/or elbow unit are disengaged.

Apply the test force F at the load application point P (or any appropriate reference point to be specified by the test laboratory/facility) to the lower (distal) end attachment or the special grip device for the terminal device with the load line along or parallel to the long axis of the test sample as illustrated in Figure A.2.

Increase the test force F to the value F_{min} = 10 N.

Measure and record the initial position of the lower (distal) load application point P (or the specified reference point) on the load line.

Increase the test force F smoothly at a rate of between 1 N/s and 10 N/s. Continuously record the corresponding displacement of the lower (distal) load application point P (or the specified reference point) on the load line from its initial position.

Continue the test until the test force F has reached the test load level specified by the manufacturer/submitter or failure occurs. Record the maximum test force value reached. If failure occurs, record this together with the mode of failure.

Record the final displacement of the load application point P from its initial position, measured either with the test force $F = F_{min}$ applied or immediately before failure, if this occurs.

If the test is terminated by the operation of an overload release incorporated in the test sample, record this.

If a test sample that has already gone without failing another test specified in this annex fails this test, repeat this test on a substitute test sample and record the failure and the repetition, together with all other records called for.

A.8.3 Static downward bending test (Test 2)

This test applies only to test samples incorporating an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of flexion/extension.

Prepare and align the test sample in accordance with A.3.3 and A.3.4.

If a test sample that has already completed, without failing, any of the other tests specified in this annex is used for this test in accordance with Clause A.5 (see also last paragraph of this subclause), re-align it in accordance with A.3.4. Record the re-use of the test sample.

Record the test load level to be applied, specified by the manufacturer/submitter in the test submission document (see A.6.3).

Record the initial settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm), together with the standard settings according to A.3.4.

Mount the test sample in the test equipment in accordance with the test configuration illustrated in Figure A.3.

Apply the test force F at the load application point P to the lower (distal) end attachment or the special grip device for the terminal device with the load line parallel to the long axis of the upper arm segment of the test sample as illustrated in Figure A.3.

Increase the test force F to the value F_{min} = 10 N.

Measure and record the initial position of the load application point P on the load line.

Increase the test force F smoothly at a rate of between 1 N/s and 10 N/s. Continuously record the corresponding displacement of load application point P along the load line from its initial position.

Continue the test until the test force F has reached the test load level specified by the manufacturer/submitter or failure occurs. Record the maximum test force value reached. If failure occurs, record this together with the mode of failure.

Record the final displacement of the load application point P from its initial position, measured either with the test force $F = F_{min}$ applied or immediately before failure, if this occurs.

Measure and record the final settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm) upon removal of the test sample from the test equipment.

If the test is terminated by the operation of an overload release incorporated in the test sample, record this.

If a test sample that has already completed, without failing, another test specified in this annex fails this test, repeat this test on a substitute test sample and record the failure and the repetition, together with all other records called for.

A.8.4 Static upward bending test (Test 3)

This test applies only to test samples incorporating an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of flexion/extension.

Prepare and align the test sample in accordance with A.3.3 and A.3.4.

If a test sample that has already completed, without failing, any of the other tests specified in this annex is used for this test in accordance with A.5 (see also last paragraph of this subclause), realign it in accordance with A.3.4. Record the re-use of the test sample.

Record the test load level to be applied, specified by the manufacturer/submitter in the test submission document (see A.6.3).

Record the initial settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm), together with the standard settings according to A.3.4.

Mount the test sample in the test equipment in accordance with the test configuration illustrated in Figure A.4.

Apply the test force F at the load application point P to the lower (distal) end attachment or the special grip device for the terminal device with the load line parallel to the long axis of the upper arm segment of the test sample as illustrated in Figure A.4.

Increase the test force F to the value F_{min} = 10 N.

Measure and record the initial position of the load application point P on the load line.

Increase the test force F smoothly at a rate of between 1 N/s and 10 N/s. Continuously record the corresponding displacement of load application point P along the load line from its initial position.

Continue the test until the test force F has reached the test load level specified by the manufacturer/submitter or failure occurs. Record the maximum test force value reached. If failure occurs, record this together with the mode of failure.

Record the final displacement of the load application point P from its initial position, measured either with the test force $F = F_{min}$ applied or immediately before failure, if this occurs.

Measure and record the final settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm) upon removal of the test sample from the test equipment.

If the test is terminated by the operation of an overload release incorporated in the test sample, record this.

If a test sample that has already completed, without failing, another test specified in this annex fails this test, repeat this test on a substitute test sample and record the failure and the repetition, together with all other records called for.

A.9 Cyclic tests

A.9.1 General

The cyclic tests comprise the cyclic downward bending test specified in A.9.2 and the cyclic upward bending test specified in A.9.3. The order in which the tests are described is not mandatory for their application.

Ensure that the method of applying the pulsating test force $F_c(t)$ to the test sample produces a waveform that is smooth and within the prescribed tolerances [see A.7.3 d) and e)], approximating to a sinusoidal waveform, and that the method of application avoids impact and on removal avoids kickback.

Keep a log with the test machine during testing and record the test number, the machine reference, the test loads, the dimensions, c and d, according to the table in Figure A.1, and the frequency of test. Record on the log the number of cycles completed and any changes observed. Record on the log any adjustments or machine shut-downs together with the number of cycles from the start of the test. Also include the records specifically called for in A.9.2 and A.9.3.

This log forms the basis from which to select the information to be included in the test report (see Clause A.10) in accordance with the test submission document (see A.6.1).

A.9.2 Cyclic downward bending test (Test 4)

This test applies only to test samples incorporating an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of flexion/extension.

Prepare and align the test sample in accordance with A.3.3 and A.3.4.

If a test sample which has already completed, without failing, any of the other tests specified in this annex is used for this test in accordance with Clause A.5 (see also last paragraph of this subclause), realign it in accordance with A.3.4. Record the re-use of the test sample.

Record the cyclic range $F_{cr} = F_{cmax} - F_{cmin}$ of the pulsating test force $F_c(t)$ to be applied, together with the preferred frequency and the endurance (required number of load cycles), specified by the manufacturer/submitter in the test submission document (see A.6.3).

Record the initial settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm), together with the standard settings according to A.3.4.

Mount the test sample in the test equipment in accordance with the test configuration illustrated in Figure A.3.

Apply the test force F at the load application point P to the lower (distal) end attachment or the special grip device for the terminal device with the load line parallel to the long axis of the upper arm segment of the test sample as illustrated in Figure A.3.

Increase the test force F to the value F_{cmin} = 10 N.

Measure and record the initial position of the load application point P on the load line.

Apply the pulsating test force $F_c(t)$ determined by the minimum test force F_{cmin} = 10 N, the cyclic range F_{cr} specified by the manufacturer/submitter and the maximum test force F_{cmax} = F_{cmin} + F_{cr} at a waveform satisfying the general requirement of A.9.1 and at a maximum frequency of 0,5 Hz for a minimum of 300 000 cycles.

Measure with the test force F_{cmin} applied and record the final displacement of load application point P from its initial position.

Measure and record the final settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm) upon removal of the test sample from the test equipment.

If any part of the structure of the test sample fails in the cyclic test, the test sample does not satisfy the requirement of this subclause (but see last paragraph).

Record failure of the test sample together with the number of load cycles achieved.

Visually examine any test sample satisfying the test requirements and record any signs of damage in the log.

If a test sample that has already completed, without failing, another test specified in this annex fails this test, repeat this test on a substitute test sample and record the failure and the repetition, together with all other records called for.

A.9.3 Cyclic upward bending test (Test 5)

This test applies only to test samples incorporating an elbow and/or shoulder unit with a locking mechanism or other means of maintaining the angle of flexion/extension.

Prepare and align the test sample in accordance with A.3.3 and A.3.4.

If a test sample that has already completed, without failing, any of the other tests specified in this annex is used for this test in accordance with A.5 (see also last paragraph of this subclause), re-align it in accordance with A.3.4. Record the re-use of the test sample.

Record the cyclic range F_{cr} = F_{cmax} − F_{cmin} of the pulsating test force $F_c(t)$ to be applied, together with the preferred frequency and the endurance (required number of load cycles), specified by the manufacturer/submitter in the test submission document (see A.6.3).

Record the initial settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm), together with the standard settings according to A.3.4.

Mount the test sample in the test equipment in accordance with the test configuration illustrated in Figure A.4.

Apply the test force F at the load application point P to the lower (distal) end attachment or the special grip device for the terminal device with the load line parallel to the long axis of the upper arm segment of the test sample as illustrated in Figure A.4.

Increase the test force F to the value F_{cmin} = 10 N.

Measure and record the initial position of the load application point P on the load line.

Apply the pulsating test force $F_c(t)$ determined by the minimum test force F_{cmin} = 10 N, the cyclic range F_{cr} specified by the manufacturer/submitter and the maximum test force F_{cmax} = F_{cmin} + F_{cr} at a waveform satisfying the general requirement of A.9.1 and at a maximum frequency of 0,5 Hz for a minimum of 300 000 cycles.

Measure with the test force F_{cmin} applied and record the final displacement of load application point P from its initial position.

Measure and record the final settings of the (flexion/extension) positions of the shoulder unit and the elbow unit (elbow angle between the long axes of the upper and lower arm) upon removal of the test sample from the test equipment.

If any part of the structure of the test sample fails in the cyclic test, the test sample does not satisfy the requirement of this subclause (but see last paragraph).

Record failure of the test sample together with the number of load cycles achieved.

Visually examine any test sample satisfying the test requirements and record any signs of damage on the log.

If a test sample that has already completed, without failing, another test specified in this annex fails this test, repeat this test on a substitute test sample and record the failure and the repetition, together with all other records called for.

A.10 Test report

A.10.1 General requirements

The test laboratory/facility shall prepare a test report for the test(s) conducted and should provide at least one copy of the test sample, to the submitter.

The test laboratory/facility shall maintain another copy of the test report with the test log. This will simplify the reply to possible further inquiries of the manufacturer/submitter.

The test report shall be signed on behalf of the test laboratory/facility by a designated person.

The test laboratory/facility shall clearly indicate a name and address for communication.

The test laboratory/facility shall provide a unique and traceable identification for the test report (such as serial number) including identification of each page, and the total number of pages of the report. The test laboratory/facility should maintain a record of such identification.

The submitter of the test sample and the test laboratory/facility identification shall be clearly indicated.

The date of receipt of test samples and date(s) of preparation of the test report shall be clearly indicated.

A.10.2 Specific requirements

For each type of test conducted (see Table A.1), the test report shall specifically refer to Annex A of ISO 22523:2006, the subclauses related to the specific type of test performed (see A.8.2, A.8.3, A.8.4, A.9.2 or A.9.3), the test loading conditions applied (test load level for static tests or pulsating test force, test frequency and endurance for cyclic tests), and which special test set-ups were used.

For each upper-limb prosthetic device, for which an appropriate batch or batches of test samples have been submitted for test, the test report shall state the tests in which compliance with requirements of this annex has been demonstrated. The test report shall also state the tests conducted, in which compliance has not been demonstrated.

A.10.3 Options

The test report shall include any additional information, specifically requested in the test submission document (see A.6.1).

Upon request of the submitter, the test laboratory/facility shall copy from the test log (see A.8.1 and A.9.1) to the test report any further records of samples and test results called for.

Annex B
(normative)

Method of determining the mechanical properties of knee joint assemblies for lower-limb orthotic devices

B.1 General

This annex is based on BS 2574-3 and describes methods of test for knee joint assemblies intended for use in the manufacture of lower limb orthoses. Procedures are described for determining the strength and ductility and for establishing the mode of failure. These test procedures are only suitable for joint assemblies (see 3.11) if the test rollers can be placed on parallel sections of the side members.

These test procedures are intended to assist in the selection of knee joint assemblies, but are not intended for the testing of complete lower limb orthoses.

For the definitions that apply for the purposes of this annex see 3.9 to 3.19.

B.2 Principle

Samples of knee joint assemblies for lower limb orthoses are loaded in bending by means of a special test rig, each sample being loaded in one out of four mutually perpendicular directions. The bending moment is generated through application of a four-point loading configuration, carried out through application of two equal and opposite force couples by two pairs of rollers which can be rotated (see B.3 and Figure B.1). The tests are carried out to establish the resistance to bending and the mode of failure of these samples (see B.5.4). The measurements allow the calculation of the bending moment at the limit of proportionality (see B.6.1), the bending stiffness (see B.6.2), the maximum bending moment (see B.6.3) and the bending deformation at the maximum bending moment (see B.6.4).

B.3 Test rig

The test rig shall be designed to apply a four-point loading system to the test sample as illustrated in Figures B.2 and B.3.

A suitable test rig, shown in Figure B.1, shall comprise the following.

a) Two pairs of rollers of cylindrical form and of equal diameter, constrained so that their axes remain parallel during the test. Each pair of rollers shall be mounted so that they can be rotated about an axis midway between their axes, and parallel to them.

   In order to ensure the uniformity of tests carried out at different places and the comparability of test results, the following dimensions are fixed (see Figure B.1 and also NOTES 1 and 2):

   — the distance, a, between the axes about which each pair of rollers can be rotated;

   — the distance, b, between the axes of each pair of rollers;

   — the diameter, d, of each roller.

   The values of these dimensions are specified as shown in Figure B.1.

b) A mechanical testing machine, to apply an equal and opposite torque to the two shafts which carry the mountings of the two pairs of rollers. The machine permits the pairs of rollers to rotate through not less

than 90° with respect to each other without the test sample fouling the apparatus. This rotation has to be free to follow asymmetrical bending of the test sample, if this occurs.

c) A means of measuring and recording the values of angular rotation, α_1 and α_2, of the two shafts which carry the mountings of the two pairs of rollers.

d) A means of measuring and recording the applied torque.

NOTE 1 The dimensions of the test rig described in a) and illustrated in Figure B.1 are such that the inner points of loading of the four-point loading system will usually be applied to the test sample at distances of

— $x_1 \geqslant 2\, w_{1,2}$ [see Figures B.2 (a) to B.3 (e)];

— $y \geqslant 4\, w_3$ [see Figure B.3 (f)].

NOTE 2 For a particular design of knee joint assembly with, e.g. stepped side members, it may be necessary to change the value of certain dimensions (principally "a") of the test rig illustrated in Figure B.1. Such modifications should be recorded and included in the test report.

NOTE 3 External means may be necessary to prevent the test sample twisting during load application. Such means should not prevent bending deformation of the test sample nor affect the accuracy of load application (see also NOTE 3 of B.5.1).

NOTE 4 A system for displaying the relationship between the angular rotation $\alpha_1 + \alpha_2$ (measure of the bending deformation of the test sample) and the applied torque (measure of the bending moment applied to the test sample) is a useful aid to following the progress of the tests.

B.4 Preparation of test samples

Select, at random, sufficient replicate test samples for each design and size of joint assembly (see B.5.1).

Adjust the lock, if fitted, on each test sample so that it is in the fully engaged position as described by the manufacturer of the joint assembly. If the side members are not an integral part of the joint assembly, ensure that they are connected to the joint in the manner described by the manufacturer.

NOTE The test sample is tested as supplied by the manufacturer/submitter before holes are drilled which may be necessary to accommodate the components securing the orthosis to the limb.

B.5 Procedure

B.5.1 General

Carry out no more than one bending test on each test sample, except for certain test samples with stepped side members (see NOTE to B.5.3.2).

Carry out each bending test on at least three replicate test samples. In successive tests, apply the bending moment in each of the directions in which the joint assembly is intended to provide support or to restrain motion.

NOTE 1 There are usually four mutually perpendicular directions (orientations) in which the test is to be carried out (see Figure B.4), i.e. in each of the opposing directions parallel to the axis of flexion and in each of the opposing directions perpendicular to the axis of flexion. For the determination of resistance to bending and mode of failure, it is necessary that at least three replicate samples of each design and size of joint assembly be tested in each loading direction. Thus, for joints with locks, usually at least 12 joint assemblies of each design and size are tested in accordance with B.5.4 (but see NOTE 2).

NOTE 2 If the design of the components at the knee is symmetrical in the medio-lateral plane, i.e. the plane including the axis of flexion (see Figure B.4), testing will generally be necessary only in one direction, applying either inward or outward bending.

NOTE 3 When the test sample is loaded in a plane perpendicular to the axis of flexion, it may be necessary to constrain torsional rotation (about the long axis) when the load is applied. This constraint will usually be applied at one end of the test sample only. If it is necessary to apply a constraint at both ends, this should neither restrict longitudinal movement nor exert any bending constraint on the test sample. (It has been found to be suitable to use rollers which are profiled to accommodate the shape of the side members of the test sample.)

B.5.2 Test samples with parallel side members

Position the test sample in the test rig (see B.3) so that the inner loading points are at approximately equal distances, x, from the axis of flexion and/or x_1 from any change in cross section where the side member meets the joint [see Figure B.2 (a)].

Carry out the test described in B.5.4.

NOTE Some test samples may be too short to apply both pairs of forces F. These test samples can be tested after having attached suitable extension pieces in a manner that does not affect the application of the force F at the inner points of loading and the strength of the part of the test sample between them. This method corresponds to that specified in B.5.3.1 b) and illustrated in Figure B.3 (e) with the exception that extension pieces are attached instead of strengthening members.

B.5.3 Test samples with stepped side members

B.5.3.1 Testing the central portion of the test sample

If possible, position the test sample in the test rig so that both pairs of forces F are applied to the central portion of the stepped side members with the loading points of the inner forces F at the distances, x, and/or x_1, specified in B.5.2 [see Figure B.2 (b)]. If this is not possible because the central portion of the test sample is too short to apply both pairs of forces F, position the central portion in one of the following ways.

a) With the inner forces F applied as described above, apply the outer force(s) F on the smaller cross section(s) if the proportions of the test sample are such that the smaller section(s) will not bend during the test [see Figures B.2(c) and B.3(d)].

b) If the part of the member(s) of smaller cross section is permanently bent during the test, repeat the test with suitable strengthening member(s) attached to the smaller cross section(s), taking care to avoid affecting the strength of the part of the test sample between the inner loading points [see Figure B.3 (e)].

Carry out the test described in B.5.4.

B.5.3.2 Testing the outer portion of the test sample

Position the test sample in the test rig so that both pairs of forces F are applied to the portion of the side member with the smaller cross section [see Figure B.3 (f)].

Carry out the test described in B.5.4.

NOTE The test sample tested in B.5.3.1 may be used for the test described in B.5.3.2 if the length of the side member of smaller cross section has not been subjected to any bending moment during the earlier test.

B.5.4 Test to establish resistance to bending and mode of failure

B.5.4.1 Establishing the resistance to bending

Place the test sample in the test rig in the selected orientation (see NOTES 1 to 3 of B.5.1).

Apply equal forces F at each of the loading points (see Figures B.2 and B.3) through application of equal torque at each pair of rollers (see Figure B.1) and gradually increase the loads.

As a measure of the bending moment exerted on the test sample, record the torque applied to each pair of rollers or the value of test force generating this torque.

As a measure of the bending deformation of the test sample, record the angular rotation α_1 and α_2 of the two shafts that carry the mountings of the two pairs of rollers or the related linear displacement of the point of application of the test force.

Apply the load in a smooth continuous manner in a testing machine and record the values of torque or related force and angular rotation α_1 and α_2 or related displacement continuously (see NOTES 1 and 2 below).

Carry out the measurements and take records in such a way that the relationship between bending moment and bending deformation can be presented in the form of a graph and can permit the subsequent determination of

a) the bending moment at the limit of proportionality, M_p;

b) the bending stiffness, i.e. the mean slope of the graph below the limit of proportionality;

c) the maximum bending moment, M_{max};

d) the bending deformation at the maximum bending moment.

NOTE 1 When applying the test rig described in B.3, an angular rotation velocity less than 1°/s has been found to be suitable. In other applications a cross head speed of the testing machine between 0,4 mm/s and 0,8 mm/s has been found to be suitable.

NOTE 2 The application of load in increments is considered to be inappropriate.

B.5.4.2 Terminating the test

Continue to increase the load until any of the following apply, and then terminate the test.

a) Any part of the joint assembly fractures.

b) The mechanism of the joint lock fails (the lock opens under load).

c) The deformation of the test sample becomes so great that the loading geometry is adversely affected and/or

   1) the test sample fouls the apparatus;

   2) the mechanism becomes unsafe;

   3) one pair of loading points has rotated through an angle of greater than 90° with respect to the other.

B.5.4.3 Concluding the test and establishing the mode of failure

At the conclusion of the test, carry out the following.

a) Assign and mark a unique identification (see NOTE 1) to the test sample.

b) Remove the test sample from the rig and examine it visually.

c) Record the reason why the test was terminated.

d) Record the condition of the test sample, the details of any deformation, cracks or other failure (including whether or not the lock mechanism has remained in the fully engaged position) and identify the mode of failure (see NOTE 2).

e) Mark the test sample with the unique identification.

NOTE 1 The unique identification should enable the batch number or the order number of the test sample to be traced.

NOTE 2 Examples of the modes of failure and the coding system by which these modes may be indicated (see Table B.1) are

- A – plastic yield of the side member(s);
- B – complete shear of the main pivot pin or screw;
- C – crushing of the male tongue-loaded face;
- D – bowing of the ring loaded face following indentation by the male tongue;
- E – opening of the female clevis following bending of the side cheeks;
- F – failure of the fabricated construction at the side member;
- G – failure of the fabricated construction at the head joint.

NOTE 3 In an extensive series of tests on a range of joint assemblies, the most common mode of failure was A.

B.6 Calculation of results

NOTE It should be noted that, due to the compound nature of the test samples, the variability of the test method and, as a consequence, the spread of the data obtained is likely to be greater than would be experienced with test samples of a single homogeneous material. This will affect the results of the calculations specified in B.6.1 to B.6.4.

For orientation: The results of the evaluation of this test method, carried out by two laboratories as part of a programme of laboratory tests, show that at least 75% of the measurements made lie within a range of ± 10% to ± 15% of the mean.

B.6.1 Bending moment at the limit of proportionality (M_p)

For each test sample determine the bending moment at the limit of proportionality M_p, (see 3.16) expressed in N·m, from the bending moment/angular deflection relationship (see Figures B.5 and B.6) and calculate the mean for each of the four mutually perpendicular directions of loading illustrated in Figure B.4 (but see NOTE 2 of B.5.1).

NOTE The bending moment/angular deflection relationship may be derived from a graph or may be indicated by instrumentation incorporated into the test apparatus or by other data-handling equipment.

B.6.2 Bending stiffness

For a definition see 3.17.

For each test sample determine the slope of the graph, expressed in N·m/degree, in the linear region below the limit of proportionality of the bending moment/angular deflection relationship (see Figures B.5 and B.6) and calculate the mean for each of the four mutually perpendicular directions of loading illustrated in Figure B.4 (but see NOTE 2 of B.5.1).

B.6.3 Maximum bending moment (M_{max})

For a definition see 3.18.

For each test sample determine the maximum bending moment M_{max}, expressed in N·m, from the bending moment/angular deflection relationship (see Figures B.5 and B.6) and calculate the mean for each of the four mutually perpendicular directions of loading illustrated in Figure B.4 (but see NOTE 2 of B.5.1). See NOTE to B.6.1.

B.6.4 Bending deformation at the maximum bending moment

For a definition see 3.19.

For each test sample determine the bending deformation at the maximum bending moment M_{max}, expressed in degrees, from the bending moment/angular deflection relationship (see Figures B.5 and B.6) as the amount of angular deflection (see 3.15) when the bending moment is M_{max} (see 3.18), and calculate the mean for each direction of loading.

NOTE It may be useful to additionally determine the "maximum bending deformation" as the "maximum angle of bend" at failure, applying the criterion used for the determination of the bending deformation at M_{max}, accordingly.

B.7 Test report

The test report, an example of which is shown in Table B.1, shall include the following information for each joint assembly tested:

a) identity of the joint assembly, including the name and address of the manufacturer/submitter, together with any trade mark or registered trade name;

b) type and size of the joint assembly as described by the manufacturer/submitter, including the catalogue or other reference number;

c) batch or individual serial number;

d) date(s) of the tests;

e) reason for the termination of each test in accordance with B.5.4.2.

NOTE Attention is drawn to the need to indicate any premature failures [i.e. for all tests terminated for one of the reasons listed in item c) of B.5.4.2].

f) For test samples with parallel side members, the test results (including the mean values) obtained from loading in the antero-posterior plane and from loading in the medio-lateral plane, in each direction of loading, for each of the following properties:

1) the bending moment at the limit of proportionality, M_p, expressed in newton metres, (see B.6.1);

2) the bending stiffness, expressed in newton metres per degree, (see B.6.2);

3) the maximum bending moment M_{max}, expressed in newton metres, (see B.6.3);

4) the bending deformation at the maximum bending moment, expressed in degrees, (see B.6.4).

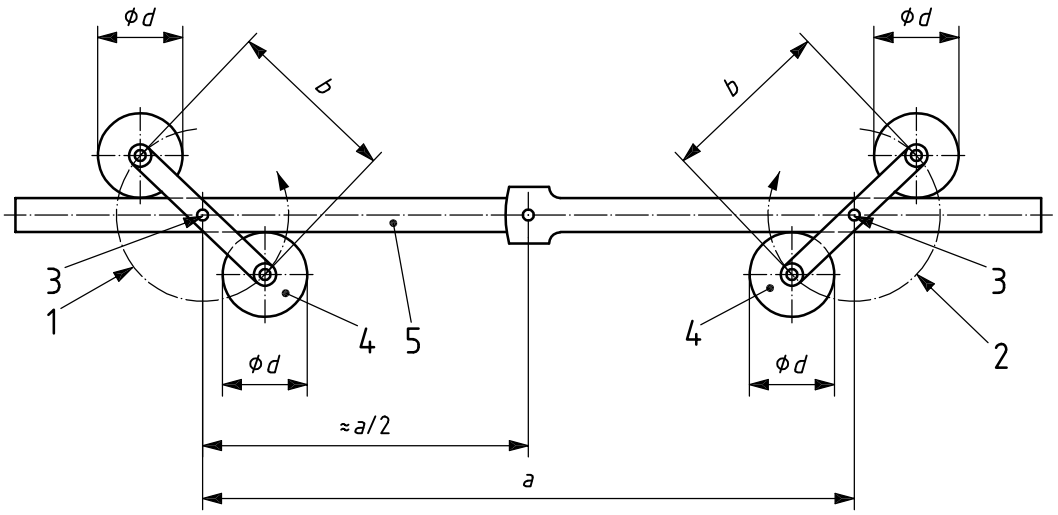
NOTE Attention is drawn to the need for caution in interpreting these values, particularly if the test sample has fouled the apparatus. See both the NOTE to B.4 and the NOTE to B.6.

g) For test samples with stepped side members, the values given in item f) for both the central portion of the joint assembly and the portion of the side member with the smaller cross section;

h) graphs for each test sample showing the bending moment/angular deflection relationship in each direction of loading, with the scales of the coordinates clearly indicated.

The graphs should also be available for inspection on request and should be included in the manufacturer's/submitter's data sheets and/or catalogue(s).

i) A description of the condition of the test sample after termination of the test in accordance with item d) of B.5.4.3.



Key

1 moment M and angular rotation α_1 [a]

2 moment M and angular rotation α_2 [a]

3 centre of rotation

4 roller

5 test sample

Arrangement for joint assembly with side members within the rig:

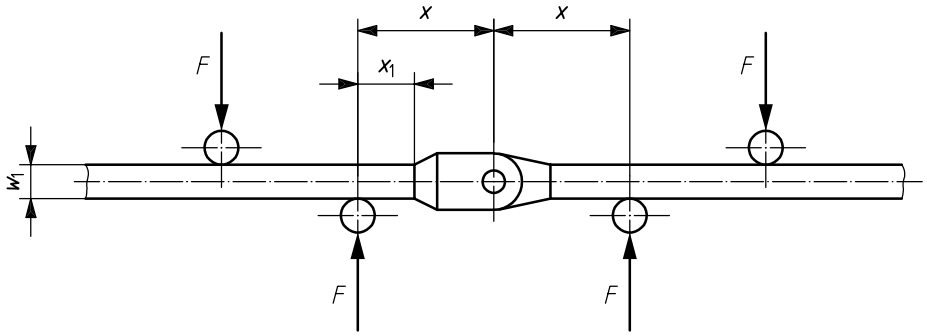
a = 280 mm

b = 100 mm

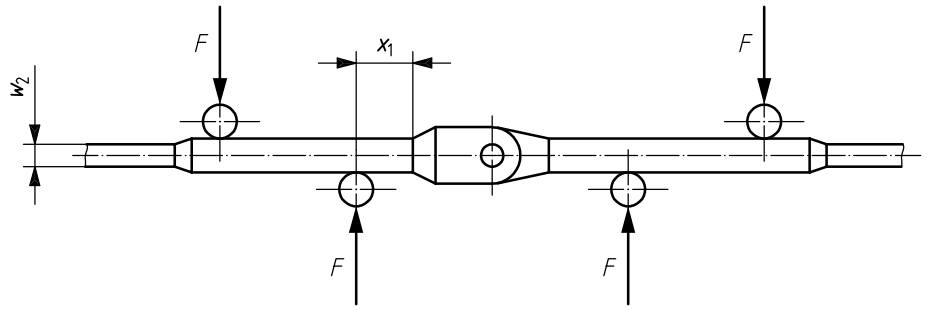
d = 30 mm

[a] One pair of rollers may rotate more than the other whilst still applying equal moment to each end of the test sample.

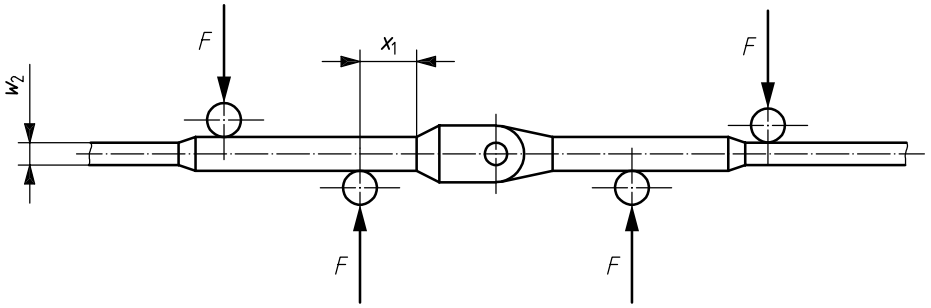
Figure B.1 — Example of a test rig design suitable for the application of the four-point loading system



(a) Arrangement for joint assembly with parallel side members (see B.5.2)



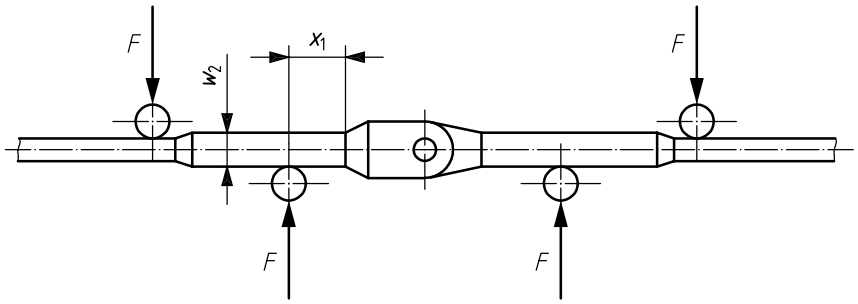
(b) Arrangement for joint assembly with stepped side members (see B.5.3.1)



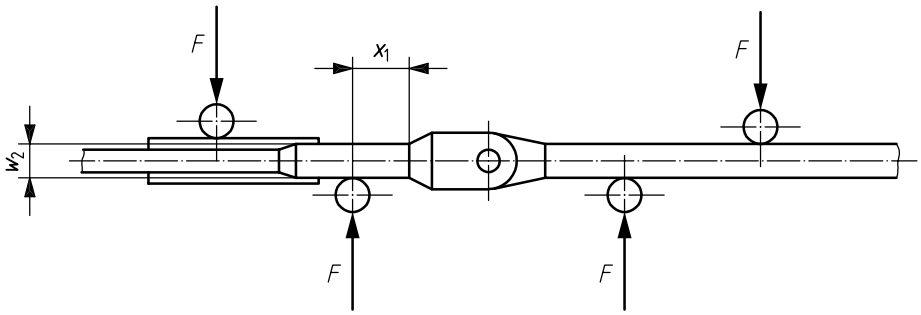
(c) Arrangement for joint assembly with unequal stepped side members [see B.5.3.1 a)]

NOTE For clarity, the locking mechanism is not represented on these diagrams.

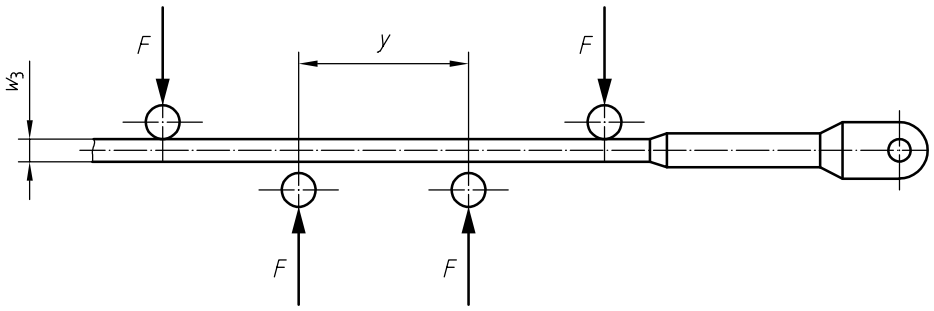
Figure B.2 — Arrangements of the four-point loading system
(continued on Figure B.3)



(d) Arrangement for joint assembly with extended stepped side members [see B.5.3.1(a)]

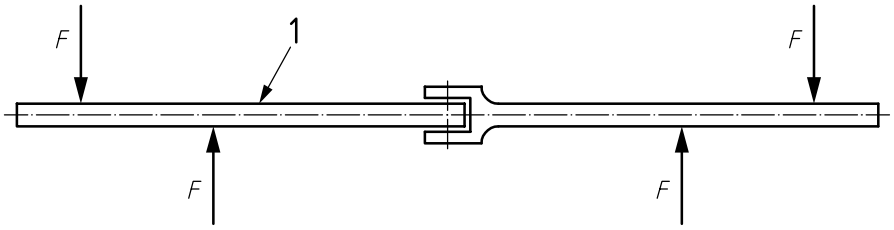


(e) Arrangement for joint assembly with extended stepped side member requiring additional strength [see B.5.3.1(b)]

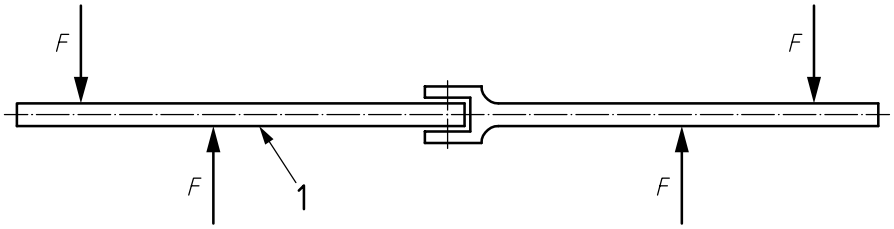


(f) Arrangement for testing outer portion of joint assembly with stepped side member (see B.5.3.2)

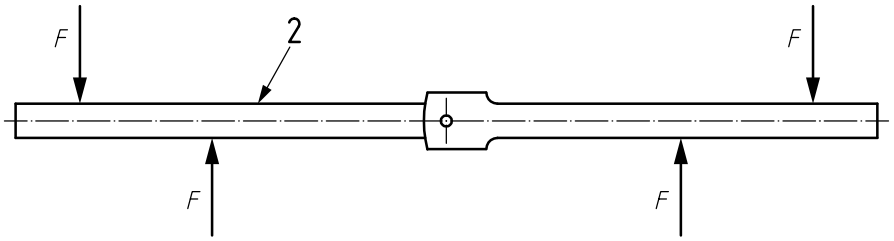
Figure B.3 — Arrangements of the four-point loading system
(continued from Figure B.2)



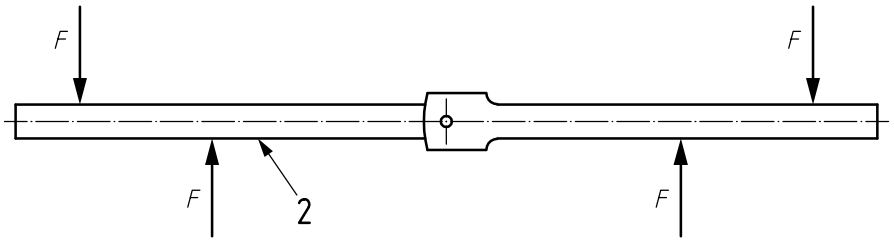
(a) Medio-lateral plane: inward bending



(b) Medio-lateral plane: outward bending



(c) Antero-posterior plane: flexing



(d) Antero-posterior plane: extending

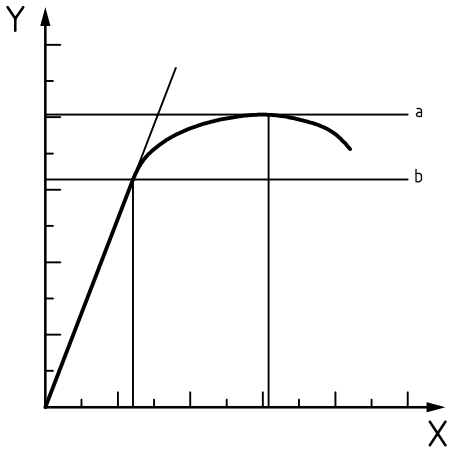
Key

1 face X (inner face)

2 edge Y (front edge)

NOTE *F* indicates the direction of loading. Face X (i.e. the face that is to be placed adjacent to the patient's knee) and edge Y are shown for identification only. For clarity, the locking mechanism is not represented in these diagrams.

Figure B.4 — Test orientations for joint assemblies intended to restrain motion in four directions mutually at right angles (see B.5.1)



Key

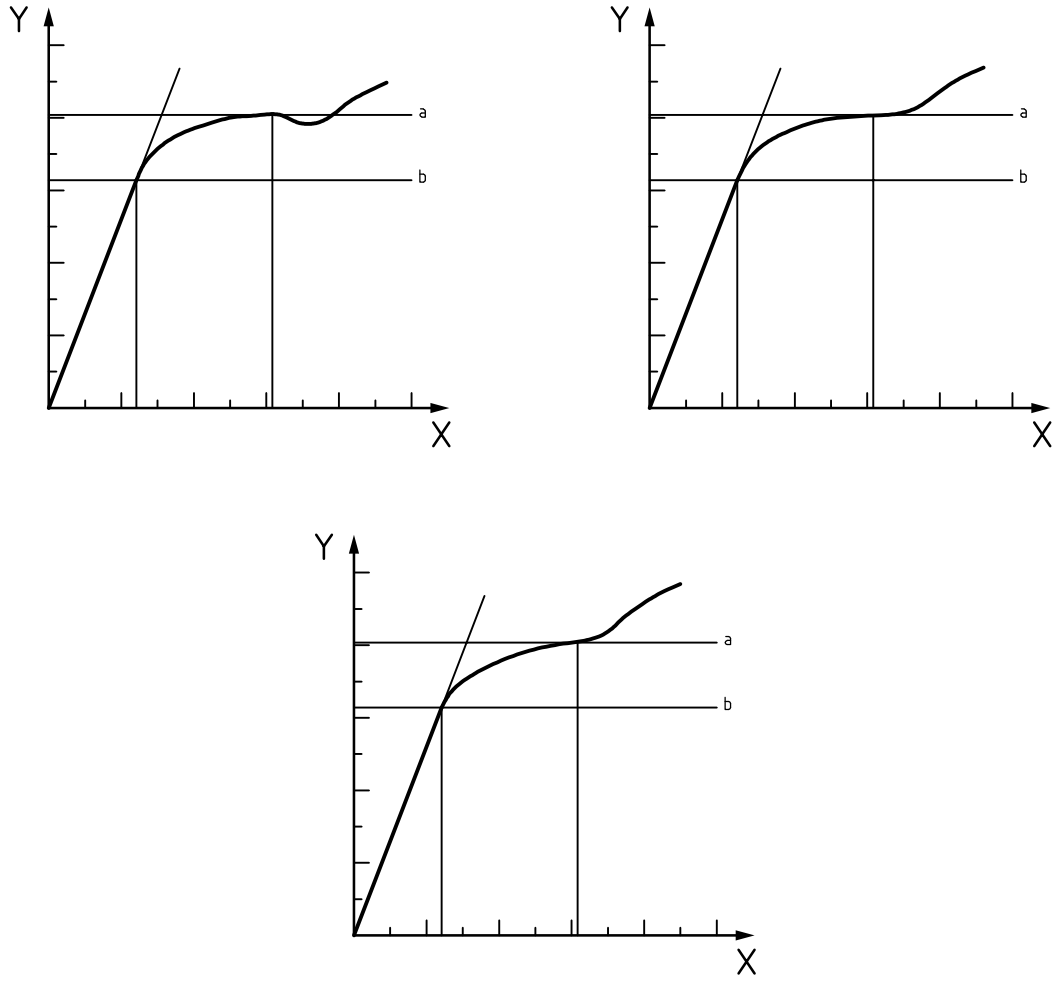
X angular deflection in degrees

Y bending moment in N·m

a Maximum bending moment.

b Limit of proportionality.

Figure B.5 — Example of a bending moment/angular deflection curve: single-stage failure
(see 3.17, 3.18 and 3.19)



Key

X angular deflection in degrees

Y bending moment in N·m

a Maximum bending moment.

b Limit of proportionality.

Figure B.6 — Examples of a bending moment/angular deflection curve: two-stage failures
(see 3.17, 3.18 and 3.19)

Table B.1 — Example of test report

Description of joint assembly and catalogue number				Knee joint AB/AB 1234		
Manufacturer's/submitter's name and address				XYZ Limited, Any Street, Any Town		
Joint assembly: **Type** R/C manual steel **Size** Adult						
Date(s) of the tests and name of the tester				February 1996/MZ		
Results [a] [minimum of three in each direction and in each attitude of restraint (see B.5.1)] **Test mode**	**Bending moment at the limit of proportionality** (M_p) N·m	**Bending stiffness** N·m/°	**Maximum bending moment** (M_{max}) N·m	**Bending deformation at the maximum bending moment** °	**Mode of failure** [b]	**Description of condition of test sample** [b] **and/or reason for stopping the test**
Antero-posterior in extension	59,7	22,4	159,1	19,7	A, F	
	57,8	22,3	160,4	18,5	A, F	
	44,1	23,7	159,0	19,2	A, F	
Mean	53,9	22,8	159,5	19,2		
Antero-posterior in flexion	46,0	20,5	117,7	12,2	E	
	62,6	17,5	118,5	10,6	C	
	52,3	20,7	104,9	9,6	E	
Mean	53,6	19,6	113,7	10,8		
Medio-lateral inward bending [c]	27,7	2,1	40,7	50,0	A	
	28,3	2,2	41,0	49,6	A	
	26,9	2,1	40,5	50,3	A	
Mean	27,6	2,1	40,7	50,0		
Medio-lateral outward bending [c]	28,5	2,0	39,7	41,7	A	
	25,7	2,2	39,1	49,5	A	
	30,9	2,0	40,3	48,2	A	
Mean	28,4	2,1	39,7	46,5		

[a] If the test samples have stepped side members, the values shall be reported for both the central portion and that portion with the smaller cross section. If this occurs, a second table should be used [see B.7 (g)].

[b] See B.5.4.3 NOTE 2.

[c] See Figures B.6 (a) and (b).

Annex C
(informative)

Guidance on methods of determining the flammability and toxicity of combustion products of lower-limb prosthetic devices

C.1 General

It is important that whenever potentially flammable materials are present and where there is the risk of fire occurring and of people being exposed to combustion products, the hazards shall be minimized. In the case of lower limb prostheses, there is a risk of fire by contact with a hot surface or by exposure to flame.

The majority of injuries in fire are caused by the smoke and toxic/irritant gases produced; the remainder are caused by burns. The toxic hazard comprises the toxic effect of smoke and gas produced during combustion and the rate at which they are produced, which is a function of the flammability characteristics of the burning materials.

This annex gives guidance on methods for assessing the ignition and burning characteristics (including toxic hazard) of lower-limb prosthetic devices when subjected to radiant and naked flame heat sources. This International Standard does not include tests where the prosthetic device is covered by clothing.

C.2 Principle

The principle is to subject complete prosthetic devices to two separate tests; a radiant heat source test (i.e. without flame) and a naked flame source test (as described in ISO 8191-2).

C.3 Test submission document

A test submission document identifying the test sample shall be supplied by the manufacturer/submitter. If a test sample is submitted by the manufacturer, the test submission document shall identify all materials, cosmesis, covers, adhesives, fastenings, etc. used in the construction of the test sample.

C.4 Safety requirements

There are hazards encountered when conducting fire tests and it is essential that adequate precautions be taken.

Pay particular attention to the handling of flammable gases, the evolution of potentially toxic gases and the fact that extensive inflaming of test samples may occur.

Provide adequate means of extinguishing the test sample, bearing in mind that some test samples may produce severe flaming during the test. Ensure that a hand-held CO_2 fire extinguisher that can be directed over the burning area is available.

NOTE In some cases, smouldering may be difficult to extinguish completely and immersion of the test sample in water may be necessary.

C.5 Test samples

C.5.1 Sample, nature and source

Complete lower-limb prosthetic devices shall be tested, although surrogate skeletal components may be used if it can be shown that these would not affect the test results.

NOTE If submitted by the manufacturer, a test sample should in all other respects be fully representative of the manufacturer's sealed design/specification and proposed or actual production standard. The manufacturer should furnish evidence to confirm that the samples are in accordance with the specified design and that quality assurance requirements controlling materials have been met.

All combinations of materials, cosmesis, covers etc. supplied as test samples shall represent typical lower-limb prosthetic assemblies that it is proposed to supply.

C.5.2 Sample identification

Ensure that the test samples are clearly identified by the manufacturer/submitter and where submitted by the manufacturer, all interfaces between differing materials that make up the cosmesis/finished article (including foot cosmesis) are clearly shown and/or indelibly marked on the outer cosmetic covering. Ensure that these locations, if present, are recorded on the test submission document. Ensure that the sample identification bears the manufacturer's/submitter's name and a reference number traceable to the test submission document.

C.5.3 Sample dimensions

Build all test samples of lower-limb prosthetic devices in accordance with the dimensions given in Figures C.1 and C.2. Use standard size “dummy” sockets for both trans-tibial and trans-femoral test samples (see Figures C.3 and C.4).

C.5.4 Sample conditioning

Condition test samples before test for at least 4 d at a temperature of (23 ± 2) °C and a relative humidity of (50 ± 5) % (see NOTE 1) and until constant mass is achieved (see NOTE 2). Report the final mass.

Arrange the test samples within the conditioning environment so that air can circulate around each side of each test sample.

NOTE 1 These conditions correspond to the atmosphere described in ISO 554.

NOTE 2 Constant mass is considered to be reached when two successive weighing operations, carried out at an interval of 24 h, do not differ by more than 0,1 % of the last mass of the test sample, or 0,12 g whichever is the greater in terms of mass.

C.6 Test arrangements

C.6.1 Test room

Ensure that the test room

— is of sufficient size to easily accommodate all test equipment and apparatus and to allow space for access on all sides;

— is capable of being sealed to prevent draughts;

— has a suitable extraction system to allow smoke and fumes to be removed quickly and safely following a test;

— allows the test to be viewed clearly by observers and/or video/photographic means.

Provide means of extinguishing any burning samples.

Ensure that the room temperature at commencement of each test is (20 ± 10) °C.

Observers and control and monitoring equipment shall be located outside the room.

C.6.2 Sample support frame

Provide a suitable support frame/clamp to enable the test sample to be held in the required position and orientation for both radiant and flame exposure heat sources.

With the radiant source test retain the sample in one position (i.e. horizontally and parallel to the heat source elements, as shown in Figure C.5).

With the flame impingement test apply the flame so that the "worst case" point of application and sample orientation is tested; this requires different orientations to be assessed.

NOTE 1 This "worst case" will usually be with the flame impinging underneath the sample with the latter inclined to the horizontal (see Figure C.6).

Ensure that the support frame for the radiant exposure test allows the mass loss from the sample to be measured.

NOTE 2 To accommodate limbs of varying length at horizontal or inclined orientations, a support frame constructed from slotted angle members has been found to be suitable. This is mounted on the platform of a large capacity laboratory top-pan balance (60 kg capacity), in the form of a rectangular section frame about 900 mm high. Pulleys carried on projecting arms at the top of the frame carry suspension wires at about 200 mm beyond the edge of the balance (see Figure C.7). Wire loops are formed through holes drilled in the rim of the socket and at the toe of the limbs which are suspended from the wires via intermediate lengths of suitable wire to achieve approximate positioning. Final adjustments should be made on length adjustors incorporated in the main suspension wires.

C.6.3 Apparatus

C.6.3.1 Radiant heat source

Ensure that the electric radiant heat source is capable of providing a constant radiative heat flux of 20 kW/m^2 at the closest point of the test sample and between 15 kW/m^2 and 18 kW/m^2 at a lateral distance of 100 mm on each side of this point.

Ensure that the heat source reaches 60 % of full power within 1 min of switch-on and full power within 4 min to 5 min.

To ensure repeatability of intensity and location of the radiative heat flux either

a) provide a variable power input to the heat source so that the prescribed heat flux is produced at a known distance from it, e.g. 100 mm and at a known height (above the working surface)

or

b) use an uncontrolled heat source working directly from the mains electrical supply connected to a voltage stabilizer (if required) and determine the location where the prescribed heat flux is achieved, and use this distance as the separation between source and sample in all tests.

Regularly check the radiative heat flux in the plane of the sample with a calibrated heat flux meter.

NOTE Two quartz halogen lamps each of 2 kW power mounted in reflectors have been found to be sufficient. A suitable arrangement is shown in Figure C.5.

C.6.3.2 Flame ignition source

This ignition source is a diffusion flame with a calorific output approximating that of a burning match. A flame exposure time of (15 ± 1) s will be approximately equivalent to the burning of one match. A burner tube consists of a length of stainless steel tubing of (8,0 ± 0,1) mm outside diameter, (6,5 ± 0,1) mm internal diameter and (200 ± 0,5) mm in length. The flow meter shall be calibrated to supply a propane gas flow rate at 25 °C of (45 ± 2) ml/min.

The burner tube is connected by flexible tubing to a flow meter fitted with a flow controller and in turn to a butane gas cylinder fitted with a standard commercial 100 kPa [2)] pressure regulator. The flexible tubing between the flow meter and the tube has a nominal internal diameter of 8 mm and a length of (2,0 ± 0,2) m.

NOTE 1 Under the above conditions, the flame height from the burner is approximately 40 mm and the heat flux applied to the test sample is (40 ± 2) kW/m^2.

For remote control, incorporate a solenoid cut-off in the burner tube and locate some form of electrical igniter at the burner mouth.

Mount the burner assembly on a suitable carrier sliding on a moveable track and capable of being moved along the track from a remote position (e.g. with a pull string operated from an adjoining control room).

NOTE 2 The moveable track provides a positive location point for the burner tube when setting up the test while enabling it to be removed for checking flame height and solenoid operation etc., as necessary.

In the case of local control omit the solenoid cut-off and electrical igniter and control the test flame manually.

Mount the burner on a carrier on a track as above, so that a positive location for the flame in relation to the sample can be established prior to the test. Retract the burner, ignite and adjust the flame and then move it into the test position for starting the test.

Use adequate respiratory protection, as necessary.

Make video/photographic records of the tests, if required by the manufacturer/submitter.

C.6.3.3 Weighing platform

Use a calibrated weighing platform of suitable capacity and with a resolution of 1 g to measure the mass loss of the sample with time elapsed for the duration of the test.

Ideally, output to a suitable remotely connected device such as a data logger or a chart recorder should be available or else visual observation and recording would be satisfactory if visual access is adequate. A calibration check should be carried out before each series of tests.

C.6.3.4 Video/photographic recording

Video/photographic records should be made of tests.

C.7 Test procedures

C.7.1 General

Ensure that test operators are competent to safely carry out the test.

Make a check to ensure that operators cannot be exposed to fumes from combustion.

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2) 100 kPa = 1 bar.

Before commencing, check all equipment for correct operation.

Ensure that the test room can be cleared of smoke and decomposition products by an extractor fan or other means of ventilation, bearing in mind that the testing room atmosphere may become hazardous.

Provide adequate means of extinguishing the test sample, bearing in mind that severe flaming may be encountered. Ensure that a hand-held CO_2 extinguisher that can be directed over the burning area is available with other means, such as fire blankets.

NOTE In some cases, smouldering may be difficult to extinguish completely and immersion of the test sample in water may be necessary.

C.7.2 Radiant heat source

Drill holes at the top of the socket and at the toes and form wire loops through them for attachment to the suspension wires.

Connect each end of the sample with a string or thread stretched over the outer surface of the limb so that it touches the “high points” and delineates a datum line along the length of the sample.

Suspend the sample from the suspension wires to the sample support frame and adjust the positioning of the limb so that the datum is at the pre-determined height providing the required heat flux is at the closest point from the radiant heat source.

NOTE 1 A ruler or a strip of metal scribed at this height may be used as a gauge.

Locate the heater parallel to the datum at the pre-determined distance of approximately 100 mm to achieve the prescribed heat flux.

NOTE 2 A simple gauge may be made from a piece of 3 mm metal rod cut to this length and held in a T-handle.

Remove the string, switch on all recording equipment and start the test by applying power to the heat source.

During the test

a) record whether sustained flaming lasting longer than 4 s occurs;

b) record the mass loss at one 1 min intervals for the duration of the test, maintain the heating for 30 min or until thermal decomposition is judged to have stopped as assessed both visually and from mass loss measurements;

c) record whether debris separates and whether it is flaming or glowing.

Conduct further tests at different locations along the test sample to coincide with the interface of differing materials and/or specified areas such as calf and thigh.

NOTE 3 It may be necessary to use separate samples for different interface tests.

NOTE 4 The test sample may produce molten material which could detach and this should be taken into account while measuring mass loss. A simple tray suspended from the test sample support frame has been found to be adequate.

C.7.3 Flaming ignition source

Adjust the height of the limb on its suspension wires until the selected test area is located 39 mm vertically above the mouth of the burner, with the burner carrier positively located on its track.

NOTE 1 A retractable wire gauge 39 mm in height located on the burner tube is suggested for the final adjustment of the limb height.

Retract the burner along its track.

Establish the test flame and adjust to 41 mm using the wire gauge on the burner as a guide.

Withdraw the height marker gauge and position the burner under the test area.

Start the test by applying the burner flame for 15 s.

Note whether the propagation of flaming extends beyond the influence of the flame ignition source.

Extinguish or withdraw the flame at the expiry of the test period.

Observe the test sample after this point until it is apparent that no self-sustained flame/or flaming combustion is occurring and there is no evidence of continuing thermal decomposition.

Extinguish the sample if sustained flaming combustion persists for longer than 15 s after the removal of the flame ignition source.

Apply the flame at various points on the sample if the “worst case” situation has not been established.

NOTE 2 An angle of 45° to the horizontal as shown in Figure C.6 will normally be the “worst-case” impingement/orientation.

NOTE 3 Locations for application of the flame ignition source may be decided through consultation between the test laboratory and the manufacturer/submitter.

C.8 Determination of the “Total Toxic Potential Dose” (TTPD)

C.8.1 Rationale for the toxicity criterion based on mass loss

Although the toxic potency of the fire atmosphere arises from a wide variety of different chemical species, results from toxic potency tests suggest that the toxic potency based on the extent of conversion of the “fuel” to products during combustion (i.e. as measurable from the mass loss of the fuel) is relatively similar for many different materials. The range of toxic potency values for many common materials, both natural and synthetic, lies approximately between an LCt_{50} of 100 g·m^{-3}·min to 2 000 g·m^{-3}·min where the LCt_{50} is defined as “A measure of lethal toxic potency; the exposure dose calculated to produce lethality in 50 % of exposed test animals within a specified exposure time and post-exposure observation period. This measure can be used to compare the toxic potencies of the combustion products from different materials decomposed under different fire conditions”.

The criterion adopted in this annex uses the method described in BSI DD180 [17] to calculate the cumulative “Total Toxic Potential Dose” (TTPD) with time, based on the cumulative mass loss of the sample over fixed time periods. In BSI DD180, a value of total toxic potential dose of 200 g·m^{-3}·min is considered “incapacitating” and a value of 500 g·m^{-3}·min “life threatening”. For the purposes of this International Standard, a value of the total toxic potential dose of 100 g·m^{-3}·min is used as the pass/fail criterion, i.e. a value equal to or higher than 100 g·m^{-3}·min would constitute a fail. To enable the assessment to be made solely on the basis of cumulative mass loss, a fixed volume into which the fumes would be dispersed has to be set. For the purposes of this International Standard the reference volume V_R = 30 m^3, representative of a typically sized domestic room, should apply.

C.8.2 Calculation of the “Total Toxic Potential Dose” (TTPD)

In order to calculate the total toxic potential dose, proceed as follows (a worked example is included as Table C.1 at the end of this annex).

Step 1: Tabulate the cumulative mass loss in grams of the sample, achieved after each successive minute of the test up to 30 min.

Step 2: Divide each cumulative mass loss after each time interval by 30 (see NOTE) to achieve the toxic potential concentration (units: $g \cdot m^{-3}$).

NOTE The reference volume V_R = 30 m^3 is representative of a typically sized domestic room (see C.8.1).

Step 3: Add each successive value obtained in Step 2 to its previous value, i.e. to achieve a cumulative total toxic potential dose.

Step 4: Check the value of cumulative total toxic potential dose reached by the end of the test period against the specified limit to decide on whether the sample has passed or failed the radiant heat source test (see C.9.1).

C.9 Pass/fail criteria

C.9.1 Radiant heat source test

Failure is deemed to occur if there is an appearance of sustained flaming combustion during the test. If no flaming occurs a TTPD calculation should be performed using the mass loss data in the method described in C.8. If the TTPD is equal to, or greater than, 100 $g \cdot m^{-3} \cdot min$, the sample is deemed to have failed.

C.9.2 Flaming ignition source test

Failure is deemed to occur if for any application point or sample orientation

— propagation of flaming takes place away from the influence of the flaming ignition source during the 15 s flame ignition source applications

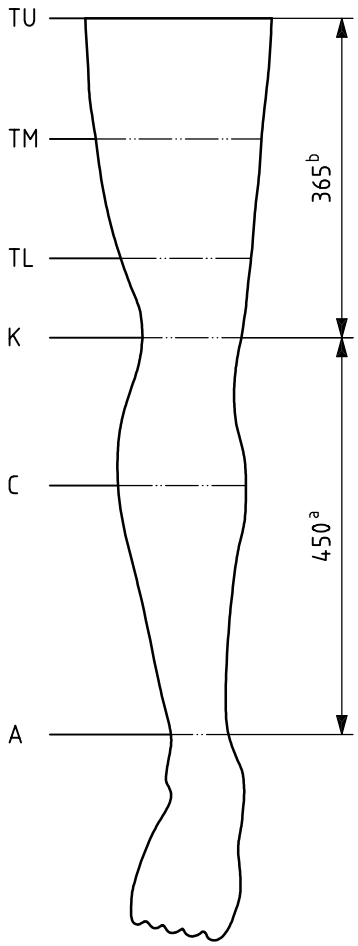
or

— if flaming combustion is still occurring 15 s after the removal of the flaming ignition source.

C.10 Test report

Record the identification of the test sample and the test submission document in a test report together with all relevant information recorded during the test. Specifically refer this annex. Issue at least one copy of the test report to the submitter.

Dimensions in millimetres



[a] Ankle to knee centre.

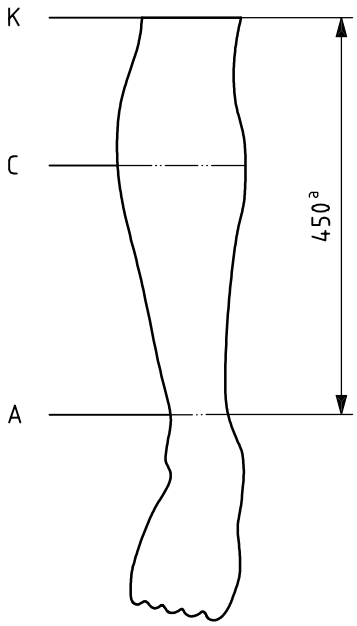
[b] Knee centre to ischium.

Level	Circumference mm
TU (upper thigh)	660
TM (mid thigh)	550
TL (lower thigh)	440
K (knee)	430
C (calf)	400
A (ankle)	235
Foot size 290 mm.	

NOTE The shape of the thigh cross section can be circular. The shape of the below knee section should conform with normal cosmetic cover manufacturing practise to ± 5%.

Figure C.1 — Test sample dimensions trans-femoral (above-knee) — Finished limb

Dimensions in millimetres



[a] Ankle to knee centre.

Level	Circumference
	mm
K (knee)	430
C (calf)	400
A (ankle)	235
Foot size 290 mm.	

NOTE The shape of the below knee section should conform with normal cosmetic cover manufacturing practise to ± 5%.

Figure C.2 — Test sample dimensions trans-tibial (below-knee) — Finished limb

Dimensions in millimetres

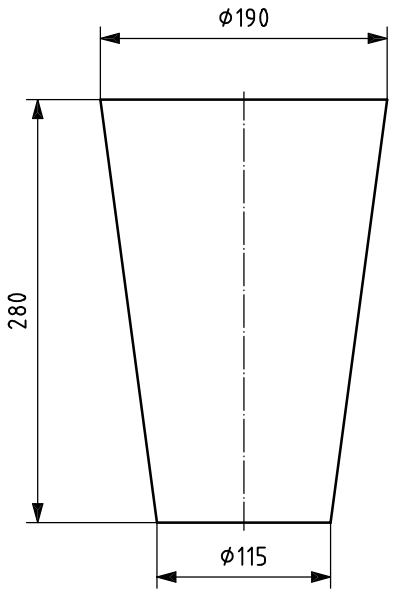


Figure C.3 — Test sample dimensions trans-femoral (above-knee) — Socket former

Dimensions in millimetres

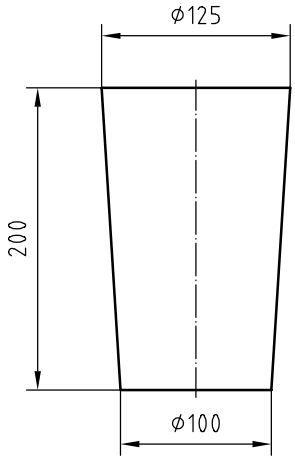
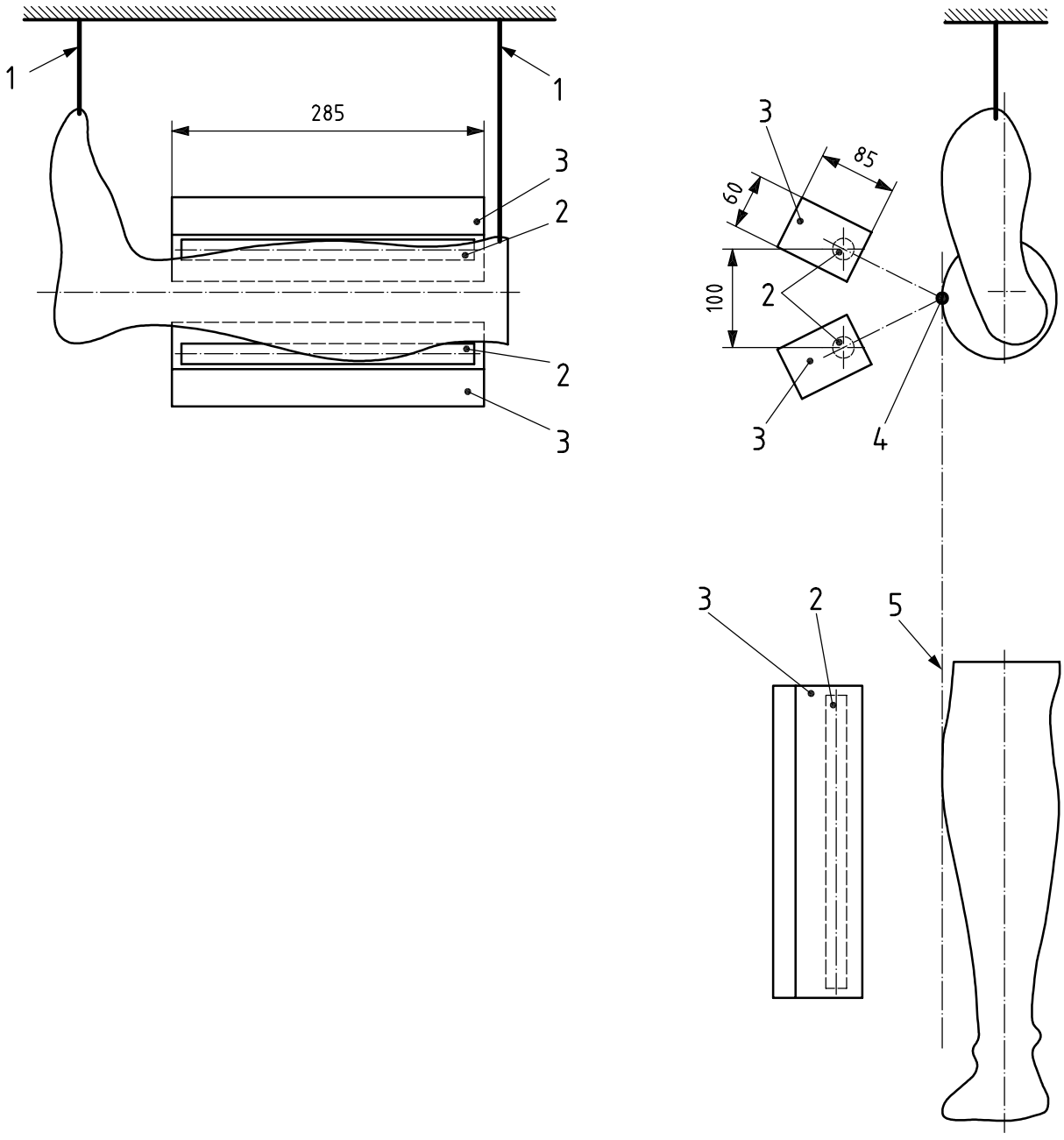


Figure C.4 — Test sample dimensions trans-tibial (below-knee) — Socket former

Dimensions in millimetres



a) lateral view **b) frontal view**

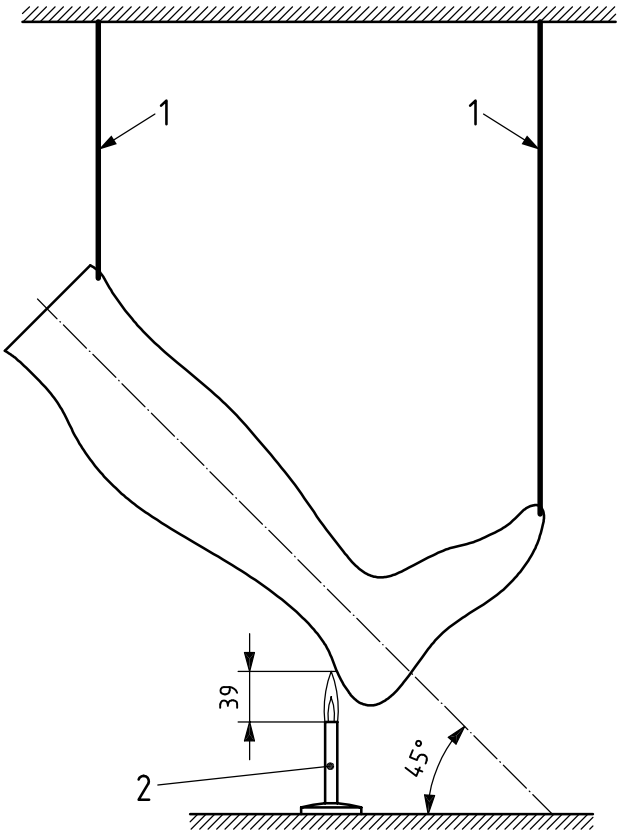
Key

1 nichrome suspension wires
2 radiant heat sources (e.g. 2 kW quartz halogen lamps)
3 reflectors angled to focus radiation at P_{HF}
4 point of measured heat flux, P_{HF}
5 datum line indicating the “high points” of the sample

NOTE Holes for the nichrome wires are predrilled in the test sample at the locations shown (e.g. socket rim and keel of foot).

Figure C.5 — Radiant heat source test

Dimensions in millimetres



Key

1 nichrome suspension wire

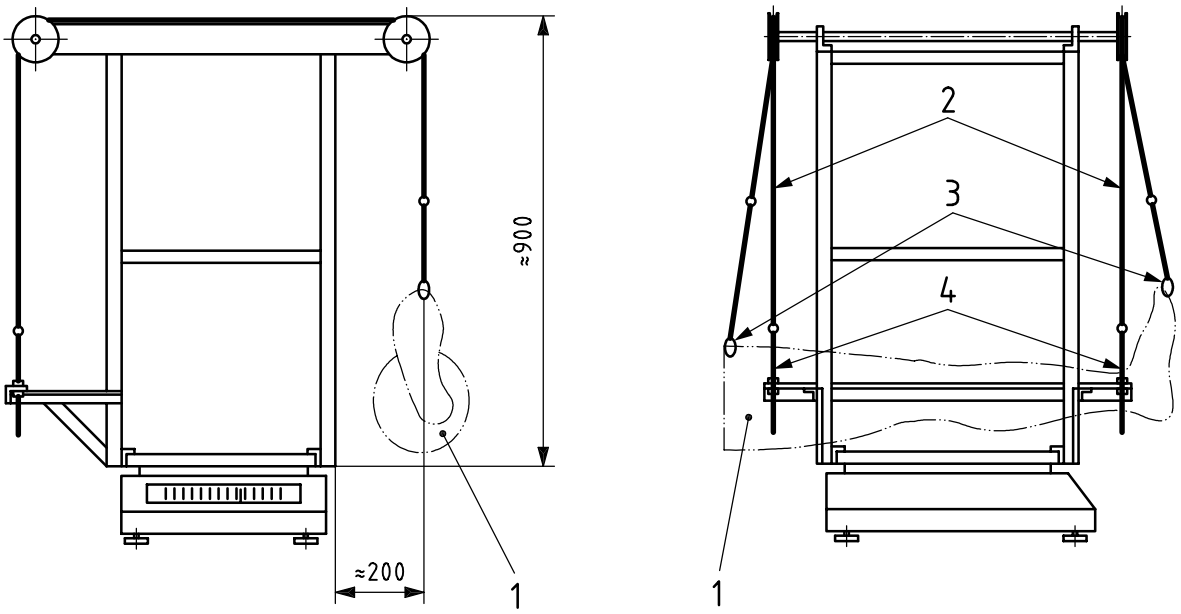
2 flame ignition source

NOTE 1 The flame ignition source is situated so as to apply the flame so that the “worst-case” point of application and sample orientation is tested as specified in C.6.2.

NOTE 2 Holes for the nichrome wires are predrilled in the test sample at the locations shown (e.g. socket rim and keel of foot).

Figure C.6 — Flaming ignition source test

Dimensions in millimetres



a) side elevation **b) front elevation**

Key

1 limb position indicated for radiant heat source test
2 suspension wires
3 wire loops at toe and socket rim
4 length adjusters

Figure C.7 — Sample support frame and weighing platform

Table C.1 — Worked example of calculating the TTPD

Time min	Cumulative mass loss at end of period (A) g	Toxic potential concentration (A/30) [a] g·m^{-3}	Total Toxic Potential Dose g·m^{-3} min
1	6	0,20	0,20
2	10	0,33	0,53
3	15	0,50	1,03
4	25	0,83	1,86
5	35	1,17	3,03
6	40	1,33	4,36
7	50	1,67	6,03
8	55	1,83	7,86
9	60	2,00	9,86
10	65	2,17	12,03
11	68	2,27	14,30
12	72	2,40	16,70
13	75	2,50	19,20
14	78	2,60	21,80
15	80	2,67	24,47
16	82	2,73	27,20
17	84	2,80	30,00
18	86	2,86	32,86
19	87	2,90	35,76
20	88	2,93	38,69
21	89	2,97	41,66
22	89	2,97	44,63
23	90	3,00	47,63
24	90	3,00	50,63
25	90	3,00	53,63
26	91	3,03	56,66
27	91	3,03	59,69
28	91	3,03	62,72
29	92	3,06	65,78
30	92	3,06	68,84

NOTE As shown in Table C.1, a TTPD value of 100 was not reached at 30 min constituting a pass.

[a] The values A/V of the toxic potential concentration are related to the reference volume V_R = 30 m^3 representative of a typically sized domestic room.

Annex D
(informative)

Guidance on methods of establishing the force or moment required to operate the control and actuating mechanisms on prosthetic and orthotic devices

D.1 General

NOTE The test methods specified in this annex have been developed since the ranges of operating force specified in EN 614-1 and/or other standards referred to therein such as EN 894-3 are not necessarily applicable to the control and actuating mechanisms on prosthetic and orthotic devices.

In order to establish a data base for orientation (see Clause D.7), the test methods specified in this annex have been applied to a selection of state of the art prosthetic and orthotic devices, including samples of all categories specified in D.3.1, except category k).

Many prosthetic and orthotic devices incorporate mechanisms designed to permit the user to control the characteristics of the functional components of these devices. The most common of these are the locks on prosthetic and orthotic joints or units. Another relevant group of prosthetic devices comprises terminal devices (e.g. prosthetic hands or hooks). Typically the operation of the mechanisms of these devices requires the application of a force or moment through some form of actuator either directly or in some instances through a linkage or cable to the mechanism.

Other prosthetic devices require the application of a force or moment to articulate, rotate or separate them or to activate their fail safe release unit.

The method of application of the operating force or moment and its optimal line of application will depend on the design of the mechanism.

This annex describes a method of establishing the required operating force when applied in the manner intended by the manufacturer to the actuator normally supplied with the mechanism.

It does not include any evaluation of the design of the actuator/operator interface.

The tests described should be repeated whenever significant design changes are made to the control or actuating mechanisms in a prosthetic or orthotic device.

D.2 Principle

The test procedures are intended to assess the force or moment required to operate the control or actuating mechanism on the test sample in a position and subject to external loading which is consistent with both the manufacturer's intentions and established user practice. For this purpose eleven different test set-ups are specified in D.6.2 to D.6.12, each suitable for testing one of the eleven categories of test samples of prosthetic or orthotic devices incorporating control or actuating mechanisms specified in D.3.1 a) to k).

NOTE The method of operating the control or actuating mechanisms of other functional components of prosthetic and orthotic devices is highly variable and depends on the design and function of the components. Methods of establishing the force or moment required to operate such mechanisms should be based on the general principles stated above and follow the procedures relating to positioning and loading described in D.6.1 to D.6.12 for tests on knee joints and units, elbow joints and units and terminal devices.

D.3 Test samples

D.3.1 Categories of test sample

a) **Test samples of orthotic knee joints with locking mechanism** — these are sub-assemblies comprising the lower leg side bar, the joint and its locking mechanism, and the upper leg side bar.

b) **Test samples of orthotic elbow joints with locking mechanism** — these are sub-assemblies comprising the lower arm side bar, the elbow joint and its locking mechanism, and the upper arm side bar.

c) **Test samples of prosthetic knee units with locking mechanism** — these are sub-assemblies comprising the socket attachment component, the knee unit and its locking mechanism, and all associated structural components below the knee unit, including the foot if preferred (see NOTE 4 of D.3.2).

d) **Test samples of prosthetic elbow units with locking mechanism** — these are sub-assemblies comprising the socket attachment component, the elbow unit and its locking mechanism, and all associated structural components below the elbow unit including a terminal device.

e) **Test samples of prosthetic elbow units with user-driven articulation** — these are sub-assemblies comprising the elbow joint's attachment component, the elbow joint and its actuating mechanism, and all associated structural components below the elbow unit, including the terminal device.

f) **Test samples of prosthetic terminal devices with built-in closing function** — these are sub-assemblies comprising the hand or hook and its actuating mechanism, and a substitute for the lower arm socket or side bar.

g) **Test samples of prosthetic terminal devices with built-in opening function** — these are sub-assemblies comprising the hand or hook and its actuating mechanism, and a substitute for the lower arm socket or side bar.

h) **Test samples of prosthetic terminal devices with no built-in closing or opening function, actuated by force application** — these are sub-assemblies comprising the hand or hook and its actuating mechanism, and a substitute for the lower arm socket or side bar.

i) **Test samples of prosthetic terminal devices with no built-in closing or opening function, actuated by torque application (rotation of the lower arm relative to the socket)** — these are sub-assemblies comprising the hand or hook and its actuating mechanism, and a substitute for the lower arm socket or side bar.

j) **Test samples of prosthetic terminal devices with break-open features for emergency situations** — these are sub-assemblies comprising the hand or hook, and a substitute for the lower arm socket or side bar.

k) **Test samples of prosthetic devices with fail-safe release units** — these are sub-assemblies comprising the prosthetic device and its fail-safe release mechanism, and all adjacent associated structural components below and above the device.

D.3.2 Preparation of test samples

Select the prosthetic and orthotic devices for testing from the normal production.

Samples selected for testing should bear orientation marks to indicate their anterior/front, lateral/outside and upper/proximal surfaces when assembled in a prosthetic or orthotic device in its position of intended use.

The intended line of action of the actuator force should be identified on the sample.

Assemble each test sample from the components listed for that category in D.3.1 a) to k).

When preparing test samples of prosthetic knee and elbow units, omit cosmetic components unless they affect the operation of the locking mechanism and/or contribute to the total mass of the test sample by more than 10 %.

When preparing test samples incorporating orthotic joints or prosthetic units of polycentric design, establish whether the manufacturer has specified the position of a reference axis to be used for orientation instead of the position of the axis of rotation of a corresponding monocentric type (see also NOTE 1).

NOTE 1 If appropriate, the position of the reference axis of orthotic joints or prosthetic units of polycentric design, to be used for orientation instead of the position of the axis of rotation of a corresponding monocentric type, should be marked on the sample or otherwise identified.

When preparing test samples of prosthetic knee units, decide on whether or not they should include an ankle-foot device (see NOTE 2).

NOTE 2 According to the experience gained during laboratory tests, the influence of ankle-foot devices in test samples of prosthetic knee units on the test results is negligible.

Provide test samples of categories D.3.1 a) to i) with a proximal end attachment (see NOTE 3) and test samples of categories D.3.1 j) and k) with a distal end attachment specified by the test laboratory to permit mounting in the test rig in the relevant manner described in Clause D.6.

If the distal end attachment of test samples of categories D.3.1 j) and k) incorporates a force transducer (or should be connected to one), ensure that this is (or can be) arranged so that the test force is acting along its measuring axis when applied in the manner described in D.6.1.

NOTE 3 For test samples of prosthetic devices a socket can be used, partially filled to provide an end attachment.

When preparing test samples of orthotic knee joints or prosthetic knee units, set the total length proximal and distal to the knee axis of rotation (or reference axis) by following either of the following procedures.

a) If appropriate, adjust or adapt the total length to 450 mm (but see NOTE 4).

b) If it is desirable to avoid such adaptations, approximate the total length to 450 mm as far as possible (see NOTE 5).

NOTE 4 Adapting of the total length of test samples of orthotic knee joints or prosthetic knee units to 450 mm may require cutting of side bars or pylons.

NOTE 5 Approximating of the total length of test samples of orthotic knee joints or prosthetic knee units to 450 mm will usually be achieved by selecting the components adjacent to the orthotic knee joint or prosthetic knee unit with the most suitable length.

Ensure that the test samples include any remote actuator and cable or linkage normally required to operate the control or actuating mechanism.

If a remote actuator is connected to the control or actuating mechanism by a (Bowden) cable, observe the following procedures (but see NOTE 6).

— Arrange the cable between the actuator and the control or actuating mechanism so that it undergoes a double 180° bend (or S-bend) with a bending radius of about 50 mm as illustrated in Figures D.1 and D.4.

— If a remote actuator is part of a control or actuating mechanism of test samples of orthotic knee joints or prosthetic knee units, position it at a distance e = 400 mm proximal to the knee axis of rotation (or reference axis) as illustrated in Figure D.4.

If the remote actuator cannot be positioned, and/or the (Bowden) cable cannot be arranged, as specified in the above paragraph (see NOTE 6), arrange the (Bowden) cable as described in the paragraph following NOTE 6.

NOTE 6 Laboratory tests have shown that it is not always possible to position the remote actuator and/or to arrange the cable as specified. In this case the cable should be arranged as described in the following paragraph.

If a remote actuator is connected to the control or actuating mechanism by a cable (wire) or linkage, ensure that the operating force to be applied to the remote actuator is transmitted through the cable (wire) or linkage in the direction/manner intended by the manufacturer and/or appropriate for its specific design, e.g.

— for designs such as “drop” or “ring” locks this force needs to be applied exactly in the direction of the operating movement/translation, otherwise jamming may occur;

— for lever type locks this force is usually applied at right angles to the lever.

Align any actuation toggles so as to minimize the force required to operate the lock.

If appropriate, adjust locking mechanisms so that they are in the fully engaged position as described by the manufacturer of the joint assembly.

Precondition the test sample by alternately engaging and disengaging its control or actuating mechanism at least ten times.

D.4 Number of required tests

Subject two samples of the prosthetic or orthotic device to each relevant test.

D.5 Accuracy

Ensure that

— linear dimensions are within ± 1 mm;

— angular dimensions are within ± 1°;

— loads are within ± 5 % of the prescribed value.

D.6 Methods of testing

D.6.1 General

Before commencing any one of the test procedures specified in D.6.2 to D.6.12, ensure that

— each test sample is assembled and prepared in accordance with the relevant instructions of D.3.2;

— the operating force is applied to the actuator in the direction/manner intended by the manufacturer and appropriate to its specific design or, if not stated, the operating force is applied parallel to (or along – see last paragraph and NOTE 2) the axis of the prosthetic device's adaptor;

— the operating moment is applied to the actuator in the orientation intended by the manufacturer or, if not stated, the operating moment is applied about the axis of the prosthetic device's adaptor;

— the locking mechanism of the test sample is fully engaged, since incomplete engagement invalidates the tests.

When applying an operating force to the actuator of test samples in the direction intended by the manufacturer, take into account the following.

— If the principal operating movement of the control or actuating mechanism is translation of a component (as e.g. the locking movement of “drop” or “ring” locks), ensure that the operating force is applied to that component exactly in the direction of its translation in order to avoid jamming.

— If the principal operating movement of the control or actuating mechanism is rotation of a component (as e.g. the locking movement of lever type locks), ensure that the operating force is applied perpendicular to its axis of rotation and at a known perpendicular distance, d, from this axis (see NOTE 1).

NOTE 1 The lever length of lever type locks for similar application is known to differ from each other in the industrially pre-fabricated state of manufacturing, depending on the design concept applied, including the possibility of individual adaptation of lever length and shape. Therefore, the assessment or comparison of the physical effort for the operation of such mechanisms may require the calculation of the operating moment as the product of the operating force and its perpendicular distance, d, from the axis of rotation of the lever, on which it acts.

When applying an operating moment to the actuator of test samples in the orientation specified by the manufacturer, take into account the following.

— If the principal operating movement of the control or actuating mechanism is axial rotation, ensure that the moment is applied to that component as a force couple about its axis of rotation.

When applying a tensile force to test samples of prosthetic terminal devices with break-open features or prosthetic devices incorporating fail-safe release units, ensure that this force is applied exactly in the specific direction of translation required to make the break open or fail safe release mechanism operate.

NOTE 2 This direction may (initially) coincide with the axis of the prosthetic device's adaptor.

D.6.2 Test set-up for sample category

D.3.1 a) *Orthotic knee joints with locking mechanism*

Position the test sample of an orthotic knee joint as shown in Figure D.2, i.e.

— with the axis of rotation (or reference axis) of the joint horizontal;

— with the long axis of the assembly inclined at $\beta = 40°$ to the horizontal;

— with the frontal face of the assembly pointing upwards;

— with the distal end of the sample resting on a horizontal surface in a manner providing low friction.

Support the proximal end of the sample in a pin joint.

Apply a vertical force, F_{m1} to the distal segment of the test sample at a distance, c, from the knee axis of rotation (or reference axis) as illustrated in Figure D.2 and specified in Table D.1 for the relevant test set-up.

NOTE 1 The vertical force F_{m1} is applied to the test sample to represent the weight of the normal body parts to which the device would be attached.

NOTE 2 To ensure that the vertical test force F_{m1} applied produces a uniform effect, it is necessary to adapt the value of the distance, c, to test set-ups with segmental lengths of the test sample differing from a = b = 450 mm.

Apply the operating force F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force F_{op} at a rate not exceeding 10 N/s until the locking mechanism disengages.

NOTE 3 The disengagement of the locking mechanism may be tested manually by attempting to flex the joint.

Record the value of operating force, F_{op1} at which the locking mechanism disengages, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Relock the knee joint and repeat the test procedure five times.

Calculate the mean of the values of operating force F_{op1} measured in the six tests.

Repeat the six tests with a vertical force F_{m2} applied to the test sample.

NOTE 4 The vertical force F_{m2} is applied to the test sample to simulate the effect of a force applied manually by the user to the front of the thigh to create a knee extension moment.

Record the value of operating force F_{op2} at which the locking mechanism disengages, together with the value of the distance, d_2, of the line of action of F_{op2} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Calculate the mean of the values of operating force F_{op2} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force F_{op} measured in both test series.

NOTE 5 For specific designs of orthotic knee joints it may also be of interest to establish the operating force required to engage the locking mechanism. For such designs the procedure of D.6.2 may be adapted for this purpose.

Table D.1 — Parameters of the test set-up for sample category D.3.1 a)

Test set-up	Segmental lengths of test sample		Distance of load application point from knee axis	Vertical force	
	a mm	b mm	c mm	F_{m1} N	F_{m2} N
Regular	450	450	280	60	120
Individual	a_i	b_i	$c_i = b_i - 85(1 + b_i/a_i)$	60	120

D.6.3 Test set-up for sample category

D.3.1 b) *Orthotic elbow joints with locking mechanism*

Position the test sample of an orthotic elbow joint with the upper arm side bar vertical and the lower arm side bar locked horizontally (see Figure D.3). If the design of the test sample does not allow these positions to be achieved in one test set-up, set the lower arm side bar horizontal and the upper arm side bar as close as possible to the vertical.

Ensure that there is no other support for the elbow joint or the lower arm side bar.

Apply a vertical force, F_m = 20 N, to the distal segment of the test sample at a distance, c = 120 mm, from the elbow axis of rotation (or reference axis) as illustrated in Figure D.3.

NOTE 1 The vertical force, F_m is applied to the test sample to represent the weight of the normal body parts to which the device would be attached.

Apply the operating force, F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force, F_{op} at a rate not exceeding 10 N/s until the locking mechanism disengages.

Record the value of operating force, F_{op1} at which the locking mechanism disengages, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present – see NOTE 2) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

NOTE 2 The operation of the type of locking mechanism on the sample of orthotic elbow joint shown in Figure D.3 does not require an actuating lever.

Relock the elbow joint and repeat the test procedure five times.

Calculate the mean of the values of operating force F_{op1} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force F_{op} measured in both test series.

NOTE 3 For specific designs of orthotic elbow joints it may also be of interest to establish the operating force required to engage the locking mechanism. For such designs the procedure of D.6.3 may be adapted for this purpose.

D.6.4 Test set-up for sample category

D.3.1 c) ***Prosthetic knee units with locking mechanism***

Position the test sample of a prosthetic knee unit as shown in Figures D.4 and D.5, i.e.:

— with its axis of rotation (or reference axis) horizontal;

— with the long axis of the assembly inclined at $\beta = 40°$ to the horizontal;

— with the frontal face of the assembly pointing upwards;

— with the heel of the prosthetic ankle-foot device (see NOTE 4 of D.3.2) or the distal end of the sample resting on a horizontal surface in a manner providing low friction.

Support the proximal end of the sample in a pin joint.

Apply the operating force F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force F_{op} at a rate not exceeding 10 N/s until the locking mechanism disengages.

NOTE 1 The disengagement of the locking mechanism may be tested manually by attempting to flex the joint.

Record the value of operating force, F_{op1} at which the locking mechanism disengages, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present – see Figure D.5) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Relock the knee joint and repeat the test procedure five times.

Calculate the mean of the values of operating force F_{op1} measured in the six tests.

Repeat the six tests with a vertical force F_m applied to the distal segment of the test sample at a distance $c \geqslant 50$ mm from the knee axis of rotation (or reference axis) as illustrated in Figures D.4 and D.5 and specified in Table D.2 for the relevant test set-up.

NOTE 2 The vertical force F_m is applied to the test sample to simulate the effect of the user either inclining his/her trunk anteriorly while standing on the prosthetic device or applying a force manually to the front of the prosthetic device, or extending his/her hip, all of which will create a knee extension moment.

NOTE 3 To ensure that the vertical test force F_m applied produces a uniform effect, it is necessary to adapt the value(s) of the distance "c" and/or the vertical force F_m to test set-ups with segmental lengths of the test sample differing from a = b = 450 mm and/or with a knee unit extending by more than 50 mm distal to the knee axis of rotation (or reference axis).

Record the value of operating force, F_{op2} at which the locking mechanism disengages, together with the value of the distance, d_2, of the line of action of F_{op2} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Calculate the mean of the values of operating force, F_{op2} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force, F_{op} measured in both test series.

NOTE 5 For specific designs of prosthetic knee unit it may also be of interest to establish the operating force required to engage the locking mechanism. For such designs the procedure of D.6.4 may be adapted for this purpose.

Table D.2 — Parameters of the test set-up for sample category D.3.1 c)

Test set-up	Segmental lengths of test sample		Distance of load application point from knee axis	Vertical force
	a	b	c	F_m
	mm	mm	mm	N
Regular	450	450	50	120
Individual	a_i	b_i	$c_i > 50$	$F_{mi} = 24 \times 10^3(a_i + b_i)/a_i(b_i - c_i)$

D.6.5 Test set-up for sample category

D.3.1 d) *Prosthetic elbow units with locking mechanism*

Position the test sample of a prosthetic elbow unit with the upper arm components vertical and the lower arm components locked horizontally (see Figure D.6). If the design of the test sample does not allow these positions to be achieved in one test set-up, set the lower arm components horizontal and the upper arm components as close as possible to the vertical.

Ensure that there is no other support for the elbow unit or the lower arm components.

Apply the operating force, F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force, F_{op} at a rate not exceeding 10 N/s until the locking mechanism disengages.

Record the value of operating force, F_{op1} at which the locking mechanism disengages, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present – see NOTE 1) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

NOTE 1 The operation of the type of locking mechanism on the sample of prosthetic elbow unit shown in Figure D.6 does not require an actuating lever.

Relock the elbow unit and repeat the test procedure five times.

Calculate the mean of the values of operating force F_{op1} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record, as the final test result, the mean of the values of operating force F_{op} measured in both test series.

NOTE 2 If appropriate, the six tests may be repeated with a vertical force F_m applied to the test sample to represent either the weight of an article carried by a terminal device or any distally applied force considered to be representative of a typical situation in daily use. In the first case the same procedures as specified in D.6.3 for test samples of orthotic elbow joints can be applied; in the second case these procedures can be adapted accordingly.

NOTE 3 For specific designs of prosthetic elbow units it may also be of interest to establish the operating force required to engage the locking mechanism. For such designs the procedure of D.6.5 may be adapted for this purpose.

D.6.6 Test set-up for sample category

D.3.1 e) *Prosthetic elbow units with user-driven articulation*

Set the lower arm of the test sample of a prosthetic elbow unit to a length of f = 250 mm when measured from the elbow joint's pivot to the adaptor surface of the terminal device. Prepare the terminal device so that it grips a rod of 40 mm diameter with its “fingers” clasping the rod as far as possible. Cut the rod so that the sum of its mass and that of the terminal device is 500 g.

If the terminal device itself has a mass of 500 g or more, prepare it without a rod and with its “fingers” “closed”. Record the mass of the terminal device.

Position the unlocked test sample of prosthetic elbow unit with the upper arm components affixed vertically and the lower arm components placed horizontally on a support arranged at their distal end as illustrated in Figure D.7.

Place the upper end of a sheet of paper between the lower arm and its support and fix to its lower end a mass of 100 g approximately.

Apply the operating force F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force F_{op} either in a continuous manner at a rate of 5 N/s or in increments of 5 N until the lower arm component lifts off the support, indicated by slipping of the sheet of paper.

Record the value of operating force F_{op1} at which this occurs.

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of operating force F_{op1} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force F_{op} measured in both test series.

D.6.7 Test set-up for sample category

D.3.1 f) *Prosthetic terminal devices with built-in closing function*

NOTE 1 This most common group of terminal devices incorporates mechanisms that provide, in their non-operated state, a “built-in” grip force of pre-determined magnitude, by means of preloaded internal spring elements, and that are opened by the application of an external operating force.

Position the test sample of a prosthetic terminal device as illustrated in Figure D.8, i.e.

— with the “fingers” pointing downwards;

— with the contact area between the “finger tips” vertical, when gripping a thin article as for example a stiff sheet of 1 mm thickness.

Place the upper end of a sheet of paper between the “finger-tips” of the device and fix to its lower end a mass of 100 g approximately.

Apply the operating force F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force, F_{op} either in a continuous manner at a rate of 1 N/s or in increments of 1 N until the terminal device opens at the “finger-tips”, indicated by slipping of the sheet of paper.

Record the minimum value of operating force, F_{op1} at which this occurs, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Increase the opening movement of the terminal device either in a continuous manner at a speed of 1 mm/s or in increments of 1 mm until the maximum opening width/(grip width) is reached and record the related operating force F_{op} continuously or step-by-step.

NOTE 2 This method of operating the terminal device requires the test equipment used to be switched over from force control to displacement control.

Record the maximum value of operating force, F_{op2} reached and the opening width at which this occurs (see NOTE 2), together with the value of the distance, d_2, of the line of action of F_{op2} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

NOTE 3 The maximum value of operating force, F_{op} may not occur at the maximum opening width.

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of operating force, F_{op1} and F_{op2} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force, F_{op} measured in both test series.

D.6.8 Test set-up for sample category

D.3.1 g) *Prosthetic terminal devices with built-in opening function*

NOTE This less common group of terminal devices incorporates mechanisms which provide a “built-in” opening force by means of preloaded internal spring elements, and which are closed by the application of an external operating force.

Position the test sample of a prosthetic terminal device with the “fingers” pointing downwards, as illustrated in Figure D.9.

Place a force transducer of a thickness of (25 $\pm$ 2) mm between the finger-tips so that the centroids of their areas of contact with the active surfaces of the force transducer are located on its measuring axis.

Apply the operating force F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force, F_{op} either in a continuous manner at a rate of 1 N/s or in increments of 1 N until a grip force of 20 N is reached.

Record the value of operating force F_{op1} at which this occurs, together with the value of the distance, d_1, of the line of action of F_{op1} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of operating force, F_{op1} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record, as the final test result, the mean of the values of operating force F_{op} measured in both test series.

D.6.9 Test set-up for sample category

D.3.1 h) ***Prosthetic terminal devices with no built-in closing or opening function, actuated by force application***

Position the test sample of a prosthetic terminal device with the “fingers” pointing downwards, as illustrated in Figure D.10.

Place a force transducer of a thickness of (25 ± 2) mm between the finger-tips so that the centroids of their areas of contact with the active surfaces of the force transducer are located on its measuring axis.

Apply the operating force, F_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating force, F_{op} either in a continuous manner at a rate of 1 N/s or in increments of 1 N until a grip force of 20 N is reached.

Record the value of operating force, F_{op1} at which this occurs, together with the value of the distance, d_1 of the line of action of F_{op1} from the axis of the actuating lever (if present) at the instant of disengagement, if appropriate (see NOTE 1 of D.6.1).

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of operating force, F_{op1} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating force, F_{op} measured in both test series.

D.6.10 Test set-up for sample category

D.3.1 i) ***Prosthetic terminal devices with no built-in closing or opening support, actuated by torque application (rotation of the forearm relative to the socket)***

Position the test sample of a prosthetic terminal device with the “fingers” pointing downwards, as illustrated in Figure D.11.

Place a force transducer of a thickness of (25 ± 2) mm between the finger-tips so that the centroids of their areas of contact with the active surfaces of the force transducer are located on its measuring axis.

Apply the operating moment, M_{op} to the actuator of the test sample in accordance with D.6.1.

Increase the operating moment, M_{op} either in a continuous manner at a rate of 0,1 N·m/s or in increments of 0,1 N·m until a grip force of 20 N is reached.

Record the value of operating moment, M_{op} at which this occurs.

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of operating moment, M_{op} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of operating moment, M_{op} measured in both test series.

D.6.11 Test set-up for sample category

D.3.1 j) *Prosthetic terminal devices with break-open feature for emergency situations*

Position the test sample of a prosthetic terminal device as illustrated in Figure D.12, i.e.

— with the axis of its adaptor vertical;

— with the “fingers” pointing downwards.

Prepare the terminal device so that it grips a rod of 40 mm diameter with its “fingers” clasping the rod as far as possible.

Connect the rod to the distal end attachment without changing its position inside the terminal device.

If appropriate, incorporate a force transducer in the distal end attachment assembly in accordance with D.3.2, as illustrated in Figure D.12.

NOTE If the force transducer is mounted in a manner differing from that shown in Figure D.12, it may be subject to offset force. In this circumstance it will be necessary to establish that it will give accurate readings.

Apply the tensile force, F to the proximal end of the test sample in accordance with D.6.1.

Increase the tensile force, F either in a continuous manner at a rate of 5 N/s or in increments of 5 N until the break-open mechanism operates, so that the “fingers” open and the rod slips out of the terminal device.

Record the maximum value of tensile force, F_{max} reached.

Re-set the terminal device to its normal operating configuration.

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of tensile force, F_{max} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of tensile force, F_{max} measured in both test series.

D.6.12 Test set-up for sample category

D.3.1 k) *Prosthetic devices with fail-safe release units*

Position the test sample of a prosthetic device with its axis vertical, as illustrated in Figure D.13 for the example of a separable prosthetic adaptor plate.

If appropriate, incorporate a force transducer in the distal end attachment assembly in accordance with D.3.2, as illustrated in Figure D.13.

NOTE 1 If the force transducer is mounted in a manner differing from that shown in Figure D.13, it may be subject to offset force. In this circumstance it will be necessary to establish that it will give accurate readings.

Apply the tensile force, F to the proximal end of the test sample in accordance with D.6.1.

NOTE 2 Several trials may be necessary to establish the most appropriate details of the test procedure.

Increase the tensile force, F either in a continuous manner at a rate of 5 N/s or in increments of 5 N until the fail-safe release unit operates and the adjacent components disconnect.

Record the maximum value of tensile force F_{max} reached.

Re-set the prosthetic device to its normal operating configuration.

Re-arrange the test set-up and repeat the test procedure five times.

Calculate the mean of the values of tensile force, F_{max} measured in the six tests.

Carry out the entire test procedure on a second test sample.

Calculate and record as the final test result the mean of the values of tensile force, F_{max} measured in both test series.

D.7 Test report

D.7.1 General requirements

For each type of test conducted, the test report should specifically refer to Annex D and state the relevant category of test sample according to Clause D.3 and the relevant test set-up according to Clause D.6.

D.7.2 Specific requirements

The details to be included in the test report are listed in Table D.3, together with the relevant test set-ups according to Clause D.6.

Table D.3 — Details of the test report

Item			Relevant test set-up
a)	**Details of the test sample**		
	1)	List of the components of which the assembly is composed	All
	2)	Dimensions a, b or f of single segments of the test sample	D.6.2, D.6.4 or D.6.6
	3)	Mass of terminal devices $m \geqslant 500$ g	D.6.6
b)	**Details of the test set-up**		
	1)	Direction of the line of action of the operating force F_{op} (tensile force F)	All, except D.6.10
	2)	Distance e of a remote actuator (if present) from the knee (reference) axis	D.6.4
	3)	Value(s) of the vertical force F_m representing the weight of body parts	D.6.4
	4)	Distance c of the vertical force F_m from the knee (reference) axis	D.6.4
	5)	Direction of the line of action (orientation) of the operating moment M_{op}	D.6.10
c)	**Results of measurements and calculations**		
	1)	Individual values of the operating force F_{op}	All, except D.6.11, D.6.12
	2)	Calculated mean value(s) of operating force $F_{op, mean}$	All, except D.6.11, D.6.12
	3)	Individual values of the distance d of the line of action of the operating force F_{op} from the axis of an actuating lever (if present)	D.6.2, D.6.3, D.6.4, D.6.5, D.6.7, D.6.8, D.6.9
	4)	Individual values of the operating moment M_{op}	D.6.10
	5)	Calculated mean value of operating moment $M_{op, mean}$	D.6.10
	6)	Individual values of the tensile force F	D.6.11, D.6.12
	7)	Calculated mean value of tensile force F_{mean}	D.6.11, D.6.12

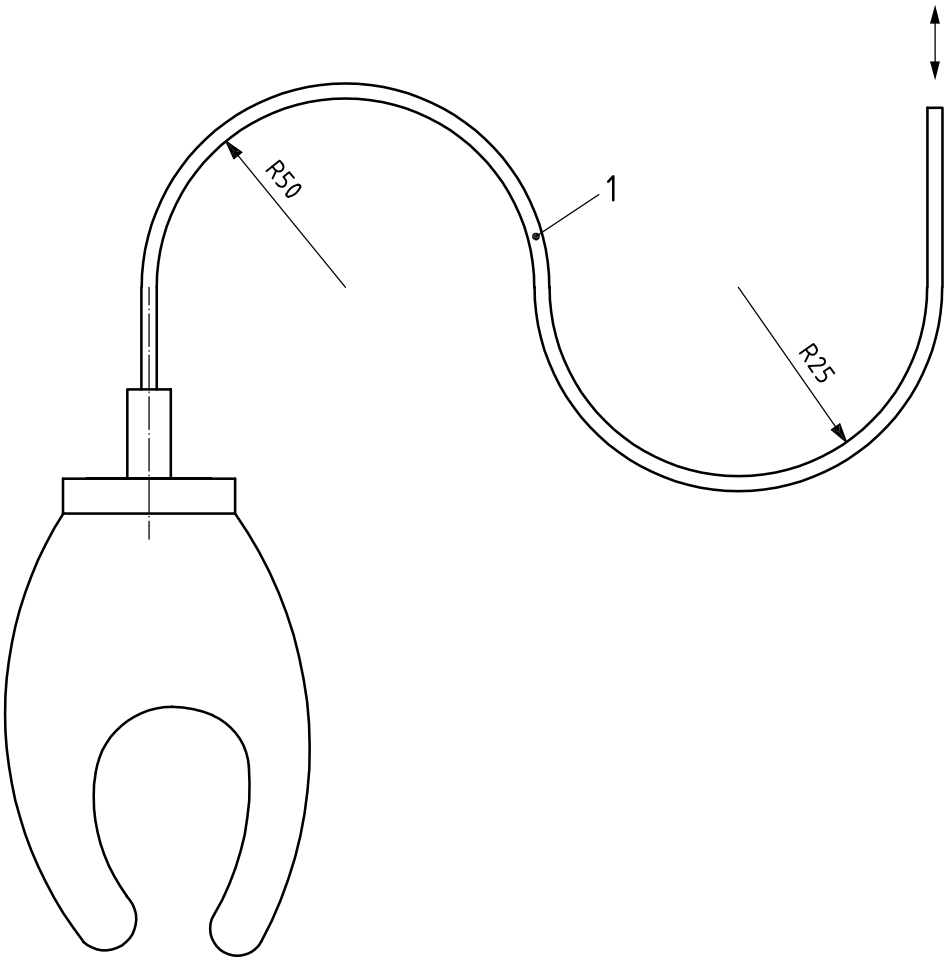
D.8 Test results

NOTE The test methods specified in Clause D.6 have been applied by several laboratories to the control and actuating mechanisms of a selection of state-of-the-art prosthetic and orthotic devices, including samples of all categories specified in D.3.1 except category D.3.1 k). In Table D.4 the ranges of operating force (and displacement) or moment which have been measured are listed for each category of test sample.

Table D.4 — Values of actuating/operating force (and displacement) and moment measured on different categories of test sample

Category of test sample	Number of samples of different types tested	Operating force (and displacement) or moment required for action/event indicated				
		Type of operating force or moment	Action/event	Range/value of force (N)	Range/value of moment (N·m)	Range/value of displacement (mm)
Orthotic knee joints with locking mechanism — D.3.1 a)	25	Release force	Unlocking	2 to 65		—
Orthotic elbow joints with locking mechanism — D.3.1 b)	1	Release force	Unlocking	25		—
Prosthetic knee units with locking mechanism — D.3.1 c)	8	Release force	Unlocking	20 to 35		—
Prosthetic elbow units with locking mechanism — D.3.1 d)	7	Locking force [a]	Locking [a]	12 to 39		3 to 14
	14	Release force	Unlocking	6 to 45		2 to 30
Prosthetic elbow units with user-driven articulation — D.3.1 e)	5	Lifting force at 90°	Elbow flexion (paper slips)	15 to 48		—
Prosthetic terminal devices with built-in closing function — D.3.1 f)	30	Opening force	Fingers opening (paper slips)	4 to 78		—
	55	Opening force	Max. opening	4 to 194		32 to 52
Prosthetic terminal devices with built-in opening function — D.3.1 g)	5	Closing force	20 N grip force at 25 mm grip width	43 to 136		—
Prosthetic terminal devices with no built-in function, force-operated — D.3.1 h)	3	Closing force	20 N grip force at 25 mm grip width	56 to 67		—
Prosthetic terminal devices with no built-in function, torque-operated — D.3.1 i)	4	Closing moment	20 N grip force at 25 mm grip width		0,6 to 0,8	—
Prosthetic terminal devices with emergency break-open feature — D.3.1 j)	1	Break-open force	Breaking free	134		—
Prosthetic devices with fail-safe release function — D.3.1 k)	—	Fail-safe release force	Fail-safe release	—		—

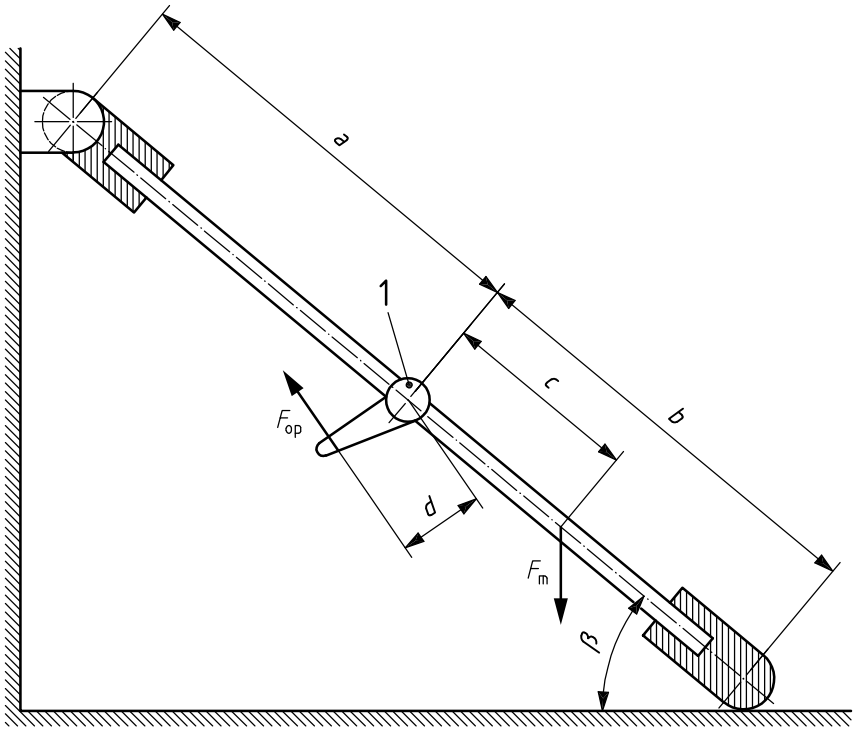
[a] See NOTE 3 of D.6.5.



Key

1 Bowden cable with double 180° bend (or S-bend)

Figure D.1 — Bowden cable arrangement during test



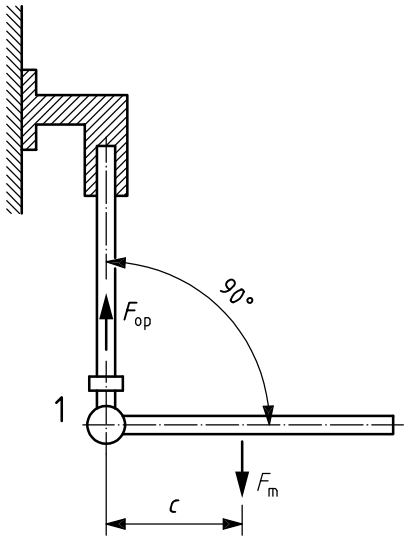
Key

1 bale lock

F_{op} operating force

F_m vertical force

Figure D.2 — Test set-up according to D.6.2 for sample category D.3.1 a) *Orthotic knee joints with locking mechanism*



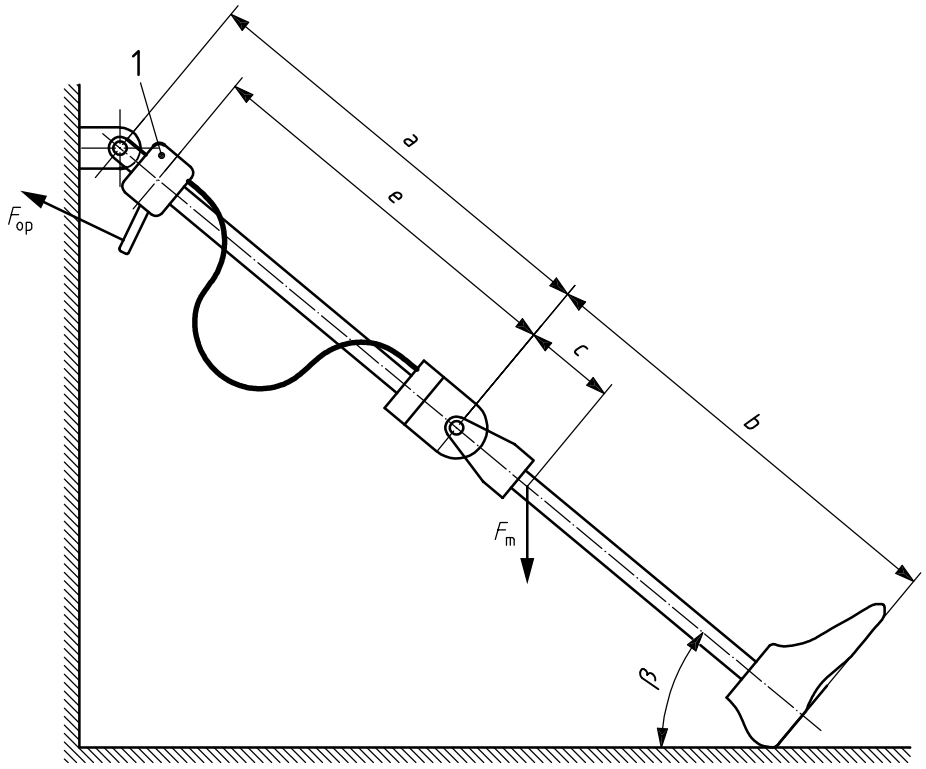
Key

1 drop or ring lock

F_{op} operating force

F_m vertical force

Figure D.3 — Test set-up according to D.6.3 for sample category D.3.1 b) *Orthotic elbow joints with locking mechanism*



Key

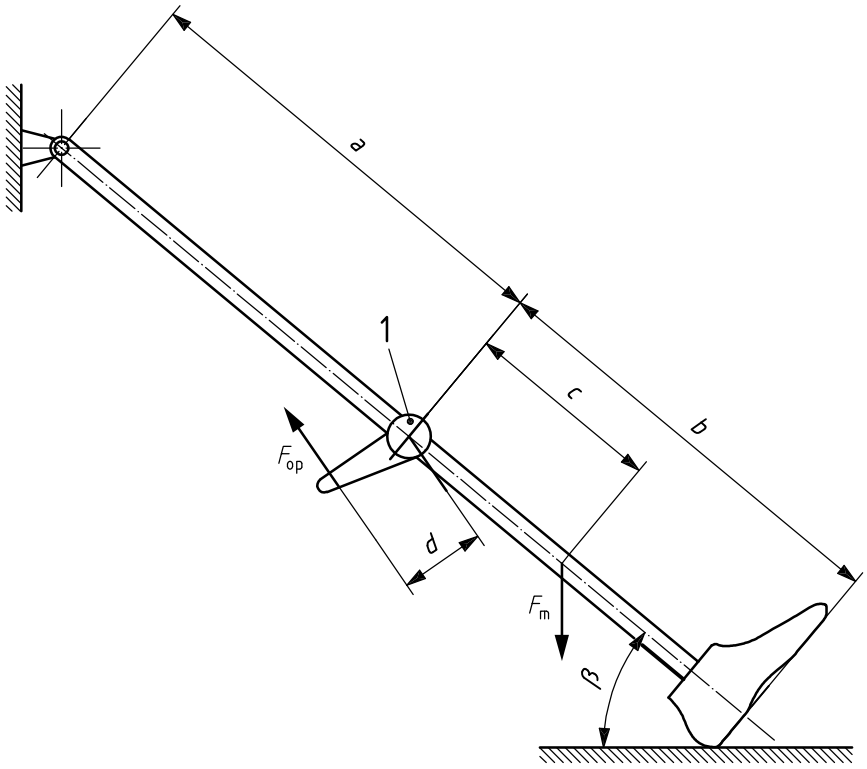
1 remote actuator

F_{op} operating force

F_m vertical force

Figure D.4 — Test set-up according to D.6.4 for sample category D.3.1 c) *Prosthetic knee units with locking mechanism*

(continued on Figure D.5)



Key

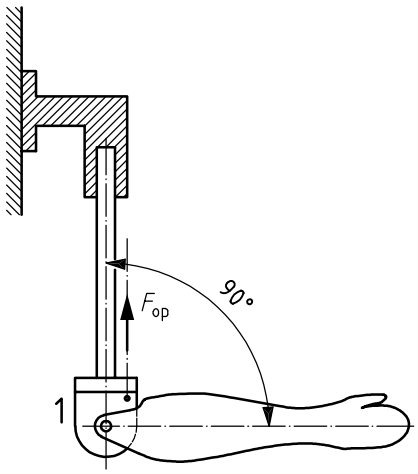
1 bale lock

F_{op} operating force

F_m vertical force

Figure D.5 — Test set-up according to D.6.4 for sample category D.3.1 c) *Prosthetic knee units with locking mechanism*

(continued from Figure D.4)

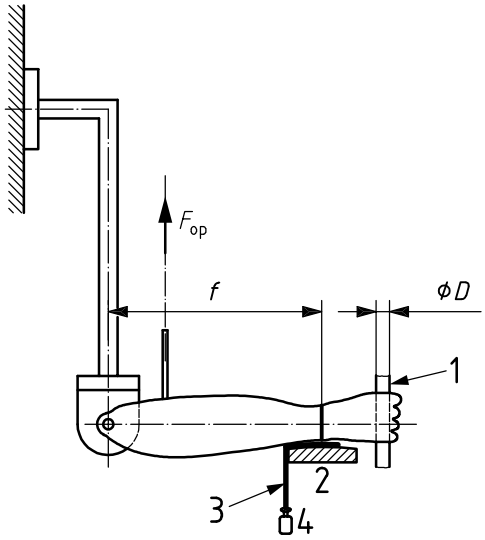


Key

1 toggle release mechanism

F_{op} operating force (acting parallel to adaptor axis unless otherwise specified by manufacturer)

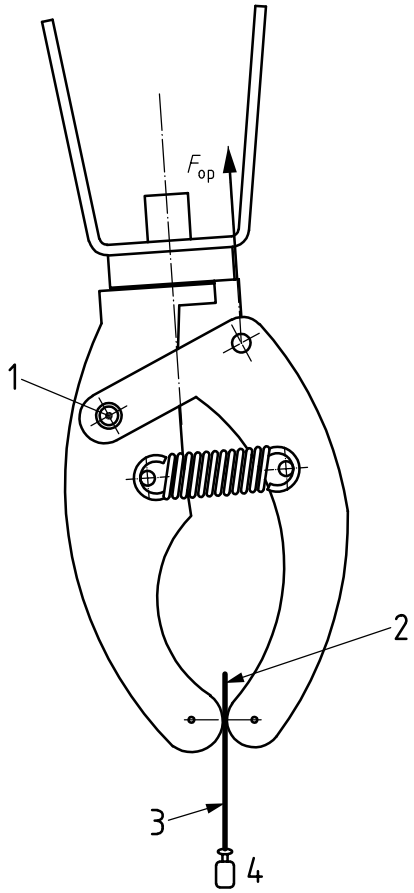
Figure D.6 — Test set-up according to D.6.5 for sample category D.3.1 d) *Prosthetic elbow units with locking mechanism*



Key

1 rod
2 support
3 sheet of paper
4 100 g mass
F_{op} operating force (acting parallel to adaptor axis unless otherwise specified by manufacturer)

Figure D.7 — Test set-up according to D.6.6 for sample category D.3.1 e) *Prosthetic elbow units with user-driven articulation*

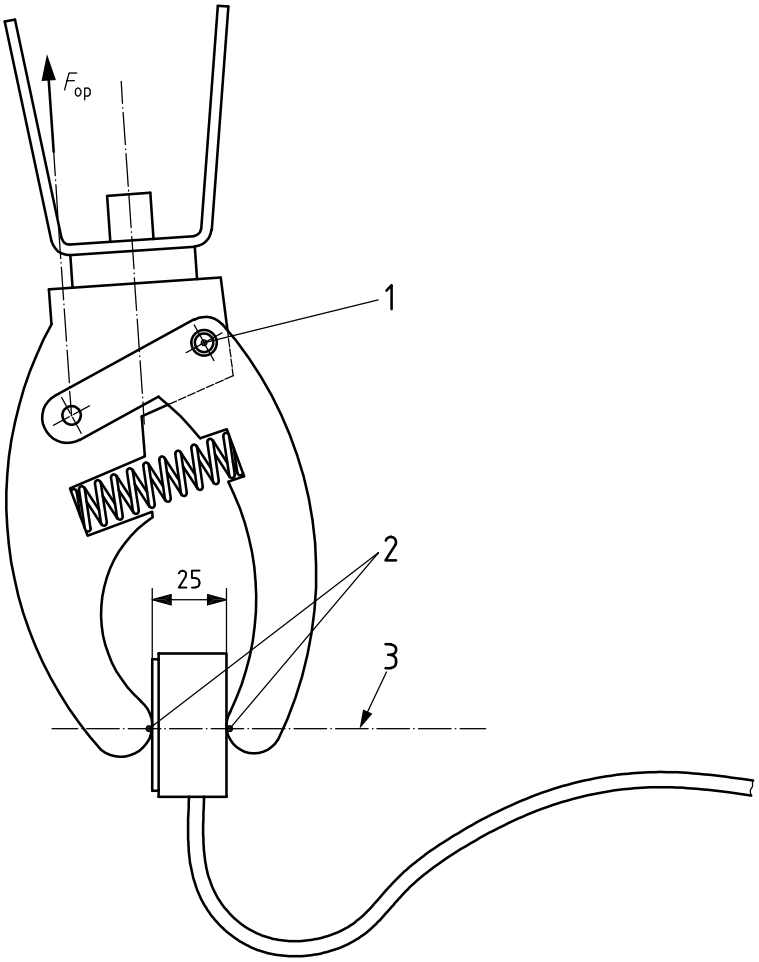


Key

1 pivot
2 contact area vertical
3 sheet of paper
4 100 g mass
F_{op} operating force (acting parallel to adaptor axis unless otherwise specified by manufacturer)

Figure D.8 — Test set-up according to D.6.7 for sample category D.3.1 f) *Terminal devices with built-in closing function*

Dimensions in millimetres

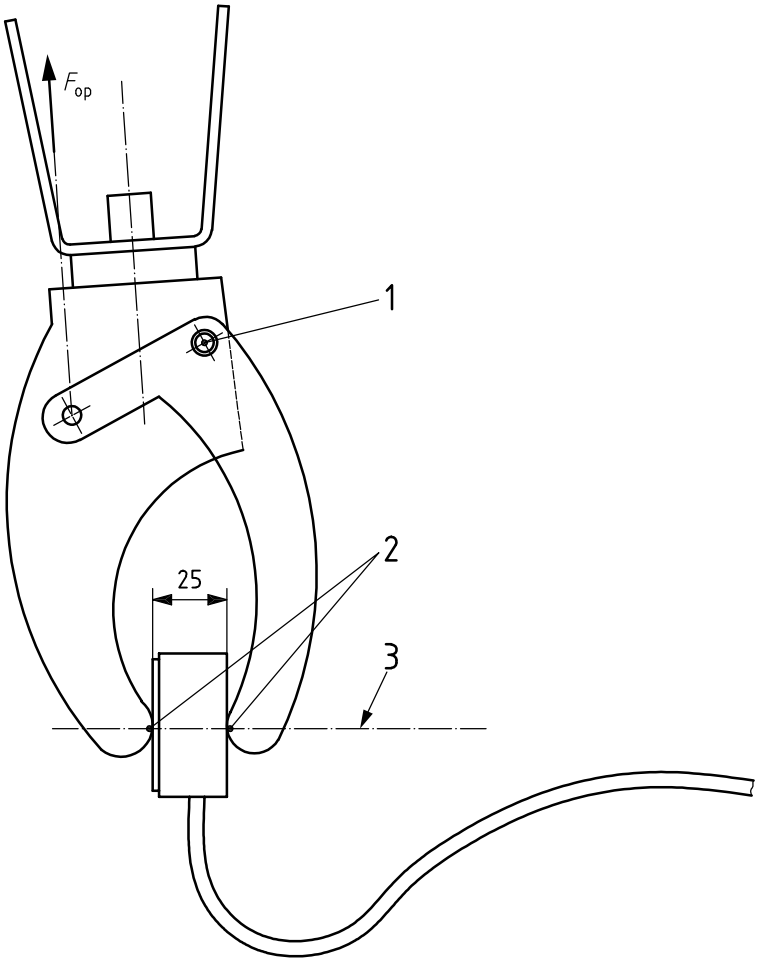


Key

1 pivot
2 centroids of contact areas
3 measuring axis of force transducer
F_{op} operating force (acting parallel to adaptor axis unless otherwise specified by manufacturer)

Figure D.9 — Test set-up according to D.6.8 for sample category D.3.1 g) *Terminal devices with built-in opening function*

Dimensions in millimetres



Key

1 pivot

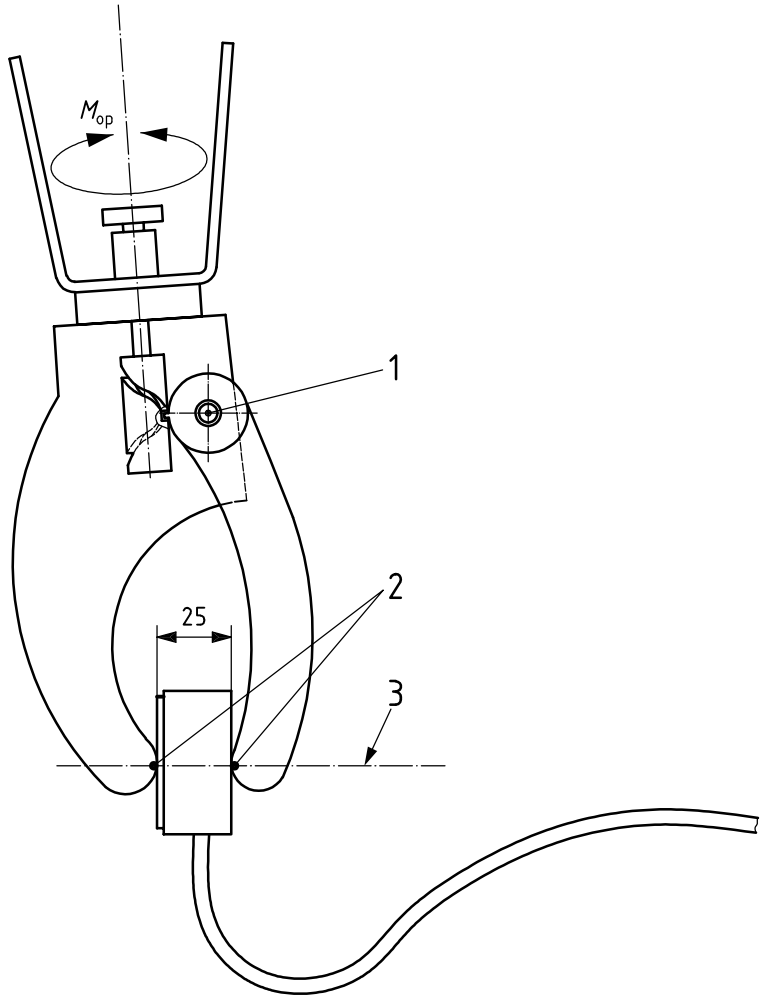
2 centroids of contact areas

3 measuring axis of force transducer

F_{op} operating force (acting parallel to adaptor axis unless otherwise specified by manufacturer)

Figure D.10 — Test set-up according to D.6.9 for sample category D.3.1 h) *Terminal devices with no built-in closing or opening function, actuated by force application*

Dimensions in millimetres



Key

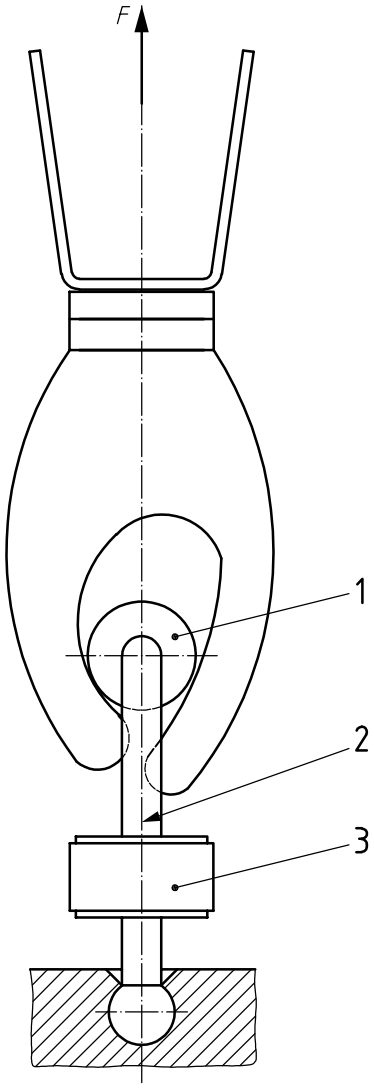
1 pivot

2 centroids of contact areas

3 measuring axis of force transducer

M_{op} operating moment (acting about its axis of rotation unless otherwise specified by manufacturer)

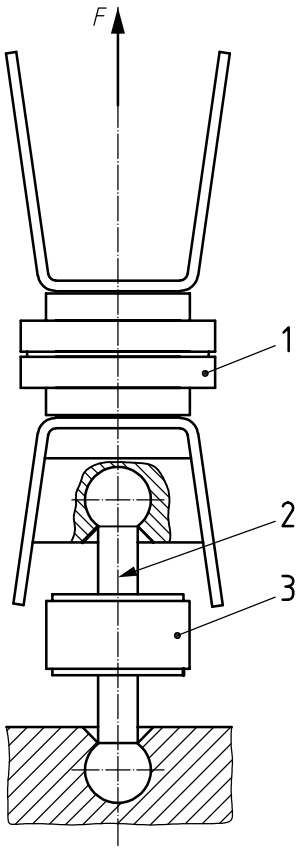
Figure D.11 — Test set-up according to D.6.10 for sample category D.3.1 i) *Terminal devices with no built-in closing or opening function, actuated by torque application*



Key

1 rod of 40 mm diameter
2 measuring axis of force transducer (initially aligned with adaptor axis, if appropriate)
3 force transducer
F tensile force (acting along measuring axis of force transducer)

Figure D.12 — Test set-up according to D.6.11 for sample category D.3.1 j) *Terminal devices with break-open feature for emergency situations*



Key

1 prosthetic device under test

2 measuring axis of force transducer (initially aligned with adaptor axis, if appropriate)

3 force transducer

F tensile force (acting along measuring axis of force transducer)

Figure D.13 — Test set-up according to D.6.12 for sample category D.3.1 k) *Prosthetic devices with fail-safe release unit*, illustrated for a separable prosthetic adaptor plate

Annex E
(informative)

Reference to the essential principles of safety and performance of medical devices in accordance with ISO/TR 16142

This International Standard has been prepared to support the essential principles of safety and performance of external limb prostheses and external orthoses as medical devices in accordance with ISO/TR 16142. This International Standard is suitable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformity with specific essential principles of ISO/TR 16142. Other means are possible.

NOTE 1 The *essential principles of safety and performance* according to ISO/TR 16142 conform, in both structure and contents, to the *essential requirements* according to Annex I of the European Directive 93/42/EEC concerning medical devices with a few exceptions.

NOTE 2 Annex E has been enclosed to provide the same information as original Annex ZA, which has been removed from this International Standard for formal reasons. Table E.1 conforms to Table ZA.1 of original Annex ZA in both structure and contents, with the exception of the column headings.

Table E.1 — Correspondence between this International Standard and the essential principles of ISO/TR 16142

Clauses/sub-clauses of this International Standard	Corresponding essential principle of ISO/TR 16142:1999	Qualifying remarks/notes
All	A.1	
All and specifically: 4.1, 5.1, 5.4, 7, 8.2, 8.3, 9, 11.1, 11.2	A.2	Specifically: risk management, flammability/toxicity, corrosion/degradation, EMC, battery-powered devices, surface temperature, moving parts, connections
All and specifically 4.2	A.3	Specifically: intended performance
All and specifically 4.2, 4.4	A.4	Specifically: intended performance, strength
All and specifically 13, 14	A.5	Specifically: information, packaging
All and specifically 4.1	A.6	Specifically: risk management
5.1, 5.2	A.7.1	Flammability/toxicity, biocompatibility/contaminants/ residues
5.2, 13, 14	A.7.2	Biocompatibility/contaminants/residues, information, packaging
5.2.2, 5.4	A.7.3	Contaminants/residues, corrosion/degradation
5.2, 5.4, 11.2	A.7.6	Biocompatibility/contaminants/residues, corrosion/ degradation, connections
5.2, 5.3	A.8.1	Biocompatibility/contaminants/residues, infection and microbiological contamination
14	A.8.5	Packaging
12.1, 13	A.9.1	Restrictions on use, information
7, 9, 11.1, 12.2,12.3	A.9.2	EMC, surface temperature, moving parts, forces on soft tissues of the human body, ergonomic principles
5.1, 8.2, 8.4	A.9.3	Flammability/toxicity, battery-powered devices
8.3	A.12.1	Electronic programmable systems
8.1, 8.2	A.12.2	Battery-powered devices
7	A.12.5	EMC
8	A.12.6	Electrical safety
11, 12	A.12.7.1	Design and mechanical requirements
6	A.12.7.2	Vibration
6	A.12.7.2	Noise
8.2, 11.2	A.12.7.3	Battery-powered devices, connections
9	A.12.7.4	Surface temperature
8.5	A.12.8.2	Skin contact electrodes stimulate by means of electrical energy and may be considered as energy supply in the sense of ER 12.8
13.1, 13.2	A.12.8.3	Information
13	A.13	Information, packaging
10	A.13	Information on sterilization if specific devices require to be sterilized for particular applications
4.3	A.14	Clinical evaluation

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[5] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[6] ISO 13485:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9001*

[7] ISO 13488, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

[8] ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

[9] ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

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