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Proteze zunanjih okončin in zunanje ortoze - Zahteve in preskusne metode (ISO/DIS 22523:2026)

External limb prostheses and external orthoses - Requirements and test methods (ISO/DIS 22523:2026)

Externe Gliedmaßenprothesen und externe Orthesen- Anforderungen und Prüfverfahren (ISO/DIS 22523:2026)

Prothèses de membre externes et orthèses externes - Exigences et méthodes d'essai (ISO/DIS 22523:2026)

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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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Contents

Page

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 22523:2006), which has been technically revised.

The main changes are as follows:

— in 4.2, the technical documentation has been revised;

— update of 5.2.1 on biocompatibility;

— the content of former Annex B has been removed.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

External limb prostheses and external orthoses — Requirements and test methods

1 Scope

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

06 03 to 06 15 Orthoses

06 18 to 06 24 Limb prostheses

This document 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 document is also applicable as guidance in the design and test of custom build orthosis and prosthesis.

NOTE The use of quality systems as described or referred to in ISO 13485 and ISO 13488 can be appropriate.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 10328, *Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 20417, *Medical devices — Information to be provided by the manufacturer*

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

IEC 60601-1, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8548, ISO 8549, ISO 13404, ISO 13405 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
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

3.2
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

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 intended to be used as part of the technical documentation required by the Medical Devices Directive for conformity assessment procedures

3.6
clinical evaluation
a set of ongoing activities that use scientifically sound methods for the assessment and analysis of clinical data to verify the safety, clinical performance and/or effectiveness of the device when use as intended by the manufacturer

[SOURCE: IMDRF MDCE WG/N56FINAL:2019]

3.7
clinical investigation
systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a medical device

[SOURCE: ISO 14155:2020, 3.8, modified – Note 1 to entry has been removed.]

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

3.9
leg dummy
part of the test setup, which mimics the orthosis users leg

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 Using 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.

The results of the risk management process may be used to select from this document 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.

The technical documentation shall specifically include a statement about the life time of the device. The number of test cycles a device underwent, e. g. when tested in accordance with ISO 10328 or ISO 22675, can be a useful indicator when determining the life time of the device.

4.3 Clinical evaluation

Any clinical investigation shall be performed in accordance with ISO 14155.

The judgement of CPO (certified prosthetist and orthotist) and biomechanical engineers is particularly relevant and should be taken into account when clinically evaluating prostheses and orthoses.

There is insufficient data on a significant portion of prosthesis and orthosis which has been placed on the market during past decades. Post market analysis of data by manufacture and organisation are the source of continuous improvement and continuous development.

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 the 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 conform with the requirement(s) of 4.4.1, the 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, ISO 22675 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.

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.

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

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

NOTE 1 An upper-limb prosthetic device can be tested, if appropriate, using the methods specified in Annex A.

NOTE 2 An orthotic device can be tested, if appropriare, using the methods specified in Annex B.

d) The manufacturer shall specify the test loading condition(s) and/or the test loading level(s) at which the test(s) shall be conducted. The specified loading condition(s) shall include the worst case situation in relation to clinical indication and patient characteristics (remaining muscle strength, deformities and contractures, spasticity, bodyweight, etc.).

4.4.5 An orthotic assembly for the lower limb shall be tested in a validated test setup, which includes a leg dummy to load the orthotic assembly as specified in 4.4.1. Functional properties of orthotic devices, claimed by manufacturers / submitters, shall be quantified prior and after the cyclic test and both shall be documented in the technical documentation.

NOTE Experience shows, that using a leg dummy which does not stabilize the orthotic assembly beyond the stabilization the users leg applies, and footwear where appropriate, and testing the strength category/categories in a static- or durability in a rollover scenario, are appropriate measures to apply the required complex loadings to orthotic assemblies. The amount of loads applied during testing can be obtained or validated through measurements using instrumented orthotic components (joints, bars etc.).

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 conform 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 conform 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, as it is of particular importance to disabled persons who might 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 test methods specified in ISO 8191-1 or UL94 or Annex C can be used. The appropriate level for testing can be determined by the manufacturer.

IEC 60601-1 shall apply for medical electrical equipment. Only parts with a volume of more than 500 mm^3 shall be evaluated as a potential risk. The manufacturer shall evaluate any risk resulting from the fume.

5.2 Biocompatibility, contaminants and residues

5.2.1 General

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 1 Guidance for biological evaluation and selection of appropriate tests is given in ISO 10993-1.

NOTE 2 For some materials assessments, using Standard 100 by OEKO-TEX® or the REACH Regulation can be useful in ascertaining that no hazardous substances are included in them, which in turn can be helpful when carrying out the biological evaluation.

5.2.2 Contaminants and residues

The risk of substances leaking from the device shall be assessed.

NOTE 1 ISO 14971 provides one approach for a risk management which might be useful.

NOTE 2 Substance that can leak include lubricants, hydraulic fluids and battery fluids.

5.3 Infection and microbial contamination

The manufacturer shall specify the method and frequency by which a prosthetic or orthotic device and/or the body surface to which it applies can be cleaned.

EXAMPLE Usually, devices are cleaned by the CPO or the patient with mild soap and clear water with a soft tissue.

The risk of infection or microbial contamination shall be evaluated.

NOTE ISO 14971 provides one approach for a risk management which might be useful.

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, can be affected by corrosion and/or degradation, risk analysis shall be used to determine the most appropriate protective measures.

For any corrosion test, the risk of combined stress and corrosion should be considered.

Annex F provides a list of symbols to describe the environmental conditions that prosthetic or orthotic components can withstand. For prosthetic components, the symbols shall be included in instructions for use, and they should be included in catalogues, brochures, marketing materials, and other product advertisements. For orthotic components, the use of the symbols is suggested. Symbols are not required on the component or component data label.

NOTE ISO 9227, ASTM G85 or ASTM B117 might be used for the assessment of corrosion resistance of metallic materials.

6 Noise and vibration

There are no specific requirements for prosthetic and orthotic devices except for medical electrical equipment

NOTE IEC 60601-1 can IEC 60601-11 be used for a guidance for medical electrical equipment.

7 Electromagnetic compatibility (EMC)

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

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).

8 Electrical safety

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 conform with the requirements of IEC 60601-1.

NOTE IEC 60601-1 and IEC 60601-1-11 can be used as guidance.

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 which results in an unacceptable risk.

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

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.

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

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.

Any software which can be used to control an electronic programmable system shall be designed to ensure its repeatability, reliability and performance according to its intended use.

NOTE IEC 60601-1,, IEC 62304 and IEC 62366 can be used as a guidance.

8.4 Electrically heated blankets, pads and similar flexible heating appliances

A prosthetic or orthotic device that incorporates flexible heating appliances should conform to the requirements of IEC 80601-2-35.

8.5 Prosthetic and orthotic devices with skin contact electrodes

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 IEC 60601-1 can be used as guidance.

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 conform with the relevant requirements of IEC 60601-1.

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.

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.

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.