SLOVENSKI STANDARD
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Proteze zunanjih okončin in zunanje ortoze - Zahteve in preskusne metode (ISO/DIS 22523:2022)

External limb prostheses and external orthoses - Requirements and test methods (ISO/DIS 22523:2022)

Externe Gliedmaßenprothesen und externe Orthesen – Anforderungen und Prüfverfahren (ISO/DIS 22523:2022)

Prothèses de membre externes et orthèses externes - Exigences et méthodes d'essai (ISO/DIS 22523:2022)

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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.

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 it is now required to the technical documentation shall specifically include a statement about the life time of the device;

— 5.2.1 was amended to reflect the fact that generally all materials that come into contact with the human body have to be assessed for biocompatibility;

— The content of Annex B was 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 - 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 document is also applicable as a guide in the design and test of custom build orthosis and prosthesis.

NOTE The application 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 8191, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

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

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15032, *Prosthetics — 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*

ISO 24562, *Prosthetics — Geometrical aspects of lower limb prosthetic adapters*

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*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*

IEC 60601-1-11, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 62304, *Medical device software — Software life cycle processes*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 80601-2-35 *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use*

CISPR 11, *Industrial, scientific and medical equipment — Radio-frequency disturbance characteristics — Limits and methods of measurement*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8548, ISO 8549 (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 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
(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 1 to entry: In this document 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 document 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

[SOURCE: ISO 14155]

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 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.

NOTE 3 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 and biomechanical engineers is particularly relevant and should be taken into account when clinically evaluating prostheses and orthoses.

NOTE CPO is a certified prosthetist and orthotist.

There is insufficient historical 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 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 NOTE 1 and NOTE 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.

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

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 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, 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.