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Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

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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).

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 10328:2016), which has been technically revised.

The main changes are as follows:

— Offsets for P3 and P4 are combined into the test offset for P5 in Table 6 and have been removed from document. Geometry of the test setup has been revised by moving the outward offset at bottom reference plane over the forward axis, resulting in the offset changing from –19 mm to +19 mm to align with results from modern gait analysis. Outwards offsets knee and ankle have been adjusted accordingly.

— Test load levels P6 through P8 previously in former Annex D have been included in Tables 5, 8 and 11 and the Annex removed from the document. Former Annex E and F have been renamed to Annex D and E and references updated. Former Annex G has been removed. New Annex F, Annex G and Annex H have been added.

— Test Ranges (R) for the strength test have been introduced, related to the intended use of the device. The ranges differ by different loading factors, while tests load levels remain unchanged apart from rounding and accommodation to changed offsets (see below).

— Test forces in Table 11 have been adjusted for P3 and P4.

— A method to analyse shock absorption capacity has been added, which eliminates the difficulty to decide whether a device passes or fails above the ultimate static lower load level.

— Separate tests on knee locks are now optional tests and the test methods on separate tests on knee locks have been removed from the document.

— Test geometry defined in this document is limited to 150 mm above knee-joint centre.

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— Clause 21 has been renamed to “Conformance to this document” and reference to Labelling has been removed from the document.

— Table 1, Table 4, Table 5, Table 6, Table 7, Table 8, Table 9, Table 10 and Table 11 have been updated and forces adjusted for new unified offsets.

— Table B.1, Table B.2, Table B.3 and Table B.4 have been updated.

— The rate of loading of between 100 N/s and 10 kN/s is now normative.

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.

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Introduction

As a result of concern in the international community about the need to provide prostheses that are safe in use, and also because of an awareness that test standards would assist the development of better prostheses, a series of meetings was held under the aegis of the International Society for Prosthetics and Orthotics (ISPO). The final one was held in Philadelphia, PA, USA in 1977 at which a preliminary consensus was reached on methods of testing and the required load values. From 1979 onwards this and following work led to the development of the ISO 10328:1996 series and consequent revisions. The test procedures might not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subjected to a series of load actions, each varying individually with time. The test methods specified in this document use static and cyclic strength tests which typically produce compound loadings by the application of a single test force.

The static tests relate to the worst loads generated in any activity. The cyclic tests relate to normal walking activities where loads occur regularly with each step. This document specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of lower-limb prostheses and their components requires controlled field trials in addition to the laboratory tests specified in this document.

The laboratory tests and field trials should be repeated when significant design changes are made to a load-bearing part of a prosthesis.

Ideally, additional laboratory tests should be carried out to deal with function, wear and tear, new material developments, environmental influences and user activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be determined.

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Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

WARNING — This document is not suitable to serve as a guide for the selection of a specific lower limb prosthetic device or structure in the prescription of an individual lower limb prosthesis. Any disregard of this warning can result in a safety risk for amputees.

1 Scope

This document specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 2) which typically produce compound loadings by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.

This document specifies Test Ranges (R) by specifying locomotion profiles for the cyclic test in relation to the intended use. According to the concept of the tests of this document, each sample of lower limb prosthetic device or structure submitted for test is, nevertheless, free to develop its individual performance under load.

The tests described in this document comprise:

— principal static and cyclic tests for all components;

— a separate static test in torsion for all components;

— separate static and cyclic tests on ankle-foot devices and foot units for all ankle-foot devices as single components including ankle units or ankle attachments and all foot units as single components;

— a separate static ultimate strength test in maximum knee flexion on knee joints and associated parts for all knee units or knee-shin-assemblies and adjacent components that normally provide the flexion stop on a complete prosthesis;

— optional separate tests on knee locks for all mechanisms which lock the knee joint in the extended position of the knee unit or knee-shin-assembly.

The tests described in this document apply to specific types of ankle-disarticulation prostheses (see NOTE 2), to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses and to the distal (lower) part of hip-disarticulation and hemi-pelvectomy prostheses (see NOTE 3). The test geometry described in this standard is only intended to be used up to a level of 150 mm above the knee-joint centre.

This document is suitable for the assessment of the conformity of lower limb prosthetic devices or structures with the strength requirements specified in ISO 22523:2006, 4.4 (see NOTE 1). Lower limb prosthetic devices or structures on the market, which have demonstrated their compliance with the strength requirements specified in ISO 22523:2006, 4.4 through submission to the relevant tests of ISO 22523:2006, need not be retested to this document.

NOTE 1 The tests can be performed on complete structures, on part structures or on individual components.

NOTE 2 The tests only apply to ankle-disarticulation prostheses which include (foot) components of prosthetic ankle-foot devices taken from the normal production line.

NOTE 3 The distal part comprises the knee unit, the ankle-foot device and all parts between. Tests on hip units are described in ISO 15032.

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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 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

ISO 22523:2006, *External limb prostheses and external orthoses — Requirements and test methods*

IEC 60417, *Graphical symbols for use on equipment*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 8549-1 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
proof strength
static load representing an occasional severe event, which can be sustained by the prosthetic device or structure and still allow it to function as intended

3.2
ultimate strength
static load representing a gross single event, which can be sustained by the prosthetic device or structure but which could render it thereafter unusable

3.3
fatigue strength
cyclic load which can be sustained by the prosthetic device or structure for a given number of cycles

3.4
batch
set of test samples of a prosthetic device or structure submitted together to a test laboratory or facility to undertake tests to demonstrate conformity with requirements

3.5
shock absorption capacity
capacity of a specimen to absorb energy by deflection without a proportional increase of force

3.6
test force
force applied to a sample under test

3.7
prosthesis
externally applied device used to replace wholly, or in part, an absent limb segment

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