International Standard

ISO 10328

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

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai

Third edition
2026-11

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Reference number
ISO 10328:2026(en)

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Foreword

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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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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).

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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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4 Symbols

Test forces; twisting moments	F, F_1, F_2; M_u
Proof test force of end attachments	F_{pa}
Stabilizing test force	F_{stab}
Settling test force	F_{set}
Static proof test force	F_{sp}
Static proof test force on heel or forefoot	F_{1sp}, F_{2sp}
Static ultimate test force	F_{su}
Static ultimate test force on heel or forefoot	F_{1su}, F_{2su}
Minimum test force	F_{cmin}
Maximum test force	F_{cmax}
Range of pulsating test force	F_{cr}
Mean test force	F_{cmean}
Amplitude of pulsating test force	F_{ca}
Pulsating test force	$F_c(t)$
Final static test force	F_{fin}
Minimum test force on heel or forefoot	F_{1cmin}, F_{2cmin}
Maximum test force on heel or forefoot	F_{1cmax}, F_{2cmax}
Range of pulsating test force on heel or forefoot	F_{1cr}, F_{2cr}
Mean test force on heel or forefoot	F_{1cmean}, F_{2cmean}
Amplitude of pulsating test force on heel or forefoot	F_{1ca}, F_{2ca}
Pulsating test force on heel or forefoot	$F_{1c}(t)$, $F_{2c}(t)$
Final static test force on heel or forefoot	F_{1fin}, F_{2fin}
Stabilizing twisting moment	$M_{u\text{-}stab}$
Settling twisting moment	$M_{u\text{-}set}$
Maximum twisting moment	$M_{u\text{-}max}$

NOTE Further details of the test forces and moments listed are given in Table 3.

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5 Strength and related performance requirements and conditions of use

5.1 A lower limb prosthetic device or structure shall have the strength to sustain the loads occurring during use by amputees in the manner intended by the manufacturer for that device according to his written instructions on its intended use in accordance with ISO 22523:2006, 4.4.1. Based on the written instructions for use, the manufacturer or submitter assigns a Test Range (R) that is appropriate to test the strength of the device for the intended use. The manufacturer or supplier is responsible for the instructions for use and the related assignment. National or international classification schemes are independent to the instructions and the related assignment. For the assessment of the strength to sustain loads occurring during use, this document provides a means of determining the four categories of strength. These are listed in Table 1, together with the related performance requirements and the test methods for their verification.

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5.2 In order to demonstrate the strength to sustain the loads occurring during use by amputees of a specific lower limb prosthetic device or structure, the following safety concept shall apply.

The device or structure shall:

a) conform with the requirements in 9.1, 9.2 and 9.3 and for a specific test loading level the requirements in 7.2;

b) be used in accordance with the body mass limit specified by the manufacturer in consideration of the intended use of that device (see NOTE);

c) be used solely for the intended use as described in the instructions for use.

The conditions in a), b) and c) are regarded in both the classification and designation of prosthetic devices or structures according to Clause 20 and their identification according to Clause 21.

NOTE The statement of the body mass limit not to be exceeded by amputees is part of the conditions of use to be specified, with justification, by the manufacturer in his written instructions on the intended use of a specific lower limb prosthetic device or structure, taking account of all other factors affecting the loads expected to be exerted on that lower limb prosthetic device or structure by amputees (see Clause B.1).

Table 1 — Categories of strength addressed in this document, together with the related performance requirements and test methods for their verification

Category of strength	Related performance requirement[a]	Test method for verification
Proof strength	Structure shall sustain static loading by proof test forces at prescribed values for prescribed times.	Principal static proof test (16.2.1), separately applied in two test configurations, separate static proof test for ankle-foot devices and foot units (17.2.3), successively applied in heel and forefoot loading.
	Permanent deformation of structure shall not exceed prescribed values in any loading condition.	Principal static proof test (16.2.1)
Ultimate strength	Structure shall sustain static loading by ultimate test forces at prescribed values.	Principal static ultimate strength test (16.2.2), separately applied in two test configurations, separate static ultimate strength test for ankle-foot devices and foot units (17.2.4), separately applied in heel and forefoot loading, separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (17.3).
Fatigue strength	Structure shall sustain successively: 1) static loading by maximum test forces at prescribed values for prescribed times; 2) cyclic loading by pulsating test forces at prescribed values for prescribed numbers of cycles; 3) final static loading by final test forces at prescribed values for prescribed times.	Principal cyclic test (16.3), separately applied in two test configurations, separate cyclic test for ankle-foot devices and foot units (17.2.5), separately applied in heel and forefoot loading.
Static strength in torsion	Structure shall sustain static loading by static test force at prescribed value for prescribed time.	Separate static test in torsion (17.1), applied in two opposite directions of twisting.
Security against slippage of clamped components	Relative angular movement between ends of structure shall not exceed prescribed value.	

[a] The performance requirements related to a specific category of strength are specified in full length in an individual subclause following the subclause in which the test method for their verification is specified.

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6 Coordinate systems and test configurations

6.1 General

6.1.1 For ease in interpretation and presentation, two test configurations are specified, one for right-sided and a mirror image for left-sided application. This measure makes it possible to apply uniform sign conventions for corresponding components of loading generated in the load-bearing structures of right and left prostheses or in asymmetrically designed prosthetic components.

6.1.2 Each test configuration shall be defined in a three-dimensional, rectangular coordinate system (see Figure 1), having an origin 0 and containing a geometric system of planes, lines and points (see Figures 2 and 3).

6.1.3 Each test configuration specifies reference parameters both for the position of the line of application of the test force and for the alignment of test samples within the coordinate system.

6.2 Axes of coordinate systems

6.2.1 The axes of each of the coordinate systems are specified in 6.2.2 to 6.2.4 in relation to a prosthesis which is standing on the ground in an upright position.

If a test sample is not in the upright position, the axes of the coordinate system shall be rotated to correspond.

6.2.2 The *u*-axis extends from the origin 0 of the coordinate systems (see Figure 1) and passes through the effective ankle-joint centre and the effective knee-joint centre (see 6.7.3 and 6.7.6 as well as Figure 6). Its positive direction is upwards (in the proximal direction).

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6.2.3 The *o*-axis extends from the origin 0 perpendicular to the *u*-axis (see Figure 1) and parallel to the effective knee-joint centreline (see 6.7.5 and Figure 6). Its positive direction is outward (in the lateral direction), which is to the left for a left prosthesis and, with the related mirrored values, to the right for a right prosthesis.

6.2.4 The *f*-axis extends from the origin 0 perpendicular to both the *o*-axis and the *u*-axis (see Figure 1). Its positive direction is forward towards the toe (in the anterior direction).

6.3 Reference planes

6.3.1 General

The reference planes (see Figures 2 and 3) shall be parallel planes perpendicular to the *u*-axis. They are specified in 6.3.2 to 6.3.5.

NOTE The reference planes specified in 6.3.2 to 6.3.5 also contain reference lines which relate to Annex B.

6.3.2 Top reference plane, T

The top reference plane, T, is located at a distance $u = u_T$ from the origin. It contains the top load application point P_T (see 6.4).

6.3.3 Knee reference plane, K

The knee reference plane, K, is located at a distance $u = u_K$ from the origin. It contains the knee load reference point P_K (see 6.4) and the effective knee-joint centre (see 6.7.6).

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