INTERNATIONAL STANDARD

ISO 10328

Second edition
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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

Reference number
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Contents

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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics*.

This second edition cancels and replaces the first edition ISO 10328:2006 which has been technically revised with the following changes:

a) Test loading levels P7 and P8 have been introduced in Table B.1, Table B.2, Table B.3, Table 4.1, Table D.1, Table D.2, Table D.3 and the clauses pointing at these tables have been updated. Additional information on P7 and P8 is given in Annex B.1;

b) Table 9 has been revised;

c) Annex D has changed from informative to normative.

Introduction

Throughout this International Standard, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent or deficient limb segment.

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 work was continued by ISO Technical Committee 168 leading to the development of ISO 10328:1996. The test procedures may 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 International Standard 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 International Standard 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 International Standard.

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.

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

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of lower limb prosthetic devices/structures with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE 1). Prosthetic ankle-foot devices and foot units on the market, which have demonstrated their compliance with the strength requirements specified in 4.4 of ISO 22523:2006 through submission to the relevant tests of ISO 10328:2006, need not be retested to ISO 22675:2016.

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

This International Standard 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.

The tests described in this International Standard 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;

— separate static and cyclic 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 International Standard 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).

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.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8549-1:1989, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

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

ISO 22675:2016, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 8549-1:1989 and the following definitions apply.

3.1
proof strength
static load representing an occasional severe event, which can be sustained by the prosthetic device/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/structure but which could render it thereafter unusable

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

3.4
batch
set of test samples of a prosthetic device/structure submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this International Standard

4 Designations and symbols of test forces and moments

The designations and symbols of all relevant test forces and moments are listed in Table 1.

Table 1 — Designations and symbols of test forces and moments

Designation	Symbol
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/forefoot	F_{1sp}, F_{2sp}
Static ultimate test force	F_{su}
Static ultimate test force on heel/forefoot	F_{1su}, F_{2su}
NOTE Further details of the test forces and moments listed are given in Table 3.	

Table 1 *(continued)*

Designation	Symbol
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/forefoot	F_{1cmin}, F_{2cmin}
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}
Mean test force on heel/forefoot	F_{1cmean}, F_{2cmean}
Amplitude of pulsating test force on heel/forefoot	F_{1ca}, F_{2ca}
Pulsating test force on heel/forefoot	$F_{1c}(t)$, $F_{2c}(t)$
Final static test force on heel/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.	

5 Strength and related performance requirements and conditions of use

5.1 According to ISO 22523:2006, 4.4.1, a lower limb prosthetic device/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*".

For the assessment of the conformity of lower limb prosthetic devices/structures with the above requirement (see also Scope), this International Standard provides a means of determining the three categories of strength defined in 3.1 to 3.3 and, in addition, the static strength in torsion and the security against slipping of clamped components.

All of these are listed in Table 2, together with the related performance requirements and the test methods for their verification.

5.2 In order to satisfy the general requirement in 5.1 for a specific lower limb prosthetic device/structure, the following safety concept shall apply.

The device/structure shall

a) comply with the requirements of this International Standard (see 9.1, 9.2 and 9.3) for a specific test loading level (see 7.2)

and

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).

The conditions in a) and b) are regarded in both the classification and designation of prosthetic devices/structures according to Clause 20 and their labelling 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/structure, taking account of all other factors affecting the loads expected to be exerted on that lower limb prosthetic device/structure by amputees (see Clause B.1).

Table 2 — Categories of strength addressed in this International Standard, 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 (see 3.1)	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, separate static proof test for knee locks (17.4.3), applied in a single test configuration.
	Permanent deformation of structure shall not exceed prescribed values in any loading condition	Principal static proof test (16.2.1), separate static proof test for knee locks (17.4.3)
Ultimate strength (see 3.2)	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), separate static ultimate strength test for knee locks (17.4.4), applied in a single test configuration
Fatigue strength (see 3.3)	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, separate cyclic test for knee locks (17.4.5), applied in a single test configuration
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.

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).

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 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

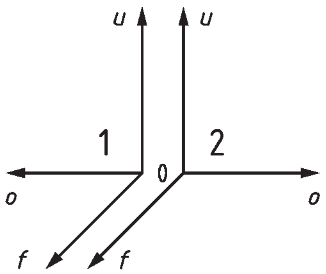
The knee reference plane, K, is located at a distance $u = u_K$ from the origin. It contains the knee load reference point P_K (see 6.4) and the effective knee-joint centre (see 6.7.6).

6.3.4 Ankle reference plane, A

The ankle reference plane, A, is located at a distance $u = u_A$ from the origin. It contains the ankle load reference point P_A (see 6.4) and the effective ankle-joint centre (see 6.7.3).

6.3.5 Bottom reference plane, B

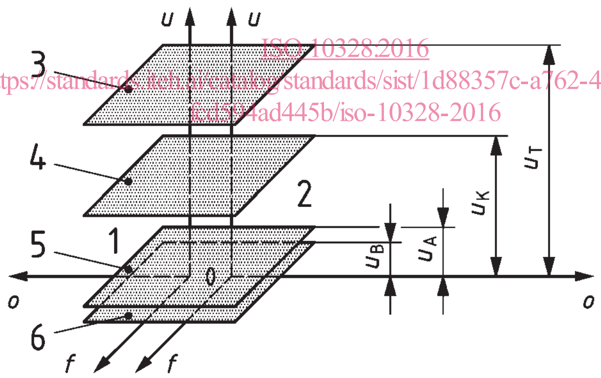
The bottom reference plane, B, is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see 6.4).



Key

1	*right*	f	forward
2	*left*	o	outward
0	*origin*	u	upward

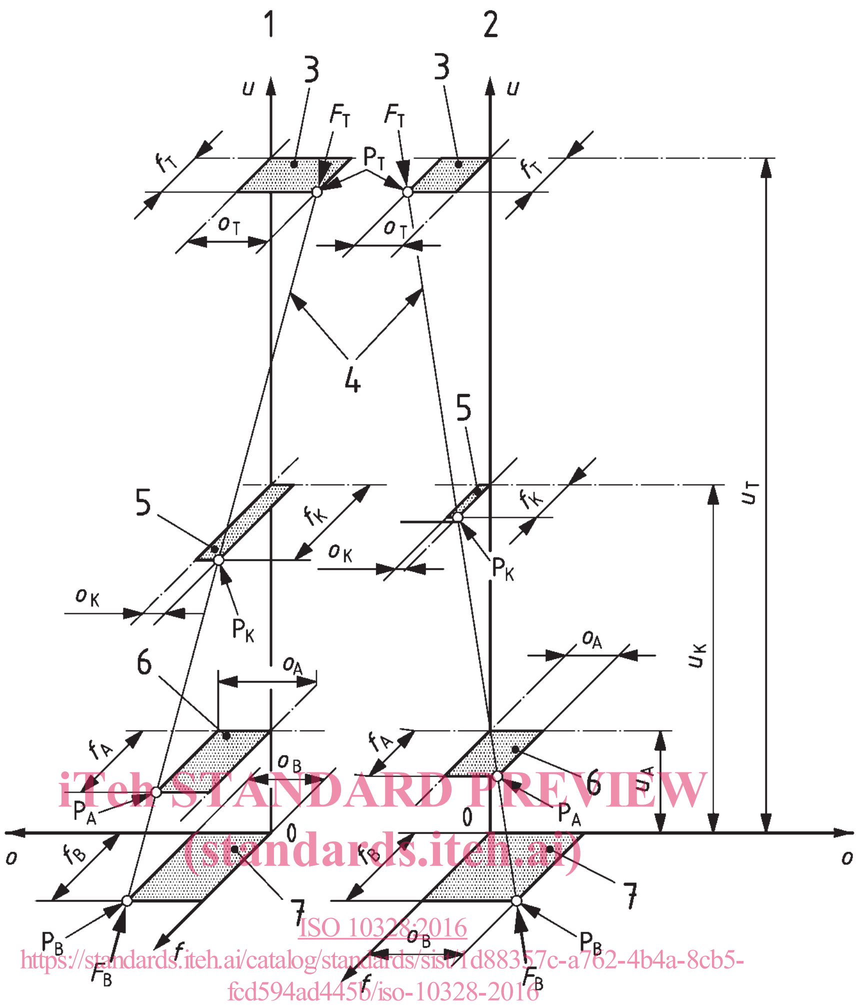
Figure 1 — Coordinate systems for right and left-sided application



Key

1	*right*	4	*knee reference plane, K*
2	*left*	5	*ankle reference plane, A*
3	*top reference plane, T*	6	*bottom reference plane, B*

Figure 2 — Coordinate systems according to Figure 1 with reference planes



Key

1 right leg

2 left leg

3 top reference plane, T

4 load line

5 knee reference plane, K

6 ankle reference plane, A

7 bottom reference plane, B

P_T top load application point

P_K knee load reference point

P_A ankle load reference point

P_B bottom load application point

NOTE This figure illustrates a typical test loading condition representative of the condition of forefoot loading during the stance phase of normal walking. It does not illustrate the test loading conditions defined in 7.1.2.

Figure 3 — Specific configuration with u_B = 0, showing coordinate systems with reference planes (see Figures 1 and 2), reference lines, reference points and test force, F, for right and left-sided application

6.4 Reference points

The reference points are the points of intersection of the load line (see 6.6) with the reference planes (see Figure 3). The coordinates of the reference points are as follows:

— top load application point, P_T (f_T, o_T, u_T)

— knee load reference point, P_K (f_K, o_K, u_K)

— ankle load reference point, P_A (f_A, o_A, u_A)

