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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



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Contents

	Page
Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Designations and symbols of test forces and moments	2
5 Strength and related performance requirements and conditions of use	3
6 Coordinate systems and test configurations	5
6.1 General.....	5
6.2 Axes of coordinate systems.....	5
6.3 Reference planes.....	5
6.3.1 General.....	5
6.3.2 Top reference plane, T.....	5
6.3.3 Knee reference plane, K.....	5
6.3.4 Ankle reference plane, A.....	6
6.3.5 Bottom reference plane, B.....	6
6.4 Reference points.....	7
6.5 Test force.....	8
6.6 Load line.....	8
6.7 Longitudinal axis of the foot and effective joint centres and centrelines.....	8
6.7.1 General.....	8
6.7.2 Longitudinal axis of the foot.....	8
6.7.3 Effective ankle-joint centre.....	8
6.7.4 Effective ankle-joint centreline.....	10
6.7.5 Effective knee-joint centreline.....	10
6.7.6 Effective knee-joint centre.....	11
6.8 Reference distances.....	11
6.8.1 Offsets.....	11
6.8.2 Combined offsets.....	11
6.8.3 Effective lever arms L_A and L_K	11
6.8.4 Distance L_{BT}	11
7 Test loading conditions and test loading levels	11
7.1 Test loading conditions.....	11
7.1.1 General.....	11
7.1.2 Test loading conditions of principal structural tests.....	12
7.1.3 Test loading conditions of separate structural tests.....	12
7.2 Test loading levels.....	12
8 Values of test loads, dimensions and cycles	13
9 Compliance	20
9.1 General.....	20
9.2 Selection of tests required to claim compliance with this International Standard.....	21
9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this International Standard.....	21
9.3.1 General.....	21
9.3.2 Particular arrangements concerning the ankle-foot device or foot unit.....	21
9.3.3 Particular arrangements and requirements concerning the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure.....	21
9.4 Number of tests and test samples required to claim compliance with this International Standard.....	22
9.5 Multiple use of test samples.....	22

9.5.1	General.....	22
9.5.2	Restriction.....	22
9.6	Testing at particular test loading levels not specified in this International Standard.....	23
10	Test samples.....	25
10.1	Selection of test samples.....	25
10.1.1	General.....	25
10.1.2	Selection of ankle-foot devices and foot units of appropriate size of foot.....	26
10.2	Types of test samples.....	27
10.2.1	Complete structure.....	27
10.2.2	Partial structure.....	29
10.2.3	Any other structure.....	29
10.3	Preparation of test samples.....	29
10.4	Identification of test samples.....	30
10.5	Alignment of test samples.....	31
10.5.1	Test samples for principal tests and separate tests on knee locks.....	31
10.5.2	Test samples for separate tests on ankle-foot devices and foot units.....	31
10.5.3	Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts.....	31
10.5.4	Test samples for separate tests on knee locks.....	32
10.6	Worst-case alignment position of test samples.....	32
11	Responsibility for test preparation.....	33
12	Test submission document.....	34
12.1	General requirements.....	34
12.2	Information required for test samples.....	35
12.2.1	All test samples.....	35
12.2.2	Test samples for tests on ankle-foot devices and foot units.....	35
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts.....	35
12.3	Information required for tests.....	35
12.3.1	General.....	35
12.3.2	For all tests.....	35
12.3.3	For static tests in torsion and on ankle-foot devices and foot units.....	36
12.3.4	For static ultimate strength tests.....	36
12.3.5	For cyclic tests.....	36
12.3.6	For tests in torsion.....	36
12.3.7	For tests on ankle-foot devices and foot units.....	36
13	Equipment.....	37
13.1	General.....	37
13.2	Equipment for the principal tests specified in 16.2 and 16.3.....	37
13.2.1	End attachments.....	37
13.2.2	Jig (optional).....	39
13.2.3	Test equipment.....	40
13.3	Equipment for the separate static test in torsion specified in 17.1.....	42
13.3.1	Test equipment.....	42
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2.....	42
13.4.1	Test equipment.....	42
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3.....	46
13.5.1	Extension pieces.....	46
13.5.2	Test equipment to perform static compression loading – (Compression testing machine or other equipment).....	46
13.6	Equipment for the separate tests on knee locks specified in 17.4.....	46
13.6.1	End attachments.....	46
13.6.2	Jig (optional).....	46
13.6.3	Test equipment.....	46
14	Accuracy.....	47

This is a preview of "ISO 10328:2016". [Click here to purchase the full version from the ANSI store.](#)

14.1	General	47
14.2	Accuracy of equipment	47
14.3	Accuracy of procedure	47
15	Test principles	48
15.1	General	48
15.2	Static test procedure	48
15.3	Cyclic test procedure	48
16	Test procedures – Principal structural tests	48
16.1	Test loading requirements	48
16.1.1	Preparation for test loading	48
16.1.2	Application of test loading	48
16.2	Principal static test procedure	50
16.2.1	Principal static proof test	50
16.2.2	Principal static ultimate strength test	55
16.3	Principal cyclic test procedure	59
16.3.1	General requirements	59
16.3.2	Test method	59
16.3.3	Performance requirements	63
16.3.4	Compliance conditions	64
17	Test procedures — Separate structural tests	68
17.1	Separate static test in torsion	68
17.1.1	General	68
17.1.2	Purpose of test	68
17.1.3	Test method	68
17.1.4	Performance requirements	70
17.1.5	Compliance conditions	70
17.2	Separate tests on ankle-foot devices and foot units	72
17.2.1	General	72
17.2.2	Purpose of tests	72
17.2.3	Separate static proof test for ankle-foot devices and foot units	72
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units	76
17.2.5	Separate cyclic test for ankle-foot devices and foot units	81
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts	86
17.3.1	General	86
17.3.2	Purpose of test	86
17.3.3	Applicability of the test to specific test samples	86
17.3.4	Test method	87
17.3.5	Performance requirement	88
17.3.6	Compliance conditions	88
17.4	Separate tests on knee locks	89
17.4.1	General	89
17.4.2	Purpose of tests	90
17.4.3	Separate static proof test for knee locks	90
17.4.4	Separate static ultimate strength test for knee locks	94
17.4.5	Separate cyclic test for knee locks	96
18	Test laboratory/facility log	105
18.1	General requirements	105
18.2	Specific requirements	105
19	Test report	105
19.1	General requirements	105
19.2	Specific requirements	106
19.3	Options	106
20	Classification and designation	106
20.1	General	106

This is a preview of "ISO 10328:2016". [Click here to purchase the full version from the ANSI store.](#)

20.2	Examples of classification and designation.....	106
21	Labelling	107
21.1	General.....	107
21.2	Use of mark “*”) and warning symbol.....	108
21.3	Examples of label layout.....	108
21.4	Label placement.....	108
Annex A	(informative) Description of internal loads and their effects	110
Annex B	(informative) Reference data for the specification of test loading conditions and test loading levels of principal cyclic tests	114
Annex C	(informative) Guidance on the application of an alternative static ultimate strength test	118
Annex D	(normative) Guidance on the application of an additional test loading levels P6, P7 and P8	119
Annex E	(informative) Summary of the records to be entered in the test laboratory/facility log 122	
Annex F	(informative) Background information on the loading profiles generated by test equipment according to 13.4.1.2 for separate cyclic tests for ankle-foot devices and foot units according to 17.2.5.1	137
Annex G	(informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142	139
Bibliography	140

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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).

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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.