INTERNATIONAL STANDARD

ISO 10328-4

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Prosthetics — Structural testing of lower-limb prostheses —

Part 4: Loading parameters of principal structural tests

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs —

Partie 4: Paramètres de charge des essais principaux de structure

INTERNATIONAL ISO

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10328-4 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

ISO 10328 consists of the following parts, under the general title *Prosthetics — Structural testing of lower-limb prostheses*:

— *Part 1: Test configurations*

— *Part 2: Test samples*

— *Part 3: Principal structural tests*

— *Part 4: Loading parameters of principal structural tests*

— *Part 5: Supplementary structural tests*

— *Part 6: Loading parameters of supplementary structural tests*

— *Part 7: Test submission document*

— *Part 8: Test report*

Annex A of this part of ISO 10328 is for information only.

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Introduction

Throughout all parts of ISO 10328, 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 meeting 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 this series of International Standards. The test procedures may not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subject to a series of load actions, each varying individually with time. The test methods specified in ISO 10328 use static and cyclic strength tests in which, with one exception, compound loadings are produced 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. ISO 10328 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 the different parts of ISO 10328.

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 specified.

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Prosthetics — Structural testing of lower-limb prostheses —

Part 4:
Loading parameters of principal structural tests

1 Scope

ISO 10328 specifies procedures for static and cyclic strength tests of lower-limb prostheses where, with one exception, compound loadings are produced 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 ISO 10328 apply to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses.

NOTE — The tests may be performed on complete structures, on partial structures, or on individual components.

This part of ISO 10328 specifies

— the values of the offsets for setting up, aligning and loading the test sample, and

— the values of the test forces to be applied for static and cyclic testing

for the different test loading conditions and test load levels in accordance with ISO 10328-3:1996, subclauses 4.3.2 and 4.4.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10328. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10328 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 10328-3:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 3: Principal structural tests.*

3 Definitions

For the purposes of this part of ISO 10328, the definitions in ISO 8549-1 apply.

4 General

4.1 Test load levels

Because of the significant differences in the characteristics of use of lower-limb prostheses by adults and by children, separate series of test load levels are required.

The series A test load levels, applied to lower-limb prostheses for adults, are designated as given in table 1. Details of each test load level are specified in tables 3 to 6.

NOTE — The details of test load levels for adults will be supplemented in due course. Test load levels for lower-limb prostheses for children are planned for future publication.

Table 1 — Designation of test load levels for adults

Test load level	A100	A80	A60

4.2 Test forces

To simplify application of ISO 10328, all relevant test forces are listed in table 2, together with references to the relevant subclauses of ISO 10328-3 and tables of this part of ISO 10328.

Table 2 — Test forces and relevant references

Test force		Reference	
		ISO 10328-3	This part of ISO 10328
Stabilizing test force	F_{stab} = 50 N	5.4.2.4 5.4.2.6 6.1.4 6.1.7 6.1.8 6.2.4 7.2.5	
Settling test force	$F_{set} = 0{,}8F_c$	5.4.2.3 6.1.3 6.2.3 7.2.4	
Proof test force of end attachments	$F_{pa} = 1{,}2F_{su,\ brittle}$	5.4.2.5 5.4.2.7 5.4.3	Table 6
Static proof test force	$F_{sp} = 1{,}75F_c$	6.1.6 7.1.5	Table 6
Static ultimate test force	$F_{su} = 1{,}5F_{sp}$ (for ductile failure) $F_{su} = 2{,}0F_{sp}$ (for brittle failure)	6.2.7 6.2.6 6.2.7	
Initial test force	F_{min} = 50 N	7.1.1 7.2.8 7.2.10	
Cyclic test force	F_c	5.4.2.3 6.1.3 6.2.3 7.1.1 7.1.3 7.2.4 7.2.9	Table 6
Maximum cyclic test force	F_{max}	7.1.1 7.1.3 7.2.7 7.2.10	Table 6

Table 3 — Total length of different types of test sample — All test load levels
(see also ISO 10328-3:1996, subclause 4.1.1, and ISO 10328-1:1996, figure 2)

Dimensions in millimetres

Reference plane level	Typical combination of structures[1]		
	A	B	C
u_T	$u_T - u_K = 150$	$u_T - u_K = 150$	$u_T - u_A = 590 - h_r$
u_K	$u_K - u_A = 440 - h_r$	$u_K - u_B = 500$	$u_T - u_A = 590 - h_r$
u_A	$u_A - u_B = 60 + h_r$	$u_K - u_B = 500$	$u_T - u_A = 590 - h_r$
u_B	$u_A - u_B = 60 + h_r$	$u_K - u_B = 500$	$u_A - u_B = 60 + h_r$
Total length	650	650	650

1) h_r = recommended heel height, in millimetres.
Complete structure: A
Partial structure: A, B, C
Any other structure: A, B, C

Table 4 — Test configurations for test loading conditions I and II — Static failure test

Dimensions in millimetres

Reference plane	Direction	Offset[2]					
		For A100		For A80		For A60	
		Loading condition		Loading condition		Loading condition	
		I	II	I	II	I	II
Top[1]	f_T	82	55	89	51	81	51
	o_T	−79	−40	−74	−44	−85	−49
Knee	f_K	52	72	56	68	49	68
	o_K	−50	−35	−48	39	−57	−43
Ankle	f_A	−32	120	−35	115	−41	115
	o_A	30	−22	25	−24	24	−26
Bottom[1]	f_B	−48	129	−52	124	−58	124
	o_B	45	−19	39	−22	39	−23

1) Only for guidance in aligning test samples.

2) See ISO 10328-3:1996, subclause 6.2.5.

Table 5 — Test configurations for test loading conditions I and II — Static proof test and cyclic test

Dimensions in millimetres

Reference plane	Direction	Offset[2]					
		For A100		For A80		For A60	
		Loading condition		Loading condition		Loading condition	
		I	II	I	II	I	II
Top[1]	f_T	82	55	89	51	81	51
	o_T	−79	−40	−74	−44	−85	−49
Knee	f_K	52	72	56	68	49	68
	o_K	−50	−35	−48	−39	−57	−43
Ankle	f_A	−32	120	−35	115	−41	115
	o_A	30	−22	25	−24	24	−26
Bottom[1]	f_B	−48	129	−52	124	−58	124
	o_B	45	−19	39	−22	39	−23

1) Only for guidance in aligning test samples.

2) See ISO 10328-3:1996, subclauses 6.1.5 and 7.2.6.

Table 6 — Test forces (see clause 4)

Test load level	Loading condition	Proof test of attachments	Static test procedure			Cyclic test procedure		
		Proof test force, F_{pa}	Proof test force, F_{sp}	Ultimate test force, F_{su}		Range of cyclic test force, F_c	Maximum test force, F_{max} (F_{min} + F_c)	Endurance
		N	N	N		N	N	(cycles)
				ductile	brittle			
A100	I	5 376	2 240	3 360	4 480	1 280	1 330	3×10^6
	II	4 830	2 013	3 019	4 025	1 150	1 200	3×10^6
A80	I	4 956	2 065	3 098	4 130	1 180	1 230	3×10^6
	II	4 347	1 811	2 717	3 623	1 035	1 085	3×10^6
A60	I	3 864	1 610	2 415	3 220	920	970	3×10^6
	II	3 348	1 395	2 092	2 790	797	847	3×10^6