INTERNATIONAL STANDARD

ISO 10328-6

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Prosthetics — Structural testing of lower-limb prostheses —

Part 6: Loading parameters of supplementary structural tests

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

Partie 6: Paramètres de charge des essais supplémentaires 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 10328-6 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*

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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 6:
Loading parameters of supplementary 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 and moments to be applied for static and cyclic testing

for the different supplementary structural tests specified in ISO 10328-5 at the test load levels defined in ISO 10328-3.

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

ISO 10328-5:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 5: Supplementary structural tests.*

3 General

3.1 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 designated as in table 1 shall be applied to lower-limb prostheses for adults. Details of each load level for supplementary structural tests are specified in clause 4 of this part of ISO 10328.

NOTE — The details of test load levels will be supplemented in due course.

Table 1 — Designation of test load levels for adults

Test load level	A100	A80	A60

3.2 Test forces and moments

For ease in application of ISO 10328, all test forces and moments relevant to each supplementary structural test for adult lower-limb prostheses as specified in ISO 10328-5 are listed separately in tables 2 to 5.

Table 2 — Moments of test in torsion

Test moment		**Reference**	
		ISO 10328-5	**This part of ISO 10328**
Stabilizing torsional moment	M_{ustab} = 1 N·m	4.3.4 4.3.6	Table 6
Settling torsional moment	M_{uset}	4.3.3	Table 6
Maximum torsional moment	M_{umax}	4.3.6	Table 6

Table 3 — Test forces on ankle-foot devices

Test force		Reference	
		ISO 10328-5	This part of ISO 10328
Static proof test force on heel	$F_{1sp} = 1{,}75F_{1c}$	5.4.1.3 5.4.1.4 5.4.3.7	Table 8
Static proof test force on forefoot	$F_{2sp} = 1{,}75F_{2c}$	5.4.1.6 5.4.1.7 5.4.3.7	Table 8
Static ultimate test force on heel	$F_{1su} = 1{,}5F_{1sp}$ (for ductile failure) $F_{1su} = 2{,}0F_{1sp}$ (for brittle failure)	5.4.2.4 5.4.2.3 5.4.2.4	Table 8
Static ultimate test force on forefoot	$F_{2su} = 1{,}5F_{2sp}$ (for ductile failure) $F_{2su} = 2{,}0F_{2sp}$ (for brittle failure)	5.4.2.7 5.4.2.6 5.4.2.7	Table 8
Initial test force	$F_{min} = 50$ N	5.4.3.3	
Cyclic test force on heel	F_{1c}	5.4.3.3 5.4.3.4	Table 8
Cyclic test force on forefoot	F_{2c}	5.4.3.3 5.4.3.4	Table 8
Maximum cyclic test force on heel	F_{1max}	5.4.3.3	Table 8
Maximum cyclic test force on forefoot	F_{2max}	5.4.3.3	Table 8

Table 4 — Test force on knee flexion stops

Test force		Reference	
		ISO 10328-5	This part of ISO 10328
Static test force	F_{sp}	6.3.2	Table 9

Table 5 — Test forces on knee locks

Test force		Reference	
		ISO 10328-5	This part of ISO 10328
Stabilizing test force	F_{stab} = 50 N	7.3.4 7.3.7 7.3.8 7.4.4	
Settling test force	$F_{set} = 0{,}8F_c$	7.3.3 7.4.3 7.5.1.4	
Static proof test force	$F_{sp} = 1{,}75F_c$	7.3.6 7.5.14	Table 11
Static ultimate test force	$F_{su} = 2{,}0F_{sp}$	7.4.7 7.4.8	Table 11
Initial test force	F_{min} = 50 N	7.5.1.5 7.5.1.8	
Cyclic test force	F_c	7.3.3 7.4.3 7.5.1.4 7.5.1.9 7.5.1.10	Table 11
Maximum cyclic test force	F_{max}	7.5.1.7	Table 11

4 Details of test load levels A100, A80 and A60

Tables 6 to 11 give details of test load levels for adult lower-limbs prostheses.

Table 6 — Torsional moments for all test load levels
(see ISO 10328-5:1996, clause 4)

Static proof test load N·m		
Settling moment, M_{uset}	**Stabilizing moment, M_{ustab}**	**Twisting moment, M_u**
3	1	35

Table 7 — Directions of loading on ankle-foot devices for all test load levels
(see ISO 10328-5:1996, clause 5)

Angle	Degrees
$\Theta_{uf1} = \Theta_{fu1}$	15
$\Theta_{uf2} = \Theta_{fu2}$	20
Θ_{fo}	7

Table 8 — Forces on ankle-foot devices for all test load levels (see ISO 10328-5:1996, clause 5)

Test load level	Application mode	Static proof test force, F_{sp} N	Static ultimate test force, F_{su} N		Cyclic test		
			Ductile	Brittle	Range of F_c N	F_{max} (= F_{min} + F_c) N	No. of cycles (endurance)
A100	Heel loading, F_1	2 240	3 360	4 480	1 280	1 330	2×10^6
	Forefoot loading, F_2	2 240	3 360	4 480	1 280	1 330	2×10^6
A80	Heel loading, F_1	2 065	3 098	4 130	1 180	1 230	2×10^6
	Forefoot loading, F_2	2 065	3 098	4 130	1 180	1 230	2×10^6
A60	Heel loading, F_1	1 610	2 415	3 220	920	970	2×10^6
	Forefoot loading, F_2	1 610	2 415	3 220	920	970	2×10^6

Table 9 — Loading parameters on knee flexion stops for all test load levels
(see ISO 10328-5:1996, clause 6)

Effective lever arms mm	Static proof test force, F_{sp} N
400	1 750

Table 10 — Offsets on knee locks for all test load levels
(see ISO 10328-5:1996, clause 7)

Reference plane	Offsets	
	Direction	Value mm
Knee	f_K	– 50
	o_K	0
Ankle	f_A	– 50
	o_A	0