INTERNATIONAL STANDARD

ISO 10328-3

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Prosthetics — Structural testing of lower-limb prostheses —

Part 3:
Principal structural tests

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

Partie 3: Essais principaux de structure

Reference number
ISO 10328-3:1996(E)

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 10328-3 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 forms an integral part of this part of ISO 10328.

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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 3:
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 methods to be used in carrying out the principal static tests;

— the methods to be used in carrying out the principal cyclic tests;

— the requirements for accuracy of the tests;

— the criteria to be met in order to claim compliance with this part of ISO 10328.

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 10328-1:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 1: Test configurations.*

ISO 10328-2:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 2: Test samples.*

ISO 10328-4:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 4: Loading parameters of principal structural tests.*

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

ISO 10328-6:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 6: Loading parameters of supplementary structural tests.*

ISO 10328-7:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 7: Test submission document.*

ISO 10328-8:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 8: Test report.*

3 Definitions

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

3.1 brittle failure: Fracture of any component without significant plastic deformation at the fracture.

3.2 ductile failure:

(1) Fracture of any component with significant plastic deformation at the fracture.

(2) Gross plastic deformation of the test sample.

The effective lever arms (see 3.3) and the distance between the bottom load application point P_B and the top load application point P_T (see 4.1.1) are defined as follows:

3.3 effective lever arm: Perpendicular distance from the load line to the effective joint centre.

L_A represents the ankle effective lever arm length and L_K the knee effective lever arm length.

3.4 test equipment: Any test machine or device adapted or specifically designed to the requirements of this part of ISO 10328.

4 General

The test laboratory/facility shall carry out the tests specified in this part of ISO 10328 and shall prepare the test submission document (see ISO 10328-7).

4.1 Test samples

4.1.1 Total sample length

For the tests, all sample types specified in ISO 10328-2:1996, clause 4, shall be aligned in accordance with ISO 10328-2:1996, clause 7, and the test submission document (see ISO 10328-7), and shall have a fixed total length L_{BT}, defined as the distance between the bottom load application point P_B and the top load application point P_T, using end attachments consisting of extension pieces and the load application levers.

This value of L_{BT} can be achieved by selecting either one of the combinations specified in table 3 of ISO 10328-4:1996 for the different types of test sample (see ISO 10328-2:1996, clause 4) and different test load levels (see 4.4 and the relevant clause of ISO 10328-4:1996) or any other relevant combination.

For the test methods, the dimension $u_T - u_B$ is represented as u_{BT}.

4.1.2 Foot length

For test samples including a foot (see ISO 10328-2:1996, clause 4) select the size of the foot in accordance with ISO 10328-2:1996, subclause 5.2.

4.2 Types of test procedure

Two principal structural test procedures are described, a static test and a cyclic test.

4.2.1 The static test procedure consists of a proof test and a failure test. This test procedure is carried out to determine the performance of the load-bearing structures under typical severe loading conditions that can occur during use as occasional isolated events.

The static test procedure is completed when the test sample has satisfied the proof test requirements and met the failure test requirements.

4.2.2 The cyclic test procedure consists of repeated applications of a prescribed load to a test sample with loading conditions typical of normal walking, followed by a final static test for which both the procedure and all requirements of the static proof test apply (see 6.1).

The cyclic test procedure is completed when either:

a) the test sample has failed, or

b) the test sample has withstood the prescribed number of cycles of load without failure and satisfied the final static test requirements.

4.3 Test loading requirements

4.3.1 Preparation for test loading

The position of the test load line within the coordinate systems is three-dimensional (see figure 1 in this part of ISO 10328 as well as relevant clauses and figures of ISO 10328-1:1996). The preparation for loading shall proceed as follows.

a) The test sample shall be assembled to a fixed length, using end attachments consisting of extension pieces, as required, and the load application levers.

b) The test sample shall be set up in the test equipment with the bottom and top load application levers having a combination of forward/backward and outward/inward offsets. Figure 2 shows the geometry for a left leg and gives the equations for the calculation of theoretical offsets.

c) No corrections shall be made to the load application levers if the test sample deflects under the test loading conditions specified in 4.3.2.

4.3.2 Test loading conditions

The loading described in 4.3.1 shall be applied in two different conditions relating to the maxima occurring at different instants during the stance phase of normal walking.

a) Test loading condition I is related to the instant of maximum loading occurring early in the stance phase of walking.

b) Test loading condition II is related to the instant of maximum loading occurring late in the stance phase of walking.

NOTE — For some prosthetic designs, it is not possible to set up a test sample in accordance with these requirements. Special test set-ups may then be used in certain cases.

4.4 Test load levels

4.4.1 The load actions to which a lower-limb prosthesis is actually subjected during use vary with individual physical parameters, locomotion characteristics of the user and other factors. For these reasons different categories of prostheses are needed and, consequently, different test load levels are specified.

4.4.2 To take into account 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 (see ISO 10328-4) shall apply to lower-limb prostheses for adults; they are designated as given in table 1.

— The series C test load levels (planned for future publication) shall apply to lower-limb prostheses for children.

NOTE — The values of the dimensions and forces of load levels for principal structural tests available at the time of publication of this part of ISO 10328 are specified in separate tables in the relevant clauses of ISO 10328-4. They will be supplemented in due course.

Table 1 — Designation of test load levels for adults

Test load level	A100	A80	A60

4.5 Compliance with ISO 10328

In order to claim compliance with ISO 10328, test samples shall satisfy all of the requirements of this part of ISO 10328, all relevant clauses of ISO 10328-5 and relevant test load conditions and test load levels of ISO 10328-4 and ISO 10328-6. Any claim of compliance and labelling shall state the test load level at which tests were conducted.

4.6 Responsibilities regarding structural tests

4.6.1 The test laboratory/facility shall carry out the tests specified in table 2.

Table 2 — Tests required to claim compliance with ISO 10328 for complete structures, partial structures or individual components

Test sample	**Principal structural tests**	**Supplementary structural tests**			
		Torsion test	**Foot test**	**Knee flexion stop tests**	**Knee lock test**
Complete transfemoral prosthesis	x	x	x	x	o
Complete transfemoral prosthesis without foot unit	x	x		x	o
Partial structure including knee unit but not foot unit	x	x		x	o
Partial structure including knee unit and foot unit	x	x	x	x	o
Foot unit only		x	x		
Partial structure including foot unit but not knee unit (transtibial prosthesis)	x	x	x		
Partial structure without knee unit and without foot unit	x	x			
NOTE — x = test required; o = test required if feature is present.					

4.6.2 The test laboratory/facility shall record the results of the test in a test report in accordance with ISO 10328-8. The test laboratory/facility shall provide a copy of the test report to the submitter.

4.6.3 Where any test sample includes a partial structure in accordance with ISO 10328-2:1996, subclause 4.2, which can be used in various prosthetic assemblies, then it shall be tested in the most adverse prosthetic assembly possible, as specified by the manufacturer/submitter in the test submission document.

5 General requirements applicable to all tests

5.1 The dimensions of the test pieces and attachments and forces to be applied during the tests are specified in ISO 10328-4. The particular requirements of any single test shall be stated in the test submission document submitted with each test sample in accordance with ISO 10328-7.

5.2 Ensure that any records called for are entered in the test laboratory/facility log and copied to the test report, in accordance with ISO 10328-8.

5.3 Ensure that the test equipment has sufficient freedom of movement to permit unrestricted deformation of the test sample.

5.4 Proof test of attachments

5.4.1 Ensure that any attachments to the test sample do not enhance or relieve the specified test loads in the structure under test.

5.4.2 Carry out a proof test of end attachments consisting of the load application levers and any extension pieces used by measuring their stiffness in the following manner.

5.4.2.1 Assemble together any nonprosthetic components used in the test sample. Set both load application levers in the *f*-*u* plane, i.e. with both o_B and $o_T = 0$.

5.4.2.2 If the load application levers are adjustable, set both lever lengths to 120 mm.

5.4.2.3 Place the assembly in the test equipment or suitable device. Apply to the assembly a settling test force

$$F_{set} = 0{,}8F_c$$

where F_c is the cyclic test force at the relevant test loading condition and test load level specified in table 6 of ISO 10328-4:1996.

Maintain this force, F_{set}, for a period not exceeding 30 s and then remove it.

5.4.2.4 Apply a stabilizing test force $F_{stab} = 50$ N to the bottom and top load application points and maintain it until the measurement of L_{BT} is completed.

Measure and record L_{BT} as L_1.

5.4.2.5 Apply the proof test force

$$F_{pa} = 1{,}2F_{su}$$

where F_{su} is the static ultimate test force for brittle failure at the relevant test loading condition and test load level specified in table 6 of ISO 10328-4:1996, and maintain it until the measurement of L_{BT} is completed.

Measure and record L_{BT} as L_2.

5.4.2.6 Reduce the test force to F_{stab} = 50 N and maintain it until the measurement of L_{BT} is completed.

Measure and record L_{BT} as L_3.

5.4.2.7 Calculate the deflection D_1 at F_{pa} and the permanent deformation D_2, respectively, as follows:

$$D_1 = L_1 - L_2$$

$$D_2 = L_1 - L_3$$

5.4.3 The values for the specified limits of deflection and permanent deformation are:

maximum deflection at F_{pa}: D_1 = 2 mm

maximum permanent deformation at 50 N: D_2 = 0,5 mm

Do not use the end attachment if the measured values exceed these limits.

5.4.4 Do not repeat the stiffness measurements if earlier test results for previously tested combinations of end attachments are available and are suitable. Record the results, giving a cross-reference if earlier test results are employed.

6 Static test procedure

6.1 Static proof test

6.1.1 Prepare and align the test sample in accordance with ISO 10328-2 and the test submission document (see ISO 10328-7) and set all dimensions in accordance with tables 3 and 5 of ISO 10328-4:1996.

6.1.2 Mount the test sample in the test equipment.

6.1.3 Apply to the test sample a settling test force

$$F_{set} = 0{,}8F_c$$

where F_c is the cyclic test force of the relevant test loading condition and test load level specified in table 6 of ISO 10328-4:1996.

Maintain this force, F_{set}, for a period not exceeding 30 s and then remove it.

6.1.4 Apply a stabilizing test force of F_{stab} = 50 N and maintain it until the adjustments and measurements of 6.1.5 are completed.

6.1.5 In accordance with the relevant test loading condition and test load level specified in table 5 of ISO 10328-4:1996, adjust the bottom and top load application levers until the ankle and knee offsets (f_A and f_K or o_A and o_K as appropriate) are correct.

Measure and record L_A and L_K.

Measure and record L_{BT} as L_4.

6.1.6 Increase the test force smoothly to the specified proof test force F_{sp} corresponding to the relevant test loading condition and test load level specified in table 6 of ISO 10328-4:1996 at a rate between 100 N/s and 250 N/s.

Maintain the test force F_{sp} at the prescribed value for 30 s.

6.1.7 Decrease the test force to F_{stab} = 50 N.

6.1.8 Maintain the stabilizing test force F_{stab} until the measurements specified below are completed. Complete the measurements within 15 min.

Measure and record L_A and L_K.

Measure and record L_{BT} as L_5.

6.1.9 Calculate and record the permanent deformation D_3 between the bottom and top load application points:

$$D_3 = L_4 - L_5$$

6.1.10 If a permanent deformation D_3 of over 15 mm occurs, the test sample does not comply with this part of ISO 10328 and ISO 10328-4.

6.1.11 If any individual component of the test sample fails to function safely after this test, record that the component does not comply with this part of ISO 10328 and ISO 10328-4.

6.1.12 For test samples that fail, record the load at failure and the nature of the failure in the test report (see ISO 10328-8).

6.2 Static failure test

NOTE — A test sample that has completed the static proof test without failure may be used for this test.

6.2.1 Prepare and align the test sample in accordance with ISO 10328-2 and the test submission document (see ISO 10328-7) and set all dimensions in accordance with tables 3 and 4 of ISO 10328-4:1996.

6.2.2 Mount the test sample in the test equipment.

6.2.3 Apply to the test sample a settling test force

$$F_{set} = 0{,}8F_c$$

where F_c is the cyclic test force of the relevant test loading condition and test load level specified in table 6 of ISO 10328-4:1996.

Maintain this force, F_{set}, for a period not exceeding 30 s and then remove it.

6.2.4 Apply a stabilizing test force F_{stab} = 50 N and maintain it until the adjustments and measurements of 6.2.5 are completed.

6.2.5 In accordance with the relevant test loading condition and test load level specified in table 4 of ISO 10328-4:1996, adjust the bottom and top load application levers until the ankle and knee offsets (f_A and f_K or o_A and o_K as appropriate) are correct.

Measure and record L_A and L_K.

6.2.6 Increase the test force F smoothly at an initial rate of between 100 N/s and 250 N/s until the test sample fails or sustains the ultimate test force F_{su} for brittle failure specified in 6.2.7. Record the maximum value of the test force F reached during the test.

6.2.7 The test force F which the test sample shall withstand in order to satisfy the requirements of this part of ISO 10328 and ISO 10328-4 is dependent upon the mode of failure that may occur (see 3.1 and 3.2).

The test sample shall satisfy the requirements of this part of ISO 10328 and ISO 10328-4 if it sustains the ultimate test force F_{su} for brittle failure, or if ductile failure occurs at a load exceeding the ultimate test foce F_{su} for ductile failure.

The values for F_{su} for the relevant test loading condition and test load level are listed in table 6 of ISO 10328-4:1996.