INTERNATIONAL STANDARD

ISO 10328-5

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Prosthetics — Structural testing of lower-limb prostheses —

Part 5:
Supplementary structural tests

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

Partie 5: Essais supplémentaires de structure

Reference number
ISO 10328-5:1996(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 10328-5 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 5:
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 structural tests and test requirements which are additional to those specified in ISO 10328-3 and ISO 10328-4. The tests, together with their required application, are as follows.

Test in torsion	All components
Tests on ankle-foot devices	All ankle-foot devices as single components, including ankle units or ankle attachments
Test on knee flexion stops	All knee units and associated parts that provide the flexion stop on a complete prosthesis
Tests on knee locks	All mechanisms which lock the knee unit in the extended position

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

ISO 10328-4:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 4: Loading parameters of principal 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 given in ISO 8549-1 apply.

4 Test in torsion

4.1 Purpose of test

Users can apply torsional loads to their prostheses which exceed the levels of the twisting moments (induced torque) generated by test loading conditions specified in ISO 10328-3 and ISO 10328-4. To ensure the torsional strength of the prosthetic structure and the security of fixations against slippage, a static load in torsion alone is applied.

4.2 General requirements

The requirements of the respective parts of ISO 10328 shall apply to all the components of a system, from the socket to the ankle-foot device.

4.3 Static proof test in torsion

4.3.1 Assemble the test sample in accordance with the manufacturer's assembly instructions, taking particular care in the tightening of bolts which clamp components together.

4.3.2 Set up the test sample with the knee unit in full extension and with the effective knee- and ankle-joint centres (see clause 7 of ISO 10328-2:1996) on the *u*-axis and with all adjustable components in their midpositions. Where this cannot be established from examination of the sample, then use the manufacturer's written alignment recommendations for the prosthesis to establish the midpositions.

4.3.3 Fix one end of the test sample and apply a twisting moment M_u to the other end to generate a settling torsional moment of M_{uset}, as specified in table 6 of ISO 10328-6:1996, about the *u*-axis. Maintain the settling torsional moment for a period not exceeding 30 s and then remove it.

4.3.4 Apply the twisting moment M_u to generate a stabilizing torsional moment of M_{ustab} as specified in table 6 of ISO 10328-6:1996, about the *u*-axis and maintain it until the markings of 4.3.5 are completed.

4.3.5 Mark the initial relative angular positions at the junctions of all parts.

4.3.6 Increase the twisting moment M_u smoothly at a rate not exceeding 4 N·m/s to generate a maximum torsional moment of M_{umax}, specified in table 6 of ISO 10328-6:1996, about the u-axis. Maintain the maximum torsional moment for 30 s and then decrease it to the stabilizing torsional moment of M_{ustab}.

4.3.7 Measure and record the final relative angular positions of the top and bottom components of the test sample. Complete the final measurement within 15 min.

4.3.8 The test sample shall satisfy the requirements of clause 4 of this part of ISO 10328 and table 6 of ISO 10328-6:1996 if the relative angular movement between the ends of the test sample after unloading does not exceed 3°, and the prosthesis or component continues to function safely.

4.3.9 Repeat the test (4.3.3 to 4.3.8) in the opposite direction.

4.3.10 Carry out the complete test on a second test sample, and check that neither fails to comply with clause 4 of this part of ISO 10328 and table 6 of ISO 10328-6:1996.

4.3.11 Record the following:

a) the tightening torque of any joint-clamping bolts which are required to be tightened to assemble the sample in the test configuration;

b) the time elapsed for testing and for measuring the relative angular movement;

c) the relative angular movement.

5 Tests on ankle-foot devices

5.1 Purpose of tests

Although, according to subclauses 4.1, 4.2 and 4.3 of ISO 10328-2:1996, ankle-foot devices can be tested as part of test samples or as single components in the test configurations of ISO 10328-1 and in the test loading conditions for the principal structural tests of ISO 10328-3 at the relevant test load level of ISO 10328-4, this part of ISO 10328 specifies special structural static and cyclic tests for ankle-foot devices in which the heel and forefoot are loaded alternately.

These tests relate to ankle-foot devices and their connections to the remainder of the prosthesis. Any report relating to these tests should apply only to the ankle-foot device in association with the connections submitted.

5.2 Selection and preparation of samples

The ankle-foot device shall be selected in accordance with ISO 10328-2:1996, subclause 5.2. It shall be submitted assembled by the manufacturer/submitter and connected to the remainder of the prosthesis, via e.g. an ankle unit, alignment device, pylon base, flexible structure or exoskeletal member.

5.3 Alignment

The alignment of the ankle-foot device within the coordinate system shall be set in accordance with ISO 10328-1 and ISO10328-2:1996, subclauses 7.1 and 7.2.

The centreline of the foot shall be turned by $\Theta_{f0} = 7°$, as shown in figure 1 and specified in table 7 of ISO 10328-6:1996, to give a "toe-out" position of the ankle-foot device.

The test forces F_1 and F_2 shall be transmitted to the heel and forefoot portion by load application plates which shall be mounted in a fixed angular position relative to the ankle-foot device and which contain appropriate technical means that minimize the transmission of transverse forces (see figure 1).

The angles of the load lines and the load application plates shown in figure 1 shall be as follows (see also table 7 of ISO 10328-6:1996):

$\Theta_{uf1} = \Theta_{fu1} = 15°$

$\Theta_{uf2} = \Theta_{fu2} = 20°$

5.4 Test procedures for ankle-foot devices

The test forces are listed and specified in tables 3 and 8 respectively of ISO 10328-6:1996.

5.4.1 Static proof test for ankle-foot devices

5.4.1.1 Prepare and align the test sample in accordance with 5.3 and the test submission document (ISO 10328-7).

5.4.1.2 Mount the test sample in the test equipment as illustrated in figure 1.

5.4.1.3 Increase the test force F_1 smoothly to the specified proof test force F_{1sp} of the relevant test load level, as specified in table 8 of ISO 10328-6:1996, at a rate between 100 N/s and 250 N/s.

5.4.1.4 Maintain the proof test force F_{1sp} at the prescribed value for 30 s.

5.4.1.5 Decrease the test force F to zero and change the direction of loading to Θ_{uf2}.

5.4.1.6 Increase the test force F_2 smoothly to the specified proof test force F_{2sp} of the relevant test load level, as specified in table 8 of ISO 10328-6:1996, at a rate between 100 N/s and 250 N/s.

5.4.1.7 Maintain the proof test force F_{2sp} at the prescribed value for 30 s.

5.4.1.8 Decrease the test force F to zero and check whether the test sample has failed to satisfy clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996. Relevant failure criteria are as follows:

a) the proof load cannot be applied;

b) the test sample fractures;

c) the test sample fails to function.

5.4.1.9 Carry out the complete test on a second test sample and check that neither fails to comply with clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996.

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

5.4.2 Static failure test for ankle-foot devices

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

5.4.2.1 Prepare and align the test sample as required in 5.3 and the test submission document (ISO 10328-7).

5.4.2.2 Mount the first test sample in the test equipment, as illustrated in figure 1.

5.4.2.3 Increase the test force F_1 smoothly at an initial rate between 100 N/s and 250 N/s until the test sample fails or sustains the ultimate test force F_{1su} for brittle failure specified in 5.4.2.4. Record the maximum value of the test force F_1 reached during the test.

5.4.2.4 The test force F_1 in the direction of loading Θ_{uf1} which the test sample shall withstand in order to satisfy the requirements of clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996 is dependent upon the mode of failure that may occur (see 3.1 and 3.2 of ISO 10328-3:1996).

The test sample shall satisfy the requirements of clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996 if it sustains the ultimate test force F_{1su} for brittle failure or if ductile failure occurs at a load exceeding the ultimate test force F_{1su} for ductile failure.

The values for F_{1su} of the relevant test load level are listed in table 8 of ISO 10328-6:1996.

NOTE — If expressly requested by the manufacturer/submitter or if requested in the test submission document, the static failure test may be continued, after the test sample has withstood the test force specified in 5.4.2.4 for brittle failure, until failure actually occurs.

5.4.2.5 Mount the second test sample in the test equipment as illustrated in figure 1. Do not use an ankle-foot device which has failed the test specified in 5.4.2.2 to 5.4.2.4.

NOTE — If an ankle-foot device satisfies the test requirements in one direction of loading, it may be used for the test in the other direction of loading.

5.4.2.6 Increase the test force F_2 smoothly at an initial rate between 100 N/s and 250 N/s until the test sample fails or sustains the ultimate test force F_{2su} for brittle failure specified in 5.4.2.7. Record the maximum value of the test force F_2 reached during the test.

5.4.2.7 The test force F_2 in the direction of loading Θ_{uf2} which the test sample shall withstand in order to satisfy the requirements of clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996 is dependent upon the mode of failure that may occur (see 3.1 and 3.2 of ISO 10328-3:1996).

The test sample shall satisfy the requirements of clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996 if it sustains the ultimate test force F_{2su} for brittle failure or if ductile failure occurs at a load exceeding the ultimate test force F_{2su} for ductile failure.

The values for F_{2su} of the relevant test load level are listed in table 8 of ISO 10328-6:1996.

NOTE — If expressly requested by the manufacturer/submitter or if requested in the test submission document, the static failure test may be continued after the test sample has withstood the test force specified in 5.4.2.7 for brittle failure until failure actually occurs.

5.4.2.8 Carry out the complete test on a second test sample and check that neither fails to comply with clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996.

5.4.2.9 If failure occurs, inspect the specimen to detect the mode of failure and record the results in the test report (see 10328-8).

5.4.3 Cyclic test for ankle-foot devices

5.4.3.1 Prepare and align the test sample in accordance with 5.3 and the test submission document (ISO 10328-7).

5.4.3.2 Mount the test sample in the test equipment as illustrated in figure 1.

5.4.3.3 Apply alternately the cyclic test force $F_{1c} = F_{1max} - F_{min}$ to the heel and the cyclic test force $F_{2c} = F_{2max} - F_{min}$ to the forefoot at a frequency between 0,5 Hz to 3 Hz, in accordance with the test submission document (ISO 10328-7). If the specified frequency cannot be achieved, then the manufacturer/submitter and the test laboratory/facility shall agree to a different frequency. Subclauses 7.1.1 to 7.1.5 of ISO 10328-3:1996 shall apply to this clause.

5.4.3.4 Inspect the waveform of the applied test forces F_{1c} and F_{2c}. Terminate the test if the waveform does not comply with 7.1.2 of ISO 10328-3:1996.

5.4.3.5 Continue the test until failure occurs or a total endurance of 2×10^6 cycles for both the heel and the forefoot has been achieved.

5.4.3.6 At the request of the manufacturer/submitter visually examine all test samples that complete a cyclic test without failing at × 4 magnification or greater, and record in the test report the presence and nature of any cracks.

5.4.3.7 Subject all test samples that successfully complete a cyclic test to a final static force $F_{1fin} = F_{1sp}$ in the direction of loading Θ_{uf1} and to a final static force $F_{2fin} = F_{2sp}$ in the direction of loading Θ_{uf2} (F_{1sp} and F_{2sp} of the relevant test load level as specified in table 8 of ISO 10328-6:1996) applied at a rate between 100 N/s and 250 N/s. Maintain the load in each direction for 30 s without failure.

5.4.3.8 Carry out the complete test on a second test sample and check that neither fails to comply with clause 5 of this part of ISO 10328 and tables 7 and 8 of ISO 10328-6:1996.

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

6 Test on knee flexion stops

6.1 Purpose of test

Users can apply high loads to prostheses in full flexion when kneeling or squatting (deep knee bend). A structural test is required in order to ensure an adequate level of safety during normal use.

6.2 General requirements

6.2.1 The requirements of clause 6 of this part of ISO 10328 shall apply to all knee units and associated parts that provide the flexion stop on a complete prosthesis.

6.2.2 The test sample shall consist of the knee unit and associated parts that provide the flexion stop on a complete prosthesis. Parts outside this may be substituted.

6.2.3 If the knee unit can be used in different assemblies, then the test sample assembly shall represent the leg assembly where the flexion stop point is nearest to the centre of rotation of the knee joint at maximum flexion of the test sample assembly.

6.2.4 The test sample construction shall accurately duplicate the flexion stop of the normal prosthesis; this may include the use of a socket and/or shin-foot assembly.

6.2.5 If the test sample can be aligned, the alignment shall be set in the most adverse position.

6.2.6 The test sample shall have extension pieces attached above and below the knee unit and aligned on the u-axis and perpendicular to the effective knee-joint centreline to represent wholly or in part the thigh and shin (but see 6.2.4). The extension pieces shall provide an effective length of 400 mm, measured from the effective knee-joint centre (see figure 2).

6.3 Static test for knee flexion stops

6.3.1 Increase the test force F between the ends of the extension pieces at a rate between 100 N/s and 250 N/s until failure occurs or the test sample has sustained the specified loads.

6.3.2 The static test force F_{sp} which the test sample shall withstand is specified in table 9 of ISO 10328-6:1996.

6.3.3 Carry out the complete test on a second test sample and check that neither fails to comply with clause 6 of this part of ISO 10328 and table 9 of ISO 10328-6:1996.

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

7 Tests on knee locks

7.1 Purpose of tests

Locked knee units are subject to flexion loading during the stance phase of walking, and a failure of the knee lock mechanism during this phase is potentially hazardous. A structural test is required in order to ensure an adequate level of safety during normal use.

7.2 General requirements for knee locks

7.2.1 The requirements of clause 7 of this part of ISO 10328 shall apply to all knee units with a flexion lock mechanism.

7.2.2 If the lock position is adjustable or alignment adjustment of the test sample moves the lock in relation to the centre of rotation, then the test sample shall be set so that the lock is as close as possible to the effective knee-joint centre (see ISO 10328-2:1996, subclause 7.4).

7.3 Static proof test for knee locks

7.3.1 Prepare and align the test sample in accordance with ISO 10328-2 and the test submission document (ISO 10328-7) and set all dimensions in accordance with table 10 of ISO 10328-6:1996.

7.3.2 Mount the test sample in the test equipment.

7.3.3 Apply to the test sample a settling test force

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

where F_c is the cyclic test force specified in table 11 of ISO 10328-6:1996.

Maintain the settling test force F_{set} for a period not exceeding 30 s and then remove it.

7.3.4 Apply a stabilizing test force $F_{stab} = 50$ N and maintain it until the adjustments and measurements of 7.3.5 are completed.

7.3.5 In accordance with table 10 of ISO 10328-6:1996, 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 the inital value of L_{BT} as L_6.

7.3.6 Increase the test force smoothly to the proof test force F_{sp} specified in table 11 of ISO 10328-6:1996 at a rate between 100 N/s and 250 N/s.

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

7.3.7 Decrease the test force F to a value of $F_{stab} = 50$ N.

7.3.8 Maintain the test force $F_{stab} = 50$ N until the measurement of L_{BT} is completed. Complete the measurement within 15 min.

Measure and record the inital value of L_{BT} as L_7.

7.3.9 Calculate the permanent deformation D_4 between the bottom and top load application points and record the value as:

$$D_4 = L_6 - L_7$$

7.3.10 Check whether the test sample has failed to satisfy clause 7 of this part of ISO 10328 and tables 10 and 11 of ISO 10328-6:1996.

Relevant failure criteria are as follows:

a) the test sample yields or fractures so that the proof load cannot be applied;

b) the permanent deformation D_4 exceeds 2 mm;

c) the test sample fails to function safely after unloading.

7.3.11 Carry out the complete test on a second test sample and check that neither fails to comply with clause 7 of this part of ISO 10328 and tables 10 and 11 of ISO 10328-6:1996.

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

7.4 Static failure test for knee locks

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

7.4.1 Prepare and align the test sample in accordance with ISO 10328-2 and the test submission document (ISO 10328-7) and set all dimensions in accordance with table 10 of ISO 10328-6:1996.

7.4.2 Mount the test sample in the equipment.

7.4.3 Apply to the test sample a settling test force

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

where F_c is the cyclic test force specified in table 11 of ISO 10328-6:1996.

Maintain the settling test force F_{set} for a period not exceeding 30 s and then remove it.

7.4.4 Apply a stabilizing test force F_{stab} = 50 N and maintain it until the adjustments of 7.4.5 are completed.

7.4.5 In accordance with table 10 of ISO 10328-6:1996, 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.

7.4.6 Increase the test force F smoothly at an initial rate of between 100 N/s and 250 N/s.

7.4.7 Continue the test until failure occurs or the applied test force F exceeds the ultimate test force F_{su} specified in table 11 of ISO 10328-6:1996. Record the maximum value of the test force F reached during the test.

7.4.8 If the deformation of flexible parts prevents an ultimate load being attained which exceeds the specified ultimate test force F_{su}, replace the flexible parts by rigid parts and repeat the test. Record all such substitutions in the test report (see ISO 10328-8).

NOTE — If expressly requested by the manufacturer/submitter or if requested in the test submission document, the static failure test may be continued after the test sample has withstood the test force specified in 7.4.7 until failure actually occurs.

7.4.9 Carry out the complete test on a second test sample and check that neither fails to comply with clause 7 of this part of ISO 10328 and tables 10 and 11 of ISO 10328-6:1996.

7.4.10 If failure occurs, inspect the specimen to detect the mode of failure and record the results in the test report (see ISO 10328-8).