INTERNATIONAL STANDARD

ISO 10328-2

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Prosthetics — Structural testing of lower-limb prostheses —

Part 2: Test samples

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

Partie 2: Échantillons d'essai

Reference number
ISO 10328-2:1996(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 10328-2 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 2:
Test samples

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 types of test samples;
— the selection of test samples;
— the preparation of test samples;
— the alignment of test samples;
— responsibilities.

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 10328-3:1996, *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 10328-5:1996, *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 given in ISO 8549-1 apply.

4 Types of test sample

There are three types of test sample, as described in 4.1 to 4.3.

4.1 Complete structure

For knee-disarticulation and transfemoral (above-knee) prostheses, a complete structure consists of a knee unit and ankle unit with all parts between. It may also contain parts above the knee unit, including the socket, and below the ankle unit, including the foot.

For a transtibial (below-knee) prosthesis, a complete structure consists of the ankle unit and the socket attachment with all parts between. It may also contain parts above the socket attachment, including the socket, and below the ankle unit, including the foot.

An example of a complete structure of a left transfemoral (above-knee) prosthesis and its alignment within the coordinate system is shown in figure 1.

4.2 Partial structure

For any type of prosthesis, a partial structure is less than a complete structure and may be a single component, such as a foot or the structural parts of a foot. When a partial structure is tested, the end connections shall have mechanical characteristics similar to those of the intended adjacent components.

4.3 Any other structure

If the design of a leg structure does not allow it to be tested as a test sample in accordance with 4.1 or 4.2, then a special set-up may be used for testing. For example, such a leg could be a one-piece flexible plastic structure that includes the foot.

If the manufacturer/submitter and the test laboratory/facility certify, in writing, in the test submission document (see ISO 10328-7) and the test report (see ISO 10328-8), respectively, that the effective geometry of the test sample and the test loading conditions comply with the requirements of ISO 10328-3 and ISO 10328-4 or ISO 10328-5 and ISO 10328-6, as appropriate, then testing may be carried out and a special test report issued in accordance with ISO 10328-8.

If the test sample satisfies the requirements of the relevant parts of ISO 10328, then compliance can be claimed with these parts. The claim should clearly indicate that the test sample complies with 4.3 of this part of ISO 10328.

If the geometry of the test sample cannot be so certified, then compliance with this part of ISO 10328 cannot be claimed.

Tests on more than one sample are required to satisfy several of the requirements of this part of ISO 10328.

5 Selection of test samples

5.1 The prosthetic structures selected for test purposes shall be drawn from standard production. Details of the selection shall be recorded in the test submission document (see ISO 10328-7). If the manufacturer/submitter supplies a certificate stating that the test sample has been taken from the normal production, this certificate shall be included in the test submission document, together with details of the sampling method.

5.2 For tests on samples including feet, the size of the foot selected shall allow the application of load in accordance with the combined bottom offset L_B specified for the test (see figures 1 and 2 and ISO 10328-4), where:

$$L_B = \sqrt{{f_B}^2 + {o_B}^2}$$

When testing a foot unit, select the size of foot as follows.

a) Select a size that gives the correct combined bottom offset, L_B.

b) If the correct size foot is not available, the next larger size shall be used.

c) If the foot available is shorter than the correct length, then increase the applied test force F to F', where:

$$F' = F \times \frac{\text{specified combined bottom offset}}{\text{actual combined bottom offset}}$$

6 Preparation of test samples

6.1 Any cosmetic components shall be omitted from the sample, unless they contribute to the structural strength.

6.2 For the static proof test (see ISO 10328-3), the samples shall include all parts normally fitted.

6.3 For the static failure test (see ISO 10328-3), subject to agreement between the test laboratory/facility and the manufacturer/submitter, compliant parts (e.g. extension stop buffers) may be replaced by rigid parts in order to avoid excessive deflection during test. All such replacements shall be recorded in the test report (see ISO 10328-8).

6.4 For cyclic tests carried out at frequencies above 1 Hz (see ISO 10328-3), subject to agreement between the test laboratory/facility and the manufacturer/submitter, compliant parts may be replaced by rigid parts if deterioration of the compliant parts adversely affects the test (but see 7.1.8 of ISO 10328-3:1996). All such replacements shall be recorded in the test report (see ISO 10328-8).

6.5 The test sample including any end fittings shall be assembled in accordance with clause 8 and the test submission document (see ISO 10328-7).

7 Alignment of test samples

In order to align the test sample within the appropriate coordinate system (see ISO 10328-1) it is necessary to identify:

a) the effective ankle joint centreline (see 7.1);

b) the effective ankle-joint centre (see 7.2);

c) the effective knee-joint centreline (see 7.3);

d) the effective knee-joint centre (see 7.4).

If the identification of any effective centreline or effective joint centre is not straightforward, the manufacturer/submitter shall provide a diagram or instructions, with justification, identifying its location in relation to the test sample.

7.1 Effective ankle-joint centreline

The effective ankle-joint centreline is the horizontal line passing through the effective ankle-joint centre transverse to the centreline of the foot (see 7.2).

7.2 Effective ankle-joint centre

The effective ankle-joint centre shall be identified as described in 7.2.1 to 7.2.3.

7.2.1 Identify the centreline of the foot as follows.

a) Use the manufacturer's/submitter's alignment instructions.

b) If such instructions do not exist, then the centreline of the foot shall be taken as passing through the centre of the widest part of the forefoot and equidistant between the medial and lateral borders of the foot at a quarter of the length of the foot from the most posterior part of the foot (see figure 2).

7.2.2 Place the foot on a horizontal surface with a block of the manufacturer's/submitter's recommended heel height h_r placed under the heel of the foot (see figure 2).

7.2.3 The effective ankle-joint centre lies:

a) in a vertical plane passing through the centreline of the foot, and

b) 60 mm above the top of the heel block (this is the ankle reference plane), and

c) a quarter of the length of the foot from the most posterior part of the foot.

7.3 Effective knee-joint centreline

7.3.1 For a monocentric knee unit which can be used without a knee lock or stance phase control mechanism, the effective knee-joint centreline shall coincide with the joint flexion axis [see figure 3 a), b) and c)].

7.3.2 For all knee units not covered by 7.3.1, the effective knee-joint centreline shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit [see figure 3 d) and e)].

7.4 Effective knee-joint centre

The effective knee-joint centre shall lie on the effective knee-joint centreline.

7.4.1 For symmetrical knee units, the effective knee-joint centre shall be the point on the effective knee-joint centreline equidistant from the external boundaries of the unit.

7.4.2 For asymmetrical or handed knee units, the position of the effective knee-joint centre shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit.

7.5 Worst-case alignment position

All tests shall be conducted in the worst-case alignment position, as defined by the following criteria.

7.5.1 The structurally worst alignment position shall, if possible, be defined by the manufacturer/submitter in the test submission document (see ISO 10328-7). It shall lie within the limitations of the manufacturer's written instruction for the alignment of the limb, as supplied with every component of that type.

7.5.2 Where the structurally worst position cannot be defined as in 7.5.1, then the sample shall be adjusted so that it is moved 90 % of the distance from neutral alignment to extreme alignment. The adjustment shall be directed away from the load line so as to increase the effective lever arm (see 3.3 of ISO 10328-3:1996).

8 Responsibilities for test preparation

8.1 The manufacturer/submitter shall be responsible for the selection and assembly of the components to be tested, and for the provision of replacement parts during test (see 6.2.8, 7.1.6, 7.2.2 and 7.2.12 of ISO 10328-3:1996).

8.2 The manufacturer/submitter shall be responsible for preparing the test submission documentation in accordance with ISO 10328-7.

8.3 The test laboratory/facility shall apply to each test sample an indelible, unique and traceable identification.

8.4 The load application levers (see 4.3.1 of ISO 10328-3:1996) shall be attached by either the manufacturer/submitter or the test laboratory/facility. Whoever assembles them shall be responsible for aligning them statically in accordance with the dimensions of the test sample and the offsets, as specified in ISO 10328-4 or ISO 10328-6, as appropriate, and the test submission document (see ISO 10328-7).

8.5 The test laboratory/facility shall be responsible for adjustment of the alignment to give the correct offsets and effective lever arms during test, as specified in ISO 10328-4 or ISO 10328-6, as appropriate, or as specified in the test submission document (ISO 10328-7).