INTERNATIONAL STANDARD

ISO 10328-7

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Prosthetics — Structural testing of lower-limb prostheses —

Part 7:
Test submission document

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

Partie 7: Document de soumission à l'essai

Reference number
ISO 10328-7:1996(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 10328-7 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 7:
Test submission document

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 information that must be provided on the test submission document which accompanies each item submitted for testing in accordance with ISO 10328-3 and ISO 10328-4, and ISO 10328-5 and ISO 10328-6.

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 10328-2:1996, *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 10328-5:1996, *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.*

3 Definitions

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

4 General requirements

4.1 The manufacturer/submitter shall prepare the test submission document with any associated information and shall provide at least one copy with every item submitted for test.

4.2 The document shall be produced on A4-sized paper with the preferred format shown in annex A. If an alternative format is used it shall provide all information listed in annex A.

4.3 The manufacturer/submitter shall clearly indicate a name and address for communication purposes. If appropriate, the identity of the original equipment manufacturer shall be provided.

4.4 A unique and traceable identification for the test submission document shall be provided by the manufacturer/submitter who shall maintain a record of such identification which shall also be indelibly marked on the test sample.

4.5 The test laboratory/facility required to conduct the test shall be clearly indicated.

4.6 The date of submission or dispatch to the test laboratory/facility shall be clearly indicated.

5 Information required for test samples

5.1 All test samples

The following information, attributable to a fully traceable identification for each test sample, shall be included in the test submission document:

a) manufacturer's name or other means of identification;

b) manufacturer's model identification name and/or number;

c) type of sample in accordance with ISO 10328-2:1996, subclause 4.1, 4.2 or 4.3;

d) any certification from the manufacturer which states that the test sample has been taken from normal production and which gives details of the method of selection;

e) any special assembly instructions for the test sample and/or attachments in accordance with ISO 10328-2:1996, subclause 6.5;

f) if not straightforward, identification of effective centrelines in accordance with ISO 10328-2:1996, clause 7;

g) identification of the worst-case alignment position in accordance with ISO 10328-2:1996, subclause 7.5.1;

h) tightening torque settings for connecting bolts;

i) record of the supply of any replacement parts provided in accordance with ISO 10328-2:1996, subclause 8.1;

j) record of any load application levers and their static alignment in accordance with ISO 10328-2:1996, subclause 8.4.

5.2 Test samples for static failure tests

The manufacturer/submitter shall include in the test submission document a record of any agreement to substitute flexible parts by rigid parts in accordance with ISO 10328-2:1996, subclause 6.3, as well as ISO 10328-3:1996, subclause 6.2.8 or ISO 10328-5:1996, subclause 7.4.8.

5.3 Test samples for cyclic tests

The manufacturer/submitter shall include in the test submission document a record of any agreement to substitute flexible parts with rigid parts in accordance with ISO 10328-2:1996, subclause 6.4, as well as ISO 10328-3:1996, subclause 7.2.2 or ISO 10328-5:1996, subclause 7.5.1.2.

5.4 Test samples of ankle-foot devices

The manufacturer/submitter shall include in the test submission document a record of any agreement on the identification of the centreline in accordance with ISO 10328-2:1996, subclause 7.2.1.

6 Information required for tests

The following information for each test sample shall be included in the test submission document.

6.1 For all tests

a) The particular test requested, with reference to the relevant clauses of ISO 10328-3 and/or ISO 10328-5;

b) the particular dimensions and forces to be applied during the test in accordance with the relevant clauses of ISO 10328-4 and/or ISO 10328-6;

c) the worst-case prosthetic assembly in accordance with ISO 10328-3:1996, subclause 4.6.3.

6.2 For static failure tests

If appropriate, request for continuation of the test until failure actually occurs in accordance with the note following subclause 6.2.7 of ISO 10328-3:1996 and/or ISO 10328-5:1996, subclause 5.4.2.4 and/or 5.4.2.7 and/or 7.4.8. This request shall include instructions concerning the documentation of test results.

6.3 For cyclic tests

a) The test frequency called for in accordance with ISO 10328-3:1996, subclause 7.2.9 and/or ISO 10328-5:1996, subclause 5.4.3.3 and/or 7.5.1.9;

b) replacement intervals of service items in accordance with ISO 10328-3:1996, subclause 7.2.12;

c) if appropriate, request for visual examination with specification of magnification in accordance with ISO 10328-3:1996, subclause 7.1.5 and/or ISO 10328-5:1996, subclause 5.4.3.6 and/or 7.5.1.13. This request shall include instructions concerning the documentation of test results.

6.4 For tests in torsion

Identification of the midpositions of all adjustable components in accordance with ISO 10328-5:1996, subclause 4.3.2.

6.5 For tests on knee flexion stops

a) Record of associated parts that provide the flexion stop on a complete prosthesis in accordance with ISO 10328-5:1996, subclause 6.2.2;

b) identification of the worst-case test sample in accordance with ISO 10328-5:1996, subclause 6.2.3;

c) identification of the worst-case alignment adjustment in accordance with ISO 10328-5:1996, subclause 6.2.5.

Annex A
(informative)

Typical test submission document

ISO 10328-7, Prosthetics — Structural testing of lower-limb prostheses **Test submission document**	
Submitted by:	(See 4.3 in ISO 10328-7)
Document identification:	(See 4.4 in ISO 10328-7)
Submitted to:	(See 4.5 in ISO 10328-7)
Date of submission:	(See 4.6 in ISO 10328-7)
Test sample:	(See clause 5 in ISO 10328-7)
Sample identification:	(See 5.1 in ISO 10328-7)
Test requested:	(See clause 6 in ISO 10328-7)