

INTERNATIONAL
STANDARD

ISO
10328-8

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**Prosthetics — Structural testing of
lower-limb prostheses —**

Part 8:
Test report
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[ISO 10328-8:1996](https://standards.iteh.ai/en/standards/iso-10328-8-1996)

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

Partie 8: Rapport d'essai

INTERNATIONAL

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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 10328-8 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 8: Test report

1 Scope

ISO 10328 specifies procedures for static and cyclic strength tests for 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 shall be provided in the test report which is prepared for each test conducted in accordance with ISO 10328-3 and ISO 10328-4 and/or 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.*

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

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 test laboratory/facility shall prepare a test report for each test conducted and shall provide at least one copy to the submitter of the test sample.

4.2 The document shall be produced on A4-sized paper with the preferred format shown by sample documents in Annex A. If an alternative format is used all the required information shall be provided. The test report shall include all the information specified in 4.3 to 4.8.

4.3 The test laboratory/facility shall clearly indicate a name and address for communication purposes.

4.4 The test laboratory/facility shall provide a unique and traceable identification for the test report (such as serial number) including identification of each page, and information of total number of pages of the report. The test laboratory/facility shall maintain a record of such identification.

4.5 The submitter of the test sample and the test laboratory/facility identification shall be clearly indicated.

4.6 The test report shall be signed on behalf of the test laboratory/facility by a designated person.

4.7 The date of receipt of test samples and date(s) of preparation of the test report shall be clearly indicated.

4.8 Any records called for in the relevant clauses of ISO 10328-3 and/or ISO 10328-5 shall be copied into the test report.

5 Records required for test samples

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

5.1 For all test samples

- a) A fully traceable identification for each sample tested. If the sample has no permanent identification mark, the test laboratory/facility shall affix one after the test/test(s) has/have been completed;
- b) the type of sample in accordance with ISO 10328-2:1996, subclauses 4.1, 4.2 or 4.3. In special cases refer to the test submission document (see ISO 10328-7);
- c) the most adverse prosthetic assembly possible in accordance with ISO 10328-3:1996, subclause 4.6.3 specified in the test submission document [depending on type of test sample — see b)];
- d) the load application levers used in accordance with ISO 10328-2:1996, subclause 8.4;
- e) the alignment in accordance with ISO 10328-2:1996, clause 7 and subclause 8.5.

5.2 For static failure and cyclic test samples

Any substitution of flexible parts with rigid parts in accordance with ISO 10328-2:1996, subclauses 6.3 and 6.4 as well as ISO 10328-3:1996, subclause 6.2.8 and/or 7.2.2 and/or ISO 10328-5:1996, subclause 7.4.8 and/or 7.5.1.2.

6 Records required for all tests

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

- a) The particular tests carried out in accordance with the relevant clauses of ISO 10328-3 and/or ISO 10328-5. In special cases reference to the test submission document will be necessary;
- b) the particular dimensions and forces applied during the tests in accordance with the relevant clauses of ISO 10328-4 and/or ISO 10328-6. In special cases reference to the test submission document will be necessary;
- c) proof test of attachments (if required) in accordance with ISO 10328-3:1996, subclause 5.4;
- d) accuracy of test equipment and individual measurements in accordance with ISO 10328-3:1996, clause 9.

7 Records required for results of principal structural tests

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

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7.1 For results of all static proof tests

- a) Measurements of lengths and calculation of deformation in accordance with ISO 10328-3:1996, subclauses 5.4.2.4 through 5.4.2.7, 6.1.5, 6.1.8 and 6.1.9;
- b) examination/inspection of function in accordance with ISO 10328-3:1996, subclause 6.1.11;
- c) load at, and nature of, any failure in accordance with ISO 10328-3:1996, subclause 6.1.12.

7.2 For results of all static failure tests

- a) Measurement of effective lever arms in accordance with ISO 10328-3:1996, subclause 6.2.5;
- b) the ultimate test force F_{Su} in accordance with ISO 10328-3:1996, subclauses 6.2.6 and 6.2.7;
- c) at the request of the manufacturer/submitter, results of the continuation of test until failure actually occurs in accordance with the note following ISO 10328-3:1996, subclause 6.2.7 and with ISO 10328-7:1996, subclause 6.2;
- d) the mode of failure in accordance with ISO 10328-3:1996, subclauses 3.1, 3.2 and 6.2.9.

7.3 For results of all cyclic tests

- a) All switch-off occurrences in accordance with ISO 10328-3:1996, subclause 7.2.11;
- b) replacement of normal service parts in accordance with ISO 10328-3:1996, subclause 7.2.2;
- c) measurements of lengths in accordance with ISO 10328-3:1996, subclauses 7.2.6, 7.2.7 and 7.2.10;
- d) the endurance in accordance with ISO 10328-3:1996, subclause 7.2.13;
- e) at the request of the manufacturer/submitter, the presence and nature of any cracks in accordance with ISO 10328-3:1996, subclause 7.1.5 and ISO 10328-7:1996, subclause 6.3;
- f) results of the final static test to proof load level in accordance with ISO 10328-3:1996, subclause 7.1.5;
- g) failures of components adjacent to rigid substitutes of flexible parts in accordance with ISO 10328-3:1996, subclause 7.1.6;
- h) nature of any failure in accordance with ISO 10328-3:1996, subclause 7.2.14.

8 Records required for results of supplementary structural tests

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

8.1 Results of all tests in torsion

Records in accordance with ISO 10328-5:1996, subclause 4.3.11.

8.2 Results of tests on ankle-foot devices

- a) For results of all tests on ankle-foot devices, records limited to feet and their connections in accordance with ISO 10328-5:1996, subclause 5.1.
- b) For results of static proof tests on ankle-foot devices, results in accordance with ISO 10328-5:1996, subclause 5.4.1.10.
- c) For results of static failure tests on ankle-foot devices, results in accordance with ISO 10328-5:1996, subclauses 5.4.2.3, 5.4.2.4, 5.4.2.6, 5.4.2.7 and 5.4.2.9.
- d) For results of cyclic tests on ankle-foot devices, results in accordance with ISO 10328-5:1996, subclauses 5.4.3.6, 5.4.3.7, 5.4.3.8 and 5.4.3.9.

8.3 Results of all tests on knee flexion stops

The load at and the mode of failure in accordance with ISO 10328-5:1996, subclause 6.3.4.

8.4 Results of tests on knee locks

- a) For results of static proof tests on knee locks
 - 1) Measurements of lengths and calculations of deformation in accordance with ISO 10328-5:1996, subclauses 7.3.5, 7.3.8 and 7.3.9.
 - 2) Results in accordance with ISO 10328-5:1996, subclauses 7.3.10 and 7.3.12.
- b) For results of static failure tests on knee locks
 - 1) The ultimate test force F_{SU} in accordance with ISO 10328-5:1996, subclause 7.4.7.
 - 2) At the request of the manufacturer/submitter, results of the continuation of test until failure actually occurs in accordance with the note following subclause 7.4.8 of ISO 10328-5:1996 and with ISO 10328-7:1996, subclause 6.2.
 - 3) The mode of failure in accordance with ISO 10328-5:1996, subclause 7.4.10.
- c) For results of cyclic tests on knee locks
 - 1) Measurements of lengths in accordance with ISO 10328-5:1996, subclauses 7.5.1.7 and 7.5.1.11.
 - 2) The endurance in accordance with ISO 10328-5:1996, subclause 7.5.1.12.
 - 3) At the request of the manufacturer/submitter, the presence and nature of any cracks in accordance with ISO 10328-5:1996, subclause 7.5.1.13 and ISO 10328-7:1996, subclause 6.3.
 - 4) Failures of components adjacent to rigid substitutes of flexible parts in accordance with ISO 10328-5:1996, subclause 7.5.1.15.
 - 5) The nature of any failure in accordance with ISO 10328-5:1996, subclause 7.5.1.16.

Annex A (informative)

Sample data sheets for test report

The following sample data sheets show the preferred format of the test report. Their layout allows the provision of all information concerning general requirements, as well as records required for test samples, tests and test results, as specified in clauses 4 to 8 of this part of ISO 10328.

All references to other parts of ISO 10328 refer to editions published in 1996.

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**ISO 10328-8, Prosthetics — Structural testing of lower-limb prostheses
Test report — Proof test of attachments**

Document identification:

(See 4.4)

Table A.1

Prepared by: (See 4.3)

Test laboratory/facility:

Tel. No.:

Address:

Fax No.:

Test load level: (See 4.4.2 of ISO 10328-3): **A** ____

Proof test attachments: (See 5.4 of ISO 10328-3)

Test results: (See clause 6 and 7.1)

Dimensions in millimetres

Length of load application levers	Specification according to 5.4.2.2 of ISO 10328-3	Individual lever length
Bottom load application lever	120	
Top load application lever	120	

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<https://standards.itech.ai/catalog/standards/sic/05b30e2f-1e86-455d-b505-c0b5ac8b8443/iso-10328-8-1996>

Dimensions in millimetres

Lengths and deformations	Measured value	Specified limit	Reference in clause of ISO 10328-3
L_1			5.4.2.4
L_2			5.4.2.5
L_3			5.4.2.6
D_1		2	5.4.2.7, 5.4.3
D_2		0,5	5.4.2.7, 5.4.3

Date:	Year:	Month:	Day:
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Remarks:

Signature: (See 4.6)

Date of report: (See 4.7)

ISO 10328-3 and ISO 10328-8 provide relevant information concerning this page.

ISO 10328-8, Prosthetics — Structural testing of lower-limb prostheses

Test report — Principal structural tests — Static proof test

Document identification:

(See 4.4)

Table A.2-1

Prepared by: (See 4.3)

Test laboratory/facility:

Tel. No.:

Address:

Fax No.:

Identification of test submission document and date of submission/dispatch:

Test sample(s) submitted by: (See 4.5)

Submitter:

Tel. No.:

Address:

Fax No.:

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[c0b5a8b8413/iso-10328-8-1996](https://standards.iteh.ai/catalog/standards/sist/95b39e2f-1e86-455d-b505-c0b5a8b8413/iso-10328-8-1996)

Test load level: (See 4.4.2 of ISO 10328-3):

A _____

Test sample: (See clause 5)

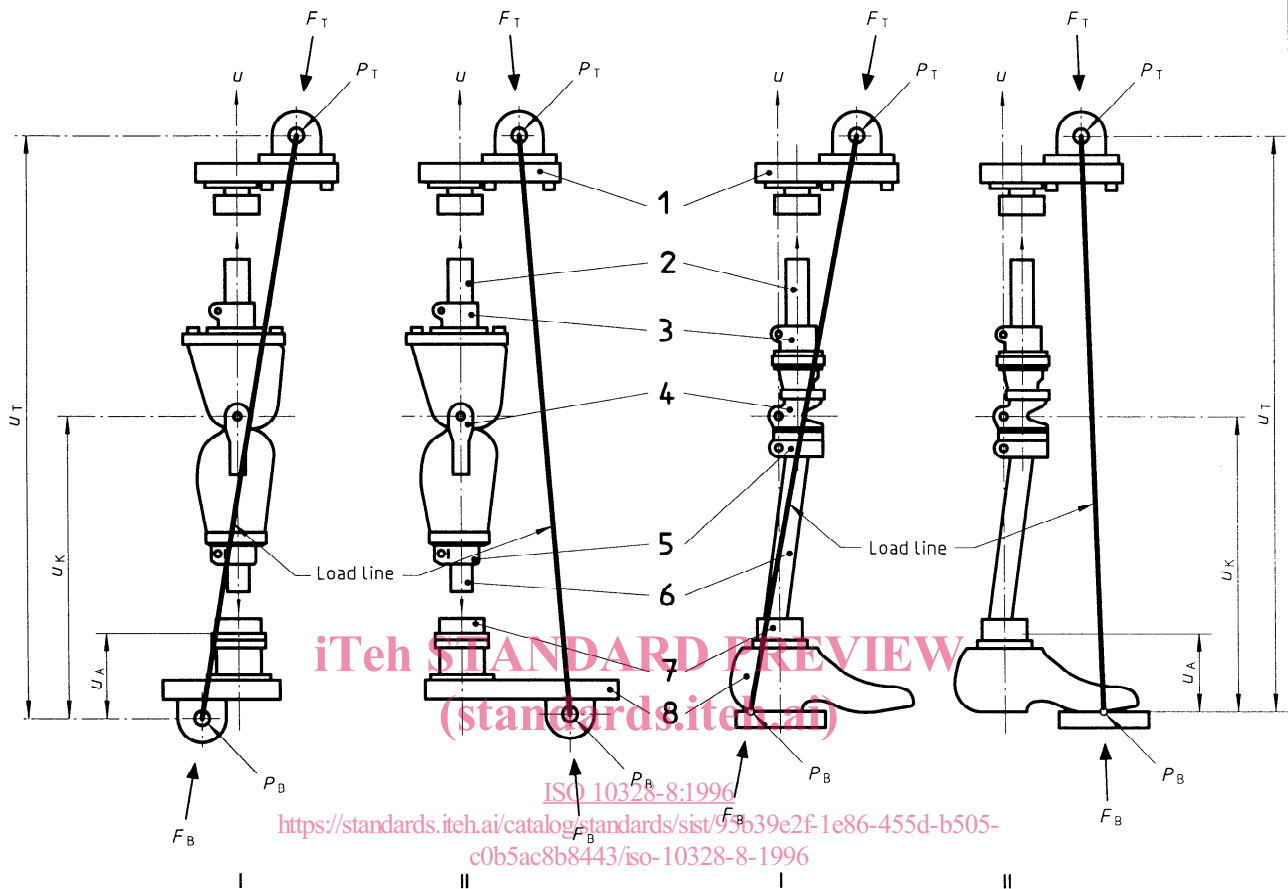
ISO 10328-8, Prosthetics — Structural testing of lower-limb prostheses

Test report — Principal structural tests — Static proof test

Document identification:

(See 4.4)

Table A.2-2



Parts used

- 1 Top load application lever:
- 2 Extension piece:
- 3 Connection piece/adaptor:
- 4 Knee unit:
- 5 Connection piece/adaptor:
- 6 Extension piece:
- 7 Adaptor/ankle unit:
- 8 Bottom load application lever:
[or foot (see note 2)]

Identification/Type of test sample (See clause 4 of ISO 10328-2)

Figure A.1 — Test assembly

NOTES

- 1 All pieces listed in figure A.1 may be part of the sample under test except the load application levers.
- 2 Where a foot or a structure including a foot is part of the sample under test or used instead of the bottom load application lever, see 5.2 of ISO 10328-2 for:

Selected foot size:

Actual combined bottom offset:

Remarks:

ISO 10328-2 and ISO 10328-8 provide relevant information concerning this page.

**ISO 10328-8, Prosthetics — Structural testing of lower-limb prostheses
Test report — Principal structural tests — Static proof test**

Document identification:

(See 4.4)

Table A.2-3

Test results: (See clause 6 and 7.1)

Forces in newtons

Test loading condition	Actual settling test force, F_{set}		Specification according to table 2 of ISO 10328-4 and		Actual proof test force, F_{sp}		Specification according to table 6 of ISO 10328-4 and	
	Sample 1	Sample 2	F_{set}	ISO 10328-3 subclause:	Sample 1	Sample 2	F_{sp}	ISO 10328-3 subclause:
I				6.1.3*)				6.1.6*)
II				6.1.3*)				6.1.6*)

*) When testing a foot or a structure including a foot, see 5.2 of ISO 10328-2.

Dimensions in millimetres

Lengths and deformation	Sample 1		Sample 2		Reference in ISO 10328-3
	Test loading condition		Test loading condition		
	I	II	I	II	
L_A					6.1.5
L_K					6.1.5
L_4					6.1.5
L_A					6.1.8
L_K					6.1.8
L_5					6.1.8
D_3 *)					6.1.9

*) Limit: $D_3 \leq 15$ mm according to 6.1.10 of ISO 10328-3.

Remarks: