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STANDARD

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JIS T 0111-8 : 1997

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(Reaffirmed : 2003)

**Prosthetics – Structural testing
of lower-limb prostheses –
Part 8 : Test report**

ICS 11. 040. 40

Descriptors : artificial limbs, artificial organs, legs, mechanical testing, strength of
materials, medical equipment, samples

Reference number : JIS T 0111-8 : 1997 (E)

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry, through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

JIS T 0111 consists of the following 8 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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4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

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M&T

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Prosthetics—Structural testing of lower-limb prostheses

—Part 8 : Test report

Introduction This Japanese Industrial Standard has been prepared based on the first edition of ISO 10328-8 *Prosthetics—Structural testing of lower-limb prostheses—Part 8 : Test report* published in 1996 without modifying the technical contents.

1 Scope

JIS T 0111 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 **JIS T 0111** apply to trans-tibial (below-knee), knee-disarticulation and trans-femoral (above-knee) prostheses.

Remarks : The tests may be performed on complete structures, on partial structures, or on individual components.

This Part 8* of **JIS T 0111** specifies the information that shall be provided in the test report which is prepared for each test conducted in accordance with Parts 3 through 6.

Note * Parts 1, 2, 3, 4, 5, 6, 7 and 8 of **JIS T 0111** are designated as **JIS T 0111-1**, **JIS T 0111-2**, **JIS T 0111-3**, **JIS T 0111-4**, **JIS T 0111-5**, **JIS T 0111-6**, **JIS T 0111-7** and **JIS T 0111-8**, respectively.

2 Normative references The normative references of this part of **JIS T 0111** are shown below:

JIS T 0101:1997 *Glossary of terms used in prosthetics and orthotics*

Remarks : **ISO 8549-1 : 1989** *Prosthetics and orthotic—Vocabulary—Part 1 : General terms for external limb prostheses and external orthoses* is equivalent to the said standard.

JIS T 0111-2 : 1977 *Prosthetics—Structural testing of lower-limb prostheses—Part 2 : Test samples*

Remarks : **ISO 10328-2 : 1996** *Prosthetics—Structural testing of lower-limb prostheses—Part 2 : Test samples* is equivalent to the said standard.

JIS T 0111-3 : 1997 *Prosthetics—Structural testing of lower-limb prostheses—Part 3 : Principal structural tests*

Remarks : ISO 10328-3 : 1996 *Prosthetics—Structural testing of lower-limb prostheses—Part 3 : Principal structural tests* is equivalent to the said standard.

JIS T 0111-4 : 1997 *Prosthetics—Structural testing of lower-limb prostheses—Part 4 : Loading parameters of principal structural tests*

Remarks : ISO 10328-4 : 1996 *Prosthetics—Structural testing of lower-limb prostheses—Part 4 : Loading parameters of principal structural tests* is equivalent to the said standard.

JIS T 0111-5 : 1997 *Prosthetics—Structural testing of lower-limb prostheses—Part 5 : Supplementary structural tests*

Remarks : ISO 10328-5 : 1996 *Prosthetics—Structural testing of lower-limb prostheses—Part 5 : Supplementary structural tests* is equivalent to the said standard.

JIS T 0111-6 : 1997 *Prosthetics—Structural testing of lower-limb prostheses—Part 6 : Loading parameters of supplementary structural tests*

Remarks : ISO 10328-6 : 1996 *Prosthetics—Structural testing of lower-limb prostheses—Part 6 : Loading parameters of supplementary structural tests* is equivalent to the said standard.

JIS T 0111-7 : 1977 *Prosthetics—Structural testing of lower-limb prostheses—Part 7 : Test submission document*

Remarks : ISO 10328-7 : 1996 *Prosthetics—Structural testing of lower-limb prostheses—Part 7 : Test submission document* is equivalent to the said standard.

3 Definition of terms For the purposes of this part of JIS T 0111, the definition given in JIS T 0101 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 test report 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 JIS T 0111-3 and/or JIS T 0111-5 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/tests has/have been completed;
- b) the type of sample in accordance with, 4.1, 4.2 or 4.3 of JIS T 0111-2. In special cases refer to the test submission document (see JIS T 0111-7);
- c) the most adverse prosthetic assembly possible in accordance with 4.6.3 of JIS T 0111-3 specified in the test submission document [depending on type of test sample —see b)];
- d) the load application levers used in accordance with 8.4 of JIS T 0111-2;
- e) the alignment in accordance with clause 7 and 8.5 of JIS T 0111-2.

5.2 For static failure and cyclic test samples Any substitution of flexible parts with rigid parts in accordance with 6.3 and 6.4 of JIS T 0111-2 as well as 6.2.8 and/or 7.2.2 of JIS T 0111-3, 7.4.8 and/or 7.5.1.2 of JIS T 0111-5.

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 JIS T 0111-3 and/or JIS T 0111-5. 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 JIS T 0111-4 and/or JIS T 0111-6. In special cases reference to the test submission document will be necessary;
- c) proof test of attachments (if required) in accordance with 5.4 of JIS T 0111-3;
- d) accuracy of test equipment and individual measurements in accordance with clause 9 of JIS T 0111-3.

7 Records required for results of principal structural tests The following information for each test sample shall be included in the test report.

7.1 For results of all static proof tests

- a) Measurements of lengths and calculation of deformation in accordance with 5.4.2.4 through 5.4.2.7, 6.1.5, 6.1.8, and 6.1.9 of JIS T 0111-3;
- b) examination/inspection of function in accordance with 6.1.11 of JIS T 0111-3;
- c) load at, and nature of, any failure in accordance with 6.1.12 of JIS T 0111-3.

7.2 For results of all static failure tests

- a) Measurement of effective lever arms in accordance with 6.2.5 of JIS T 0111-3;
- b) the ultimate test force F_{su} in accordance with 6.2.6 and 6.2.7 of JIS T 0111-3;
- c) at the request of the manufacturer/submitter, results of the continuation of test until failure actually occurs in accordance with the note following 6.2.7 of JIS T 0111-3 and with 6.2 of JIS T 0111-7;
- d) the mode of failure in accordance with 3.1, 3.2 and 6.2.9 of JIS T 0111-3.

7.3 For results of all cyclic tests

- a) All switch-off occurrences in accordance with 7.2.11 of JIS T 0111-3;
- b) replacement of normal service parts in accordance with 7.2.2 of JIS T 0111-3;
- c) measurements of lengths in accordance with 7.2.6, 7.2.7, and 7.2.10 of JIS T 0111-3;
- d) the endurance in accordance with 7.2.13 of JIS T 0111-3;
- e) at the request of the manufacturer/submitter, the presence and nature of any cracks in accordance with 7.1.5 of JIS T 0111-3 and 6.3 of JIS T 0111-7;
- f) results of the final static test to proof load level in accordance with 7.1.5 of JIS T 0111-3;
- g) failures of components adjacent to rigid substitutes of flexible parts in accordance with 7.1.6 of JIS T 0111-3;
- h) inspection results of nature of any failure in accordance with 7.2.14 of JIS T 0111-3.

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

For all torsion tests, records in accordance with 4.3.11 of JIS T 0111-5.

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 5.1 of JIS T 0111-5.
- b) For results of static proof tests on ankle-foot devices, results in accordance with 5.4.1.10 of JIS T 0111-5.
- c) For results of static failure tests on ankle-foot devices, results in accordance with 5.4.2.3, 5.4.2.4, 5.4.2.6, 5.4.2.7, and 5.4.2.9 of JIS T 0111-5.
- d) For results of cyclic tests on ankle-foot devices, results in accordance with 5.4.3.6, 5.4.3.7, 5.4.3.8, and 5.4.3.9 of JIS T 0111-5.

8.3 Results of all tests on knee flexion stops

For all results of tests of knee flexion stops, the load at and the mode of failure in accordance with 6.3.4 of JIS T 0111-5.

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 7.3.5, 7.3.8, and 7.3.9 of JIS T 0111-5.
 - 2) Results in accordance with 7.3.10 and 7.3.12 of JIS T 0111-5.
- b) For results of static failure tests on knee locks
 - 1) The ultimate test force F_{su} in accordance with 7.4.7 of JIS T 0111-5.
 - 2) At the request of the manufacturer/submitter, results of the continuation of test until failure actually occurs in accordance with the note following 7.4.8 of JIS T 0111-5, and with 6.2 of JIS T 0111-7.
 - 3) The mode of failure in accordance with 7.4.10 of JIS T 0111-5.
- c) For results of cyclic tests on knee locks
 - 1) Measurements of lengths in accordance with 7.5.1.7 and 7.5.1.11 of JIS T 0111-5.
 - 2) The endurance in accordance with 7.5.1.12 of JIS T 0111-5.
 - 3) At the request of the manufacturer/submitter, the presence and nature of any cracks in accordance with 7.5.1.13 of JIS T 0111-5 and 6.3 of JIS T 0111-7.
 - 4) Failures of components adjacent to rigid substitutes of flexible parts in accordance with 7.5.1.15 of JIS T 0111-5.
 - 5) The nature of any failure in accordance with 7.5.1.16 of JIS T 0111-5.

Annex A (informative)

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 JIS T 0111-8.

JIS T 0111-8 *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 Part 3) : A _____**Proof test for attachments :** (see 5.4 of Part 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 Part 3	Individual lever length
Bottom load application lever	120	
Top load application lever	120	

Dimensions in millimetres

Lengths and deformations	Measured value	Specified limit	Reference in clauses of Part 3
L_1		X	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 :

Remarks :

Signature : (see 4.6)

Date of report : (see 4.7)

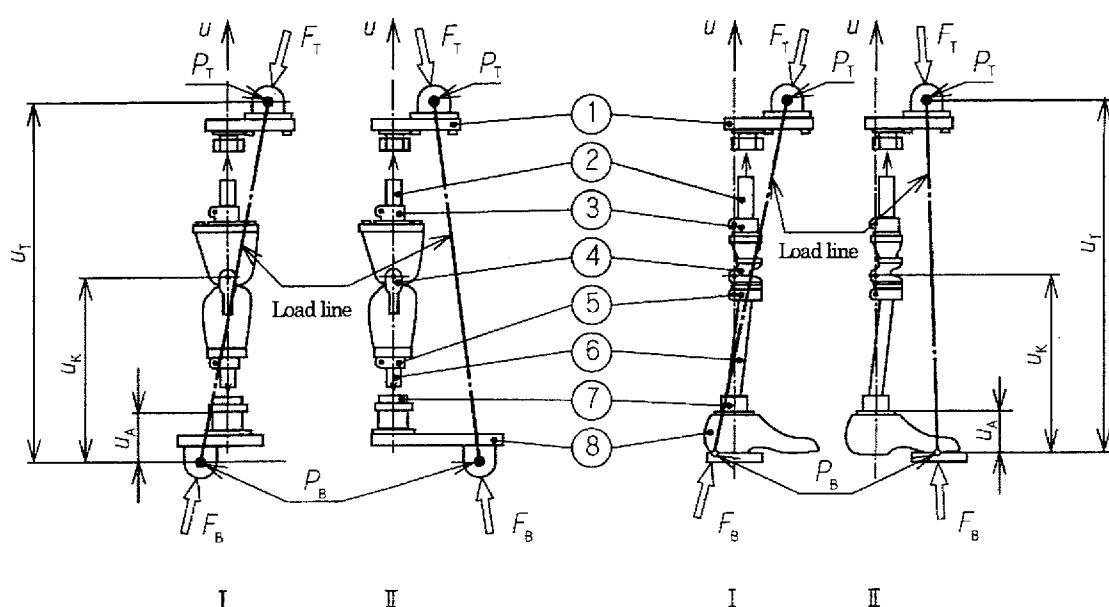
See Part 3 and Part 8.

JIS T 0111-8 <i>Prosthetics —Structural testing of lower-limb prostheses</i> <i>Test report —Principal structural tests —Static proof test</i>		
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. :
 Test load level : (see 4.4.2 of Part 3) : A_____		
 Test sample : (see clause 5)		
See Part 3 and Part 8.		

JIS T 0111-8 *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 : Identification/Type of test sample (see clause 4 of Part 2)

- 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)]

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 Part 2 for :

Selected foot size :

Actual combined bottom offset :

Remarks :

See Part 2 and Part 8.

JIS T 0111-8 *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 Part 4 and Part 3		Actual proof test force F_{sp}		Specification according to table 6 of Part 4 and Part 3	
	Sample 1	Sample 2	F_{set}	Subclause of Part 3 :	Sample 1	Sample 2	F_{sp}	Subclause of Part 3 :
I				6.1.3 ^{*)}				6.1.6 ^{*)}
II				6.1.3 ^{*)}				6.1.6 ^{*)}

Note^{*)} When testing a foot or a structure including a foot, see 5.2 of Part 2.

Dimensions in millimetres

Dimensions in millimetres

Effective lever arm lengths and deformation	Test sample 1		Test sample 2		Reference subclause in Part 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

Note^{*)} Limited to $D_3 \leq 15$ mm according to 6.1.10 of Part 3.

Remarks :

See Part 2, Part 3, Part 4 and Part 8.

JIS T 0111-8 *Prosthetics —Structural testing of lower-limb prostheses**Test report —Principal structural tests —Static proof test*

Document identification : (see 4.4)

Table A.2-4

Forces in newtons				
Sample	Test loading conditions	Sample functions safely (see 6.1.11 of Part 3)		Load at, and nature of, failure (see 6.1.12 in Part 3)
		Yes	No	
1	I	☐	☐	
	II	☐	☐	
2	I	☐	☐	
	II	☐	☐	

Remarks :

The specimen submitted for this test satisfies the relevant requirements of load level A_____ of JIS T 0111

Yes ☐No ☐

Signature :

(see 4.6)

Date of report :

(see 4.7)

See Part 3 and Part 8.