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STANDARD

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JIS T 0111-5 : 1997

(ISO 10328-5 : 1996)

(Reaffirmed : 2003)

**Prosthetics – Structural testing
of lower-limb prostheses –
Part 5 : Supplementary structural tests**

ICS 11. 040. 40

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

Reference number : JIS T 0111-5 : 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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Prosthetics—Structural testing of lower-limb prostheses

—Part 5 : Supplementary structural tests

Introduction This Japanese Industrial Standard has been prepared based on ISO 10328-5 *Prosthetics—Structural testing of lower-limb prostheses—Part 5 : Supplementary structural test* published in 1996 as the first edition **without modifying the technical contents.**

1 Scope JIS T 0111 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 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.

Part 5* of JIS T 0111 specifies structural tests and test requirements which are additional to those specified in JIS T 0111-3 and JIS T 0111-4. Each test shall be specified in the following clauses. The tests and their required application are shown below:

Tests	Application
Test in torsion	All components
Tests on ankle-foot devices	All ankle-foot devices as single components, including ankle units or ankle attachment
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 extension position

Note* : Parts 1, 2, 3, 4, 5, 6, 7, 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 orthotics—Vocabulary—Part 1 : General terms for external limb prostheses and external orthoses* is equivalent to the said standard.

JIS T 0111-1 : 1997 *Prosthetics—Structural testing of lower-limb prostheses —
Part 1 : Test configurations*

Remarks : ISO 10328-1 : 1996 *Prosthetics—Structural testing of lower-limb prostheses —
Part 1 : Test configurations* 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 *Prosthetic—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 0111-6 : 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.

JIS T 0111-8 : 1977 *Prosthetics—Structural testing of lower-limb prostheses —
Part 8 : Test report*

Remarks : ISO 10328-8 : 1996 *Prosthetics—Structural testing of lower-limb prostheses —
Part 8 : Test report* is equivalent to the said standard.

3 Definition of terms For the purposes of this part of JIS T 0111, the definitions given in JIS T 0101 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 (included torque) generated by test loading conditions specified in JIS T 0111-3 and JIS T 0111-4. 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 clause 4 in this part of JIS T 0111 shall apply to all the components of a system, from the socket to the ankle-foot device.

4.3 Static proof test

4.3.1 Assemble the test sample in accordance with the manufacturer's/submitter'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 JIS T 0111-2) 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/ submitter'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 JIS T 0111-6, about the u -axis. Maintain the settling torsional moment for a period not exceeding 30s 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 JIS T 0111-6, 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 Nm/s to generate a maximum torsional moment of M_{umax} , specified in table 6 of JIS T 0111-6, about the u -axis. Maintain the maximum torsional moment for 30s 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 JIS T 0111 and table 6 of JIS T 0111-6 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 JIS T 0111 and table 6 of JIS T 0111-6.