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JIS T 0111-3 : 1997

(ISO 10328-3 : 1996)

(Reaffirmed : 2003)

**Prosthetics – Structural testing
of lower-limb prostheses –
Part 3 : Principal structural tests**

ICS 11. 040. 40

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

Reference number : JIS T 0111-3 : 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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Prosthetics—Structural testing of lower-limb prostheses

Part 3 : Principal structural tests

Introduction This Japanese Industrial Standard has been prepared based on the first edition of ISO 10328-3 *Prosthetics—Structural testing of lower-limb prostheses—Part 3 : Principal structural tests* published in 1996 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 3* of JIS T 0111 specifies :

- the methods to be used in carrying out the principal static tests;
- the methods to be used in carrying out the principal cyclic tests;
- the requirements for accuracy of the tests;
- the criteria to be met in order to claim compliance with this part of JIS T 0111.

Note* : Parts 1, 2, 3, 4, 5, 6, 7, 8 of JIS T 0111 are referred to 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 : 1997 *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 0111-4 : 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 : 1997 *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 : 1997 *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 Definitions of terms For the purpose of this part of JIS T 0111, the definitions given in JIS T 0101 and the following definitions apply :

3.1 brittle failure fracture of any component without significant plastic deformation at the fracture

3.2 ductile failure

- 1) fracture of any component with significant plastic deformation at the fracture
- 2) gross plastic deformation of the test sample

The effective lever arms (see 3.3) and the distance between the bottom load application point P_B and the top load application point P_T (see subclause 4.1.1) are defined as follows :

3.3 effective lever arm Perpendicular distance from the load line to the effective joint centre. L_A represents the ankle effective lever arm length and L_K the knee effective lever arm length.

3.4 distance between the bottom load application point and the top load application point L_{BT} shall be the distance between the bottom load application point P_B and top load application point P_T .

3.5 test equipment Any test machine or device adapted or specifically designed to the requirements of this part of JIS T 0111.

4 General requirements Test laboratory/facility shall carry out the tests specified in this part of JIS T 0111 and shall prepare the test submission document (see JIS T 0111-7).

4.1 Test samples

4.1.1 Total sample length For the tests, all sample types specified in JIS T 0111-2, clause 4 shall be aligned in accordance with JIS T 0111-2, clause 7 and the test submission document (see JIS T 0111-7). In this case, these test samples shall have a fixed total length L_{BT} specified in 3.4, using end attachments consisting of extension pieces and the load application levers. L_{BT} is defined as the distance between the bottom load application point P_B and the top load application point P_T . It shall be measured by aligning end attachments consisting of required extension parts and the load application levers.

This value of L_{BT} can be achieved by selecting from the different types of test samples (see JIS T 0111-2, clause 4) or test load configuration and test force specified in table 1 of 4.4 and JIS T 0111-4, otherwise, by other appropriate combinations.

For the test methods, the dimension $u_T - u_B$ is represented as u_{BT} .

4.1.2 Foot length For test samples including a foot (see clause 4 of JIS T 0111-2,) select the size of the foot in accordance with JIS T 0111-2, 5.2.

4.2 Types of test procedure Two principal structural test procedures are described, a static test and a cyclic test.

4.2.1 The static test procedure consists of a proof test and a failure test. This test procedure is carried out to determine the performance of the load-bearing structures under typical severe loading conditions that can occur during use as occasional isolated events.

The static test procedure is completed when the test sample has satisfied the proof test requirements and met the failure test requirements.

4.2.2 The cyclic test procedure consists of repeated applications of a prescribed load to a test sample with loading conditions typical of normal walking, followed by a final static test for which both the procedure and all requirements of the static proof test apply (see clause 7).

The cyclic test procedure is completed when either :

- a) the test sample has failed, or
- b) the test sample has withstood the prescribed number of cycles of load without failure and satisfied the final static test requirements.

4.3 Test loading requirements

4.3.1 Preparation for test loading The position of the test load line within the coordinate systems is three-dimensional (see figure 1 in this part of JIS T 0111 as well as relevant clauses and figures of JIS T 0111-1). The preparation for loading shall proceed as follows.

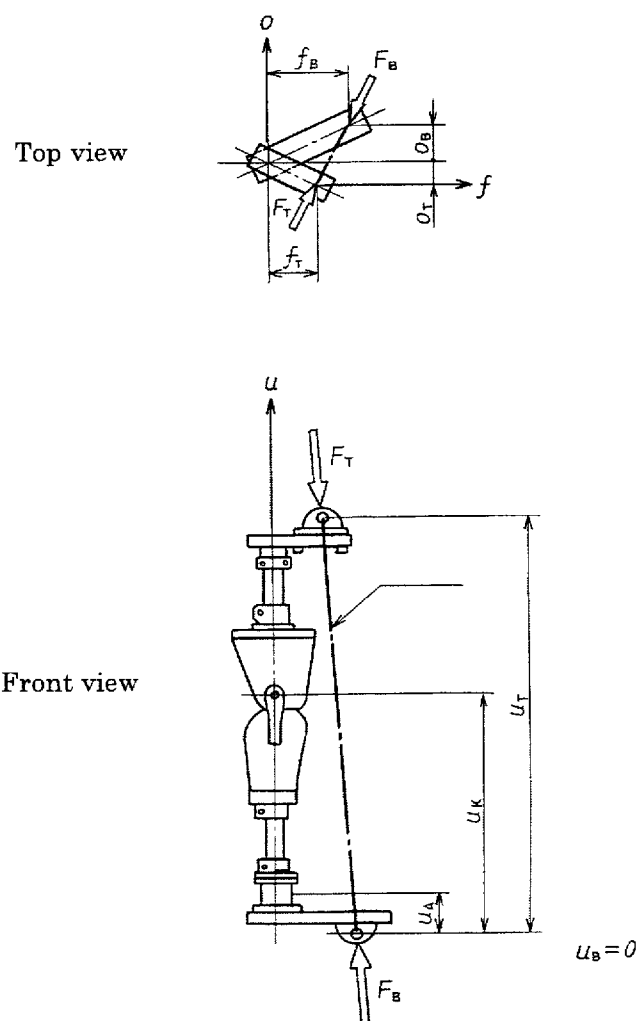
- a) The test sample shall be assembled to a fixed length, using end attachments consisting of extension pieces, as required, and the load application levers.
- b) The test sample shall be set up in the test equipment with the bottom and top load application levers having a combination of forward/backward and outward/inward offsets. Figure 2 shows the geometry for a left leg and gives the equations for the calculation of theoretical offsets.
- c) No corrections shall be made to the load application levers if the test sample deflects under the test loading conditions specified in 4.3.2.

4.3.2 Test loading conditions The loading described in 4.3.1 shall be applied in two different conditions relating to the maxima occurring at different instants during the stance phase of normal walking.

Test loading condition I is related to the instant of maximum loading occurring early in the stance phase of walking.

Test loading condition II is related to the instant of maximum loading occurring late in the stance phase of walking.

Note : For some prosthetic designs, it is not possible to set up a test sample in accordance with these requirements. Special test set-ups may then be used in certain cases.



Note : This figure illustrates a typical test loading condition that occurs in normal gait. It does not illustrate the test loading conditions I and II specified in 4.3.

Figure 1 Test loading principle applied to a knee unit with attachments aligned to simulate a left-sided test sample (Example of left-sided test samples)