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**Prostheses—Structural testing
of hip units**

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Foreword

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

This Standard has been made based on **ISO 15032 : 2000 *Prostheses—Structural testing of hip units*** for the purposes of making easy to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of International Standard which is based on Japanese Industrial Standard.

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Prostheses—Structural testing of hip units

Introduction This Japanese Industrial Standard has been prepared based on the first edition of **ISO 15032** *Prostheses—Structural testing of hip units* published in 2000 without modifying the technical contents.

1 Scope This Standard specifies test methods for components and assemblies of hip disarticulation prostheses which are arranged at hip and thigh level. It does not apply to other components of lower limb prostheses for which test methods are given in **JIS T 0111** series.

This Standard specifies procedures for simplified static and cyclic strength tests in which the antero-posterior (A-P) and medio-lateral (M-L) components of loading are produced in separate tests by the application of test forces in two different test planes. The components of loading produced 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.

NOTE : The International Standard corresponding to this Standard is as follows.

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are **IDT** (identical), **MOD** (modified), and **NEQ** (not equivalent) according to **ISO/IEC Guide 21**.

ISO 15032 : 2000 *Prostheses—Structural testing of hip units* (**IDT**)

2 Normative references The following standards contain provisions which, through reference in this Standard, constitute provisions of this Standard. If the indication of the year of coming into effect is given to these referred standards, only the edition of indicated year constitutes the provision of this Standard but the revision and amendment made thereafter are not applied.

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

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

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

3 Terms and definitions For the purposes of this Standard, 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

- a) fracture of any component with significant plastic deformation at the fracture.
- b) gross plastic deformation of the test sample.

3.3 test equipment any test machine or device adapted or specifically designed to the test requirements of this Standard and complying with the requirements on accuracy of 6.8.

4 Test configurations

4.1 General

4.1.1 For ease in interpretation, presentation and application of this Standard, two test configurations are specified, one for right-sided application and a mirror image for left-sided application. This approach enables the application of uniform sign conventions for corresponding components of loading generated in the load-bearing structures of right and left prostheses or asymmetrically designed prosthetic components.

4.1.2 Each test configuration is defined in a three-dimensional, rectangular coordinate system, containing a geometric system of planes, lines and points (see Figures 1 and 2).

4.1.3 Each test configuration specifies reference parameters both for the position of the line of application of the test force and for the alignment of test samples within the coordinate system.

4.2 Axes of coordinate system Axes of coordinate system (see Figure 1) is as follows.

4.2.1 The axes of each of the coordinate systems have an origin at ground level and are specified in 4.2.2 to 4.2.4 in relation to a prosthesis which is standing on the ground in a vertical position.

If a test sample is not in a vertical position, the axes of the coordinate system shall be rotated to correspond.

4.2.2 The u' -axis is a line extending from the origin and passing through the effective knee-joint centre (see 5.5.2.2) and the effective hip-joint centre (see 5.5.2.4). Its positive direction is upwards (in the proximal direction).

4.2.3 The o' -axis is perpendicular to the u' -axis and parallel to the effective hip-joint centreline (see 5.5.2.3). Its positive direction is outward (in the lateral direction), which is to the left for a left prosthesis and to the right for a right prosthesis.

4.2.4 The f' -axis is perpendicular to both the o' -axis and the u' -axis. Its positive direction is forward towards the toe (in the anterior direction).

4.3 Reference planes The reference planes (see Figure 1) shall be parallel planes perpendicular to the u' -axis of the coordinate system.

4.3.1 Bottom reference plane, BK The bottom reference plane, BK, is located at a distance $u' = u'_{BK}$ from the origin. It contains the bottom load application point P_{BK} .

4.3.2 Knee reference plane, K The knee reference plane, K, is located at a distance $u' = u'_K$ from the origin. It contains the effective knee-joint centre P_K (see 5.5.2.2).

4.3.3 Hip reference plane, H The hip reference plane, H, is located at a distance $u' = u'_H$ from the origin. It contains the effective hip-joint centre P_H (see 5.5.2.4).

4.3.4 Top reference plane, TH The top reference plane, TH, is located at a distance $u' = u'_{TH}$ from the origin. It contains the top load application point P_{TH} .

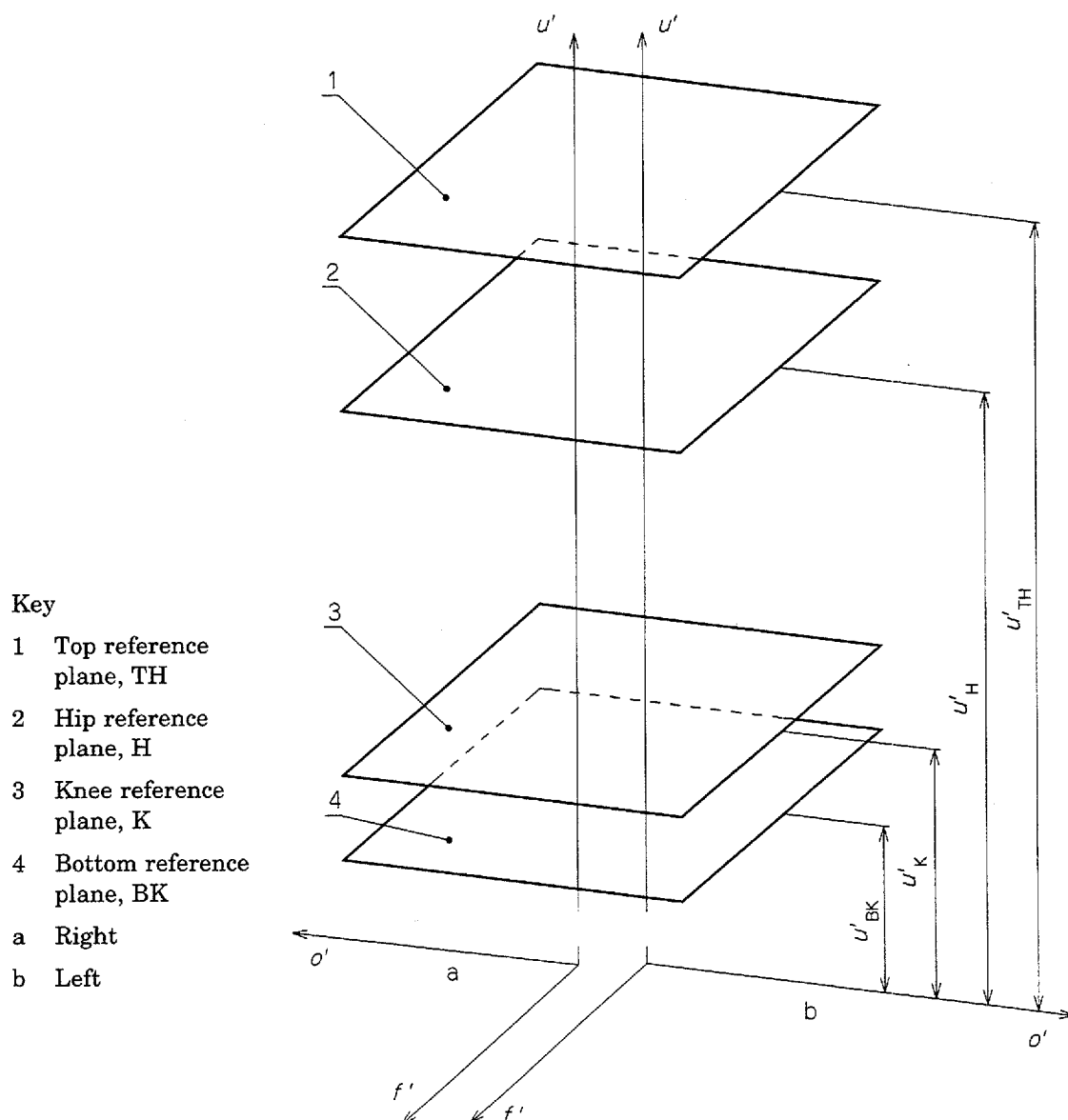


Figure 1 Coordinate system according to 4.2 with reference planes according to 4.3

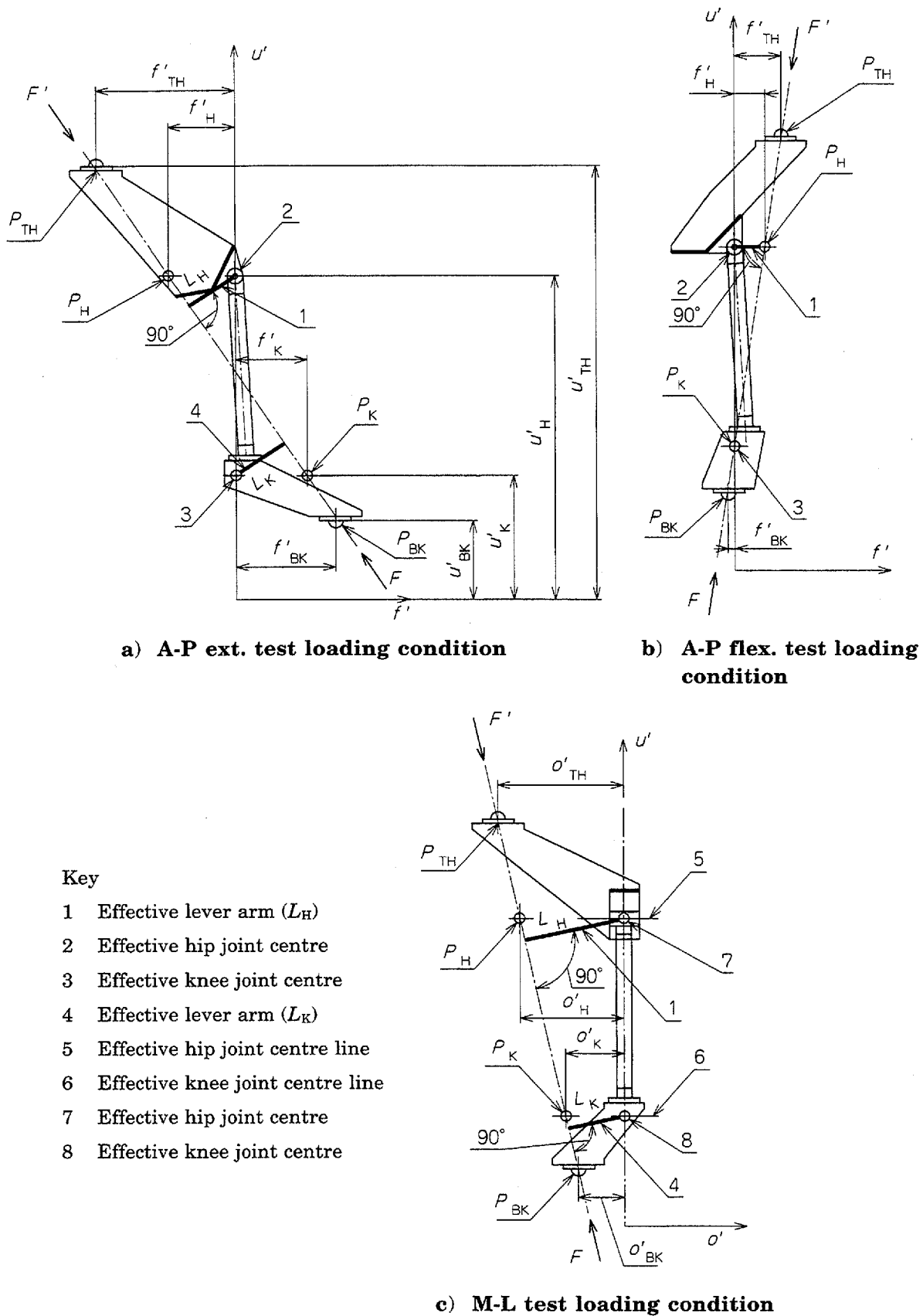


Figure 2 Test configurations for A-P and M-L tests in f' - u' - and o' - u' -plane

4.4 Reference points The reference points shall be the points of intersection of the load line (see 4.6) with the reference planes. The coordinates of the reference points are as follows:

bottom load application point P_{BK} (f'_{BK} , o'_{BK} , u'_{BK});
 knee load reference point P_K (f'_K , o'_K , u'_K);
 hip load reference point P_H (f'_H , o'_H , u'_H);
 top load application point P_{TH} (f'_{TH} , o'_{TH} , u'_{TH}).

NOTE : In the following text the f' - and o' -coordinates are also referred to as offsets (see also 4.7).

4.5 Test force The test force F shall be a single compressive load applied to the bottom and top load application points P_{BK} and P_{TH} .

4.6 Load line The load line shall be the line of application of the test force F which passes through the reference points P_K and P_H .

4.7 Reference distances

4.7.1 Offsets The offsets shall be the perpendicular distances of the reference points (see 4.3.1 and 4.4) from the o - u -plane and the u - f -plane of the coordinate systems (see 4.1 and 4.2). They are identical with the corresponding f' - or o' -coordinates, respectively, of these reference points.

4.7.2 Effective lever arms The effective lever arms shall be the perpendicular distances from the load line to the effective joint centres (see 5.5.2.2 and 5.5.2.4), where L_K represents the knee effective lever arm and L_H the hip effective lever arm.

4.7.3 Distance L_{BK-TH} L_{BK-TH} shall be the distance between the bottom load application point P_{BK} (see 4.3.1 and 4.4) and the top load application point P_{TH} (see 4.3.4 and 4.4).

5 Test samples

5.1 Types of test sample

5.1.1 Number of types There are two types of test sample, as described in 5.1.2 and 5.1.3.

5.1.2 Complete structure The complete structure shall comprise the hip unit and at least the following:

- a) thigh segment or suitable attachment;
- b) any special attachment at the knee; and/or
- c) any parts above the hip unit including the socket.

5.1.3 Hip unit The hip unit shall be attached to suitable attachments to give the same overall dimensions as the complete structure.

The interface of such attachments shall have mechanical characteristics similar to those of the intended adjacent components.

5.2 Responsibilities regarding selection, preparation and alignment of test samples

5.2.1 The manufacturer/submitter shall be responsible for the selection and assembly of the components to be tested, and for the provision of specified parts to be replaced during the cyclic tests.

5.2.2 The manufacturer/submitter shall be responsible for preparing the test submission document complete with alignment and/or service instructions, as necessary.

5.2.3 The manufacturer/submitter shall apply a unique and traceable identification to each test sample.

5.2.4 The load application levers (see **6.2.1**) shall be attached by either the manufacturer/submitter or the test laboratory/facility.

5.2.5 The test laboratory/facility shall seek the advice of the manufacturer/submitter if the specific design of hip units incorporates any special characteristics.

5.2.6 The test laboratory/facility shall be responsible for adjustment of the alignment to give the correct offsets and effective lever arms during test.

5.3 Selection of test samples If appropriate, the prosthetic structures selected for test shall be drawn from standard production. Details of the selection shall be recorded in the test submission document. If the manufacturer/submitter supplies a certificate stating that the test sample has been taken from the normal production, this certificate shall be included in the test submission document, together with details of the sampling method.

5.4 Preparation of test samples Any cosmetic components shall be omitted from the test sample, unless they contribute to the structural strength.

The test samples shall include all parts normally fitted.

NOTE : During the course of the cyclic tests, specified parts are replaced when the number of cycles has reached a value at which such replacement is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document.

The test sample including any end fittings shall be assembled in accordance with the responsibilities regarding the preparation of the test sample and the test submission document.

5.5 Alignment of test samples

5.5.1 General requirement All test samples shall be aligned in accordance with the responsibilities regarding the alignment of the test samples (see **5.2**) and the requirements specified in **5.5.2**.

5.5.2 Description of effective centres and effective centrelines

5.5.2.1 Effective knee-joint centreline For a monocentric knee unit without a lock or stance phase control mechanism, the effective knee-joint centreline shall coincide with the joint flexion axis.

For all other knee units, the effective knee-joint centreline shall be established from the manufacturer's/submitter's written alignment instructions included in or submitted with the test submission document.

The effective knee-joint centreline shall lie in the $o'-u'$ -plane of the coordinate system parallel to the effective hip-joint centreline.

5.5.2.2 Effective knee-joint centre The effective knee-joint centre shall lie on the effective knee-joint centreline.

For symmetrical knee units, the effective knee-joint centre shall be the point on the effective knee-joint centreline equidistant from the external boundaries of the unit.

For asymmetrical or handed knee units, the position of the effective knee-joint centre shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit included in or submitted with the test submission document.

5.5.2.3 Effective hip-joint centreline For a monocentric hip unit without a lock or stance phase control mechanism, the effective hip-joint centreline shall coincide with the joint flexion axis.

For all other hip units, the effective hip-joint centreline shall be established from the manufacturer's/submitter's written alignment instructions included in or submitted with the test submission document.

The effective hip-joint centreline shall lie in the $o'-u'$ -plane of the coordinate system parallel to the o' -axis.

5.5.2.4 Effective hip-joint centre The effective hip-joint centre shall lie on the effective hip-joint centreline.

For symmetrical hip units, the effective hip-joint centre shall be the point on the effective hip-joint centreline equidistant from the external boundaries of the unit.

For asymmetrical or handed hip units, the position of the effective hip-joint centre shall be established from the manufacturer's/submitter's written alignment instructions for the hip unit included in or submitted with the test submission document.

5.5.3 Worst case alignment The structurally worst alignment position of the test sample shall be defined by the manufacturer/submitter in the test submission document. It shall lie within the limitations of the manufacturer's/submitter's written instructions for the alignment of the limb as supplied with every component of the type.

Where the structurally worst position cannot be defined, then the test sample shall be adjusted so that it is moved 90 % of the distance from neutral alignment to extreme alignment. The adjustment shall be directed away from the load line so as to increase the effective lever arm.

6 Test requirements and conditions

6.1 Types of test

6.1.1 Static tests Each static test shall consist of a single load application to a sample.

The static tests shall consist of a static proof test, a static failure test and a static torsional proof test.

6.1.2 Cyclic tests The cyclic tests shall consist of repeated applications of a load to a test sample.

Each cyclic test shall be followed by a final static load test.

6.2 Test loading requirements

6.2.1 Test loading principle In order to allow the test loading conditions to be applied in a uniform and reproducible manner, the position of the load line in relation to the test sample shall be established through application of the following test loading principle:

- a) for loading, the positions of the load line within the coordinate system shall be such that the test force is applied either in the $f'-u'$ -plane or in the $o'-u'$ -plane (see Figures 1 and 2);
- b) the test sample shall be assembled to a fixed length using end attachments consisting of extension pieces as required and the load application levers;
- c) the test sample shall be set up either in the $f'-u'$ -plane or in the $o'-u'$ -plane of the coordinate system with the bottom and top load application levers adjusted so that the knee and hip offsets are correct;
- d) no corrections shall be made to the load application levers if the test sample deflects under the test loading conditions, and this deflection alters the initial knee and hip offsets.

6.2.2 Test loading conditions

6.2.2.1 General The test loading conditions for A-P, M-L and torsional tests are based on internal reference loads, consisting of an axial force, bending moments and a twisting moment. These are described in annex A together with their effects.

NOTE : Further reference data are given in annex B together with several sets of formulae for calculating specific values of axial force, effective lever arms and offsets.

6.2.2.2 A-P plane test loading conditions In the A-P plane test loading conditions shown in Figures 2 a) and 2 b), the components of loading shall be produced by the application of a single test force in the $f'-u'$ -plane of the coordinate system.

Two different A-P plane test loading conditions are specified and each shall be applied in a static proof and failure test procedure and a cyclic test procedure (see 6.4):

- a) the A-P extension test loading condition shown in Figure 2 a) shall be applied to all hip units;
- b) the A-P flexion test loading condition shown in Figure 2 b) shall be applied to hip units with a stride limiter in addition to the A-P extension test loading condition.

6.2.2.3 M-L plane test loading condition In the M-L plane test loading condition shown in Figure 2 c), the components of loading shall be produced by the application of a single test force in the $o'-u'$ -plane of the coordinate system.

The M-L plane test loading condition shall be applied in a static proof and failure test procedure and a cyclic test procedure (see 6.4).

6.2.2.4 Torsional test loading condition The A-P plane and M-L plane test loading conditions shall be supplemented by a separate torsional test loading condition to be applied about the u' -axis in a static and a cyclic test procedure (see 6.5).

6.2.3 Test loading levels The load actions to which a lower limb prosthesis is actually subjected during use vary with individual physical parameters, locomotion characteristics of the user and other factors. For these reasons different categories of prostheses are needed and, consequently, different test loading levels are specified.

The series A test loading levels A100, A80 and A60 shall apply to lower-limb prostheses for adults.

- NOTES
- 1 For test loading levels A100, A80 and A60, the values for the dimensions and test loads of the A-P, M-L and torsional test loading conditions are specified in Tables 3 and 4.
 - 2 Test loading levels A100, A80 and A60 correspond to the series A test loading levels specified in JIS T 0111-3.

6.3 Requirements and conditions relevant to test procedures and equipment

6.3.1 General Set the dimensions of the test pieces and attachments, and the test loads in accordance with the values specified in clause 7. Carry out any single test in accordance with the particular requirements stated in the test submission document submitted with each test sample.

Ensure that the test equipment has sufficient freedom of movement to permit unrestricted deformation of the test sample.

Ensure that any attachments to the test sample do not enhance or relieve the specified test loads in the structure under test.

Ensure that any records called for are entered in the test laboratory/facility log and copied to the test report, in accordance with clause 9.

6.3.2 Proof test of end attachments used for A-P and M-L tests

6.3.2.1 General Carry out a proof test of end attachments consisting of the load application levers and any extension pieces used, and measure their stiffness in either of the manners specified in 6.3.2.2 and 6.3.2.3 (see note 1).

- NOTES
- 1 The method of proof test specified in **6.3.2.2** can result in test configurations in which the position of the assembly of end attachments will be inclined relative to the line of load application at a greater angle than in the relevant test situation with a test sample. If the assembly cannot be tested in such a position, the alternative method of proof test specified in **6.3.2.3** may be applied.
 - 2 It may be necessary to apply the proof test of end attachments to different sets of end attachment, individually designed to the requirements of the different test loading conditions.
 - 3 It is not necessary to repeat the proof test of end attachments if earlier test results for previously tested relevant combinations of end attachments are available and are suitable.

6.3.2.2 Standard proof test of end attachments

6.3.2.2.1 Assemble together any nonprosthetic components used in the test sample for the application of a specific test loading condition. Set both load application levers in the same direction.

If the extension pieces used have means of adjustment, this shall be set to the worst structural condition.

If it is necessary to use additional components to allow assembly of end attachments, the stiffness of these components shall not be less than the stiffness of the other nonprosthetic components when assembled in the test situation.

6.3.2.2.2 Within the range of adjustability required for the test loading condition to be applied, set both lever arms in the same direction to their maximum length.

6.3.2.2.3 Place the assembly in the test equipment.

6.3.2.2.4 Apply to the assembly the settling force F_{set} of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4.

Maintain this force, F_{set} , for a period between 10 s and 30 s, and then remove it.

6.3.2.2.5 Apply to the assembly the stabilizing test force F_{stab} specified in Table 4 and maintain it until the measurement specified below is completed.

Measure and record the distance $L_{\text{BK-TH}}$ as L_1 or the displacement δ of the moving load application point (e.g. the cross-head) from its reference position in the test equipment as δ_1 .

6.3.2.2.6 Increase the test force smoothly at a rate between 100 N/s and 250 N/s to the proof test force F_{pa} of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4.

Maintain this force, F_{pa} , until the measurement specified below is completed.

Measure and record the distance $L_{\text{BK-TH}}$ as L_2 or the displacement δ of the moving load application point (e.g. the cross-head) from its reference position in the test equipment as δ_2 .

6.3.2.2.7 Decrease the test force to F_{stab} and maintain it until the measurement specified below is completed.

Measure and record the distance L_{BK-TH} as L_3 or the displacement δ of the moving load application point (e.g. the cross-head) from its reference position in the test equipment as δ_3 .

6.3.2.2.8 Calculate and record the deflection D_1 at F_{pa} , and the permanent deformation D_2 at F_{stab} , respectively, between the bottom and top load application points as follows:

$$D_1 = L_1 - L_2 \quad \text{or} \quad D_1 = \delta_2 - \delta_1$$

$$D_2 = L_1 - L_3 \quad \text{or} \quad D_2 = \delta_3 - \delta_1$$

6.3.2.2.9 Do not use the end attachments if the measured values exceed the following limits:

maximum deflection at F_{pa}	$D_1 = 2 \text{ mm};$
maximum permanent deformation at F_{stab}	$D_2 = 1 \text{ mm}.$

6.3.2.2.10 Record the results of the test.

6.3.2.3 Alternative proof test of end attachments

6.3.2.3.1 Assemble together two identical sets of end attachment used either on the bottom or on the top side of the test sample for the application of a specific test loading condition. Set both load application levers in the same direction.

If the extension pieces used have a means of adjustment, this shall be set to the worst structural condition.

If it is necessary to use additional components to allow assembly of end attachments, the stiffness of these components shall not be less than the stiffness of the other nonprosthetic components when assembled in the test situation.

NOTE : Each set of end attachment consists of the load application lever, the extension piece and additional components, if necessary, to be connected to one end of the test sample. An example of an assembly of two identical sets of end attachment is the assembly of two bottom load application levers and associated components for the M-L test.

6.3.2.3.2 Continue the test, following the instructions in **6.3.2.2.2** to **6.3.2.2.7**.

6.3.2.3.3 Calculate the deflection of the assembly of two identical sets of end attachment $D_{1,X/Y}$ at F_{pa} , and the permanent deformation $D_{2,X/Y}$ at F_{stab} , respectively, between the bottom and the top load application points as follows:

$$D_{1,X/Y} = L_{1,X/Y} - L_{2,X/Y} \quad \text{or} \quad D_{1,X/Y} = \delta_{2,X/Y} - \delta_{1,X/Y}$$

$$D_{2,X/Y} = L_{1,X/Y} - L_{3,X/Y} \quad \text{or} \quad D_{2,X/Y} = \delta_{3,X/Y} - \delta_{1,X/Y}$$

where index X (X = AP-E, AP-F, ML) identifies the test loading condition involved (A-P extension, A-P flexion, M-L) and index Y (Y = B, T) identifies the side of application of each set of end attachment within the test sample in the test situation (B for bottom and T for top).