INTERNATIONAL STANDARD

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Prostheses — Structural testing of hip units

Prothèses — Essais portant sur la structure des prothèses de hanche

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 15032 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Annex A forms an integral part of this International Standard. Annex B is given for information only.

Introduction

Throughout this International Standard, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent or deficient limb segment.

During use a prosthesis is subject to a series of load actions each varying individually with time. The test methods specified in this International Standard use simplified static and cyclic strength tests in which 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 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. This International Standard specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of hip disarticulation prostheses and their components requires controlled field trials in addition to the laboratory tests specified in this International Standard.

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 amputee activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be specified.

Prostheses — Structural testing of hip units

1 Scope

This International 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 ISO 10328.

This International 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.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC 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.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8549-1 and the following apply.

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

3.2
ductile failure
⟨...⟩ fracture of any component with significant plastic deformation at the fracture

3.3
ductile failure
⟨...⟩ gross plastic deformation of the test sample

3.4
test equipment
any test machine or device adapted or specifically designed to the test requirements of this International 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 International 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

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 (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 (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}.

Key

1 Top reference plane, TH
2 Hip reference plane, H
3 Knee reference plane, K
4 Bottom reference plane, BK
a Right
b Left
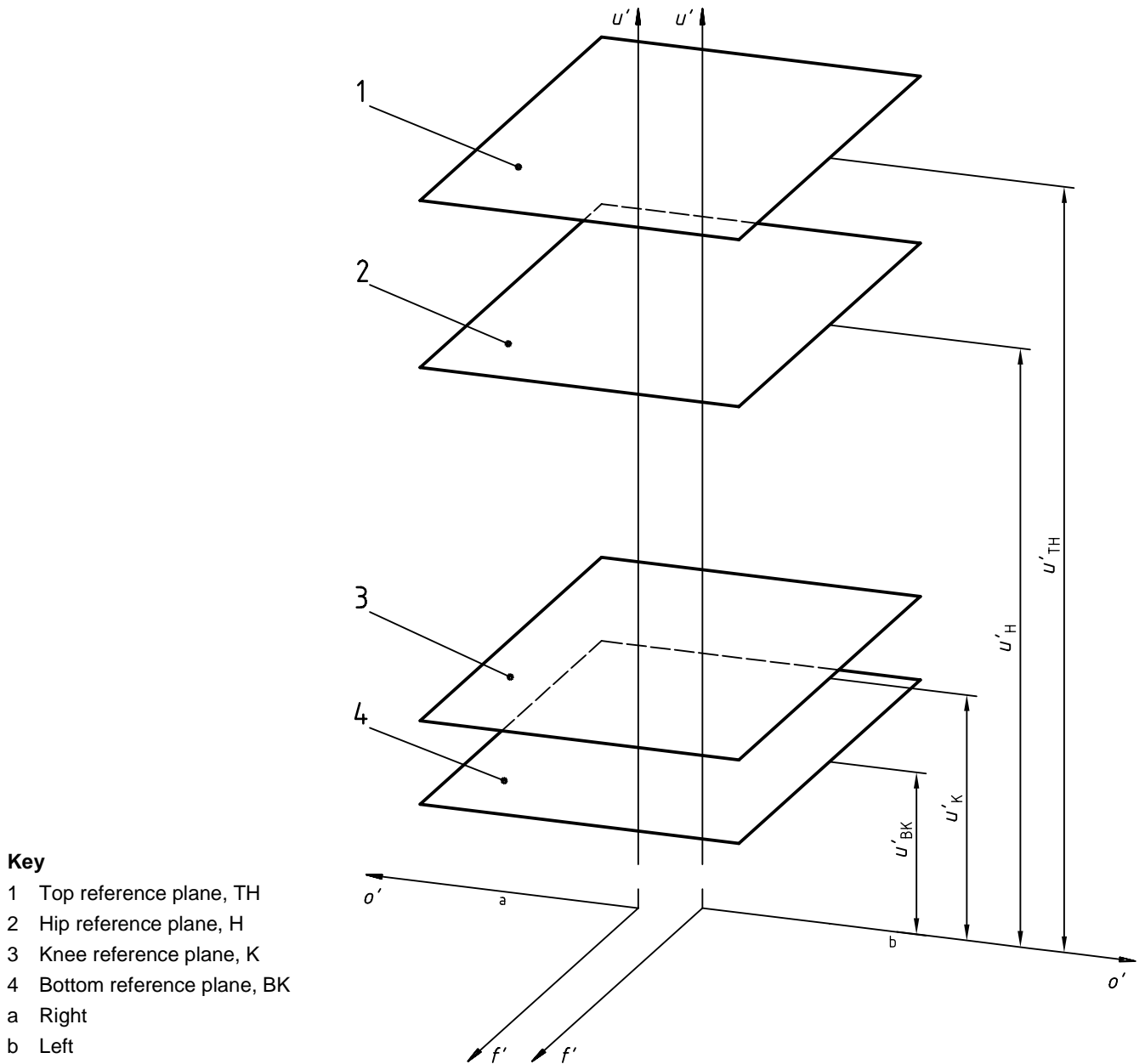
Figure 1 — Coordinate system according to 4.2 with reference planes

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a) A-P ext. test loading condition

b) A-P flex. test loading condition
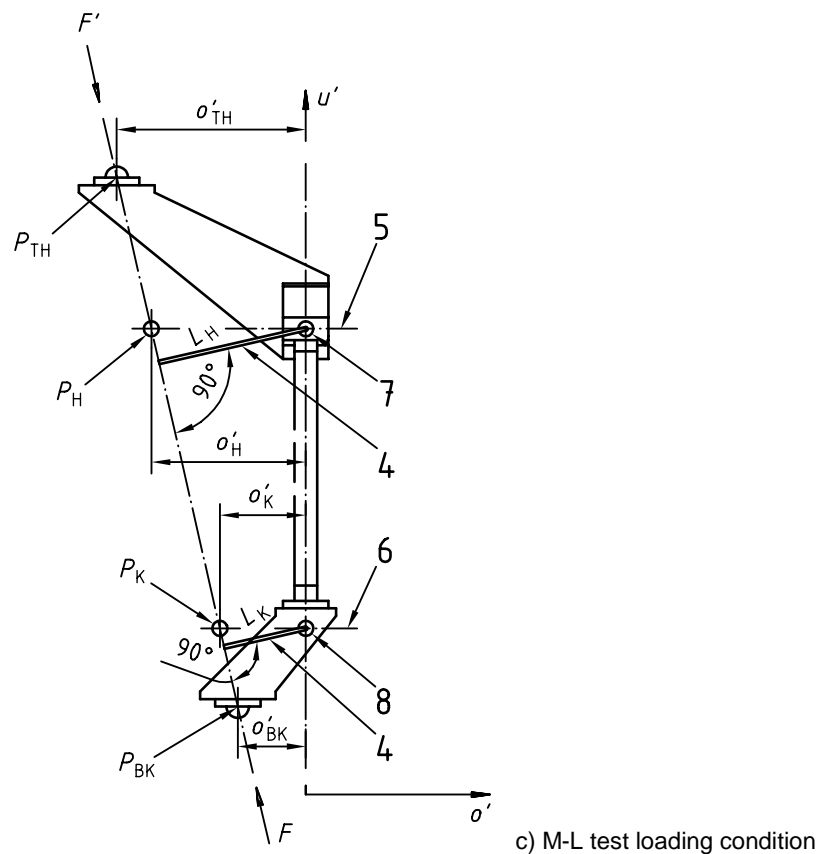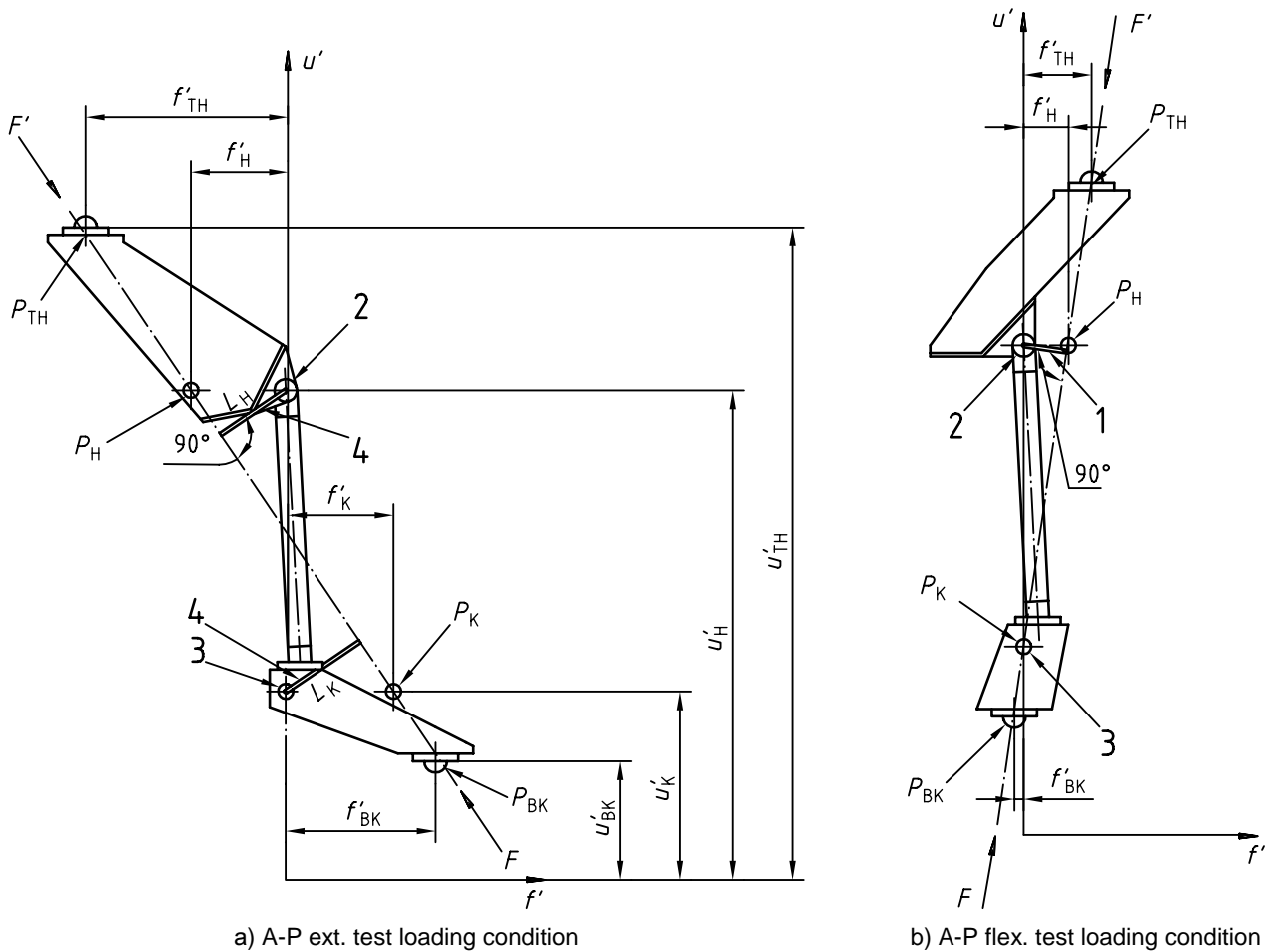
Key

1 Effective lever arm, L_H
2 Effective hip joint centre
3 Effective knee joint centre
4 Effective lever arm
5 Effective hip joint centre line
6 Effective knee joint centre line
7 Effective hip joint centre
8 Effective knee joint centre

c) M-L test loading condition

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 $L_{BK\text{-}TH}$

$L_{BK\text{-}TH}$ 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 monocentic 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:

d) 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);

e) the test sample shall be assembled to a fixed length using end attachments consisting of extension pieces as required and the load application levers;

f) 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;

g) 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.

NOTE 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.

NOTE 2 Test loading levels A100, A80 and A60 correspond to the series A test loading levels specified in ISO 10328-3.

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).

NOTE 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.

NOTE 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.

NOTE 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 $L_{BK\text{-}TH}$ 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 $L_{BK\text{-}TH}$ 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 $L_{BK\text{-}TH}$ 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:

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

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

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

maximum deflection at F_{pa} $D_1 = 2$ mm;

maximum permanent deformation at F_{stab} $D_2 = 1$ 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:

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

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

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).

NOTE   For the example given in the note of 6.3.2.3.1, the designations/symbols of the deflection and the permanent deformation read $D_{1, ML/B}$ and $D_{2, ML/B}$, respectively.

6.3.2.3.4   Do not use the sets of end attachment if the measured value of permanent deformation at F_{stab} exceeds the following limit:

maximum permanent deformation at F_{stab} $D_{2, X/Y} = 1$ mm

6.3.2.3.5   Repeat 6.3.2.3.1 to 6.3.2.3.3 for two identical sets of end attachment to be connected to the opposite end of the test sample for the application of the same test loading condition.

6.3.2.3.6   Do not use the sets of end attachment if the measured value of permanent deformation at F_{stab} exceeds the following limit:

maximum permanent deformation at F_{stab} $D_{2, X/Y} = 1$ mm

6.3.2.3.7   Calculate the mean deflection $D_{1, X/mean}$ at F_{pa} of the combination of a bottom and a top set of end attachment to be used in the test sample for the application of the specific test loading condition as the mean of the values of deflection calculated in 6.3.2.3.3 and 6.3.2.3.5:

$$D_{1, X/mean} = 1/2 \, D_{1, X/B} + 1/2 \, D_{1, X/T} = 1/2 \, (D_{1, X/B} + D_{1, X/T})$$

6.3.2.3.8   Do not use the combination of bottom and top set of end attachments in the test sample for the application of the specific test loading condition if the calculated value of mean deflection at F_{pa} exceeds the following limit:

Maximum mean deflection at F_{pa} $D_{1, \text{X/mean}}$ = 2 mm

6.3.2.3.9   Record the results of the test, giving a cross-reference if earlier results are employed.

6.4   A-P and M-L test procedures

6.4.1   General

6.4.1.1   Conduct all A-P and M-L tests with the components of the test sample set in the worst case alignment position as specified in 5.5.3.

6.4.1.2   For all tests in the A-P flexion test loading condition, adjust the stride limiter with the hip unit in the fully extended position. If this is not possible, adjust the stride limiter to minimum stride length (minimum hip flexion).

In order to avoid a stride limiter of specific design being 'pushed out' during the cyclic test due to the load line being behind its pivot point, it may be necessary to alter the angle of the hip attachment plate to move the load line in front of the pivot joint. Such modifications should be agreed between the manufacturer/submitter and the test laboratory/ facility.

Record any modification(s) performed in the test report.

6.4.1.3   Carry out all M-L tests with the hip unit in the fully extended position.

NOTE   An offset in the A-P plane, not exceeding 10 mm, may be used during the M-L test to apply an extension moment in order to maintain the test sample in full extension.

Record the value of any offset in the A-P plane used in the test report.

6.4.2   Static A-P and M-L proof tests

NOTE 1   A test sample that has successfully completed the cyclic A-P or the cyclic M-L test procedure (including the final static load test) may be used for the static A-P or the static M-L proof test, respectively, after realignment (see note 1 of 6.7).

NOTE 2   The measurements specified in 6.4.2.1 to 6.4.2.5 and 6.4.2.8 may be carried out with the test sample mounted either in the test equipment or in a special jig which applies the stabilizing test force F_{stab}.

6.4.2.1   Prepare and align the test sample in accordance with clause 5 and the test submission document.

At zero load set the knee and hip offsets (f'_K, f'_H, o'_K and o'_H) and the test sample segment lengths (u'_K - u'_{BK}, u'_H - u'_K and u'_{TH} - u'_H) in accordance with the values for the relevant test loading condition and test loading level, specified in 7.2.1 and Table 3.

Measure and record

a) f'_K, f'_H, o'_K and o'_H, and

b) u'_K - u'_{BK}, u'_H - u'_K and u'_{TH} - u'_H

6.4.2.2   Apply to the test sample 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.

Allow the sample to rest at zero load for a period of at least 15 min before proceeding with 6.4.2.3.

6.4.2.3   Apply to the test sample the stabilizing test force F_{stab} specified in Table 4.

6.4.2.4   In accordance with the values for the relevant test loading condition and test loading level, specified in Table 3, adjust the bottom and top load application levers until the knee and hip offsets (f'_K, f'_H, o'_K and o'_H) are correct at the stabilizing test force F_{stab}.

6.4.2.5   Apply and maintain the stabilizing test force F_{stab} until the measurements specified below are completed.

Measure and record

a) f'_K, f'_H, o'_K, and o'_H,

b) L_K and L_H, and

c) the distance $L_{BK\text{-}TH}$ as L_4 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_4**.**

NOTE   If the measurements of a) and b) have been carried out with the test sample placed in a special jig, the stabilizing test force F_{stab} has to be removed and re-applied by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with c).

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

Maintain this force, F_{sp}, at the prescribed value for 30 s.

6.4.2.7   Decrease the test force to F_{stab}.

6.4.2.8   Maintain the stabilizing test force F_{stab} = 50 N until the measurements specified below are completed. Complete the measurements within 15 min.

Measure and record

a) the distance $L_{BK\text{-}TH}$ as L_5 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_5,

b) f'_K, f'_H, o'_K, o'_H, and

c) L_K and L_H.

NOTE   If the measurements of b) and c) are intended to be carried out with the test sample placed in a special jig, the stabilizing test force F_{stab} has to be removed and re-applied by the jig upon transfer of the test sample from the test equipment to the jig after having completed a).

6.4.2.9   Calculate and record the permanent deformation, D_3, between the bottom and top load application points:

$$D_3 = L_4 - L_5 \text{ or } D_3 = \delta_5 - \delta_4$$

6.4.2.10   If a permanent deformation D_3 exceeding 15 mm occurs, the test sample does not satisfy the requirements of the static A-P or M-L proof test of this International Standard.

6.4.2.11   If any individual component of the test sample fails to function safely after this test, record that this component does not satisfy the requirements of the static A-P or M-L proof test of this International Standard in the combination of components in the test sample.

6.4.2.12   If the test sample fails, record the load at failure and the nature of the failure in the test report.

6.4.3   Static A-P and M-L failure tests

NOTE 1   A test sample that has successfully completed the static A-P or the static M-L proof test may be used for the static A-P or the static M-L failure test, respectively, after realignment.

NOTE 2   The measurements specified in 6.4.3.1 to 6.4.3.5 may be carried out with the test sample mounted either in the test equipment or in a special jig which applies the stabilizing test force F_{stab}.

6.4.3.1   Prepare and align the test sample in accordance with clause 5 and the test submission document.

At zero load, set the knee and hip offsets (f'_K, f'_H, o'_K and o'_H) and the test sample segment lengths ($u'_K - u'_{BK}, u'_H - u'_K$ and $u'_{TH} - u'_H$) in accordance with the values for the relevant test loading condition and test loading level, specified in 7.2.1 and Table 3.

Measure and record

a) f'_K, f'_H, o'_K and o'_H, and

b) $u'_K - u'_{BK}, u'_H - u'_K$ and $u'_{TH} - u'_H$.

6.4.3.2   Apply to the test sample 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.

Allow the sample to rest at zero load for a period of at least 15 min before proceeding with 6.4.3.3.

6.4.3.3   Apply to the test sample the stabilizing test force F_{stab} specified in Table 4.

6.4.3.4   In accordance with the values for the relevant test loading condition and test loading level, specified in Table 3, adjust the bottom and top load application levers until the knee and hip offsets (f'_K, f'_H, o'_K and o'_H) are correct at the stabilizing test force F_{stab}.

6.4.3.5   Apply and maintain the stabilizing test force F_{stab} until the measurements specified below are completed.

Measure and record:

a) f'_K, f'_H, o'_K, and o'_H

b) L_K and L_H.

NOTE   If the measurements of a) and b) have been carried out with the test sample placed in a special jig, the stabilizing test force F_{stab} has to be removed and re-applied by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with 6.4.3.6.

6.4.3.6   Increase the test force smoothly at a rate between 100 N/s and 250 N/s until the test sample fails or sustains the ultimate test force for brittle failure $F_{su,brittle}$ (see 6.4.3.7).

Record the maximum value of the test force F reached during the test.

6.4.3.7   The test force F which the test sample shall withstand in order to satisfy the requirements of the static A-P or M-L failure test of this International Standard is dependent upon the mode of failure that may occur (for definition of mode of failure see 3.1, 3.2 and 3.3).

The test sample shall satisfy the requirements of the static A-P or M-L failure test if it sustains the ultimate test force for brittle failure $F_{su,brittle}$, or if ductile failure occurs at a load exceeding the ultimate test force for ductile failure $F_{su,ductile}$.

The values for F_{su} of the A-P and M-L test loading conditions at the relevant test loading level are specified in Table 4.

If expressly requested by the manufacturer/submitter, or if requested in the test submission document, the static failure test may be continued after the test sample has withstood the test force specified in Table 4 for brittle failure until failure actually occurs. In this case the attachments used need a higher value of stiffness, i.e. the values of their deflection and permanent deformation must keep within the limits specified in 6.3.2 at a higher proof load than is specified in Table 4.

6.4.3.8　　If failure occurs, inspect the specimen to detect the mode of failure and record the results in the test report.

6.4.4   Cyclic A-P and M-L tests

6.4.4.1   General requirements applicable to cyclic A-P and M-L tests

6.4.4.1.1　　The test equipment shall generate a single pulsating test force F, as shown in Figure 3, oscillating through the range of cyclic test force F_c with an initial force F_{min} to generate a maximum test force F_{max}, where

$$F_{max} = F_{min} + F_c$$

6.4.4.1.2　　The waveform of the pulsating test force F generated by the test equipment shall be sinusoidal (see Figure 3). If it is certified that a sinusoidal form is not possible, then the waveform shall be smooth with no overshoot spikes.

Key

1　Test load F, $M_{u'}$

2　Time

3　Initial test load F_{min}, $M_{u'min}$

4　Maximum test load
F_{max}, $M_{u'max}$

5　Range of cyclic test load
F_c, $M_{u'\,c}$
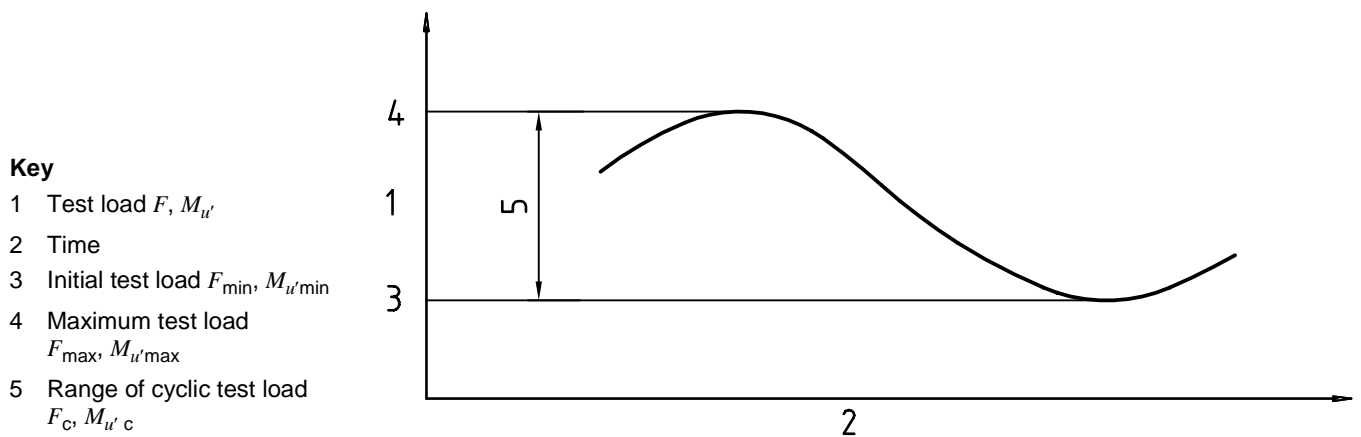
Figure 3 — Load cycle parameters for cyclic tests

6.4.4.1.3　　The test equipment shall switch off if the cyclic test force F_c deviates by more than 10 % of the maximum test force F_{max}.

The test equipment control mechanism used to generate the sinusoidal waveform may require a number of cycles to achieve the required waveform. During this settling-in period the waveform shall be smooth with no overshoot spikes, and the maximum force applied shall not exceed the maximum test force F_{max} by more than 10 %.

6.4.4.1.4　　The test equipment shall switch off if the deflection between the bottom and top load application points P_{BK} and P_{TH} at F_{max} increases by more than 5 mm from its initial value of deflection at F_{max}.

The initial deflection measurement shall be made when the test equipment is running at the prescribed load with the prescribed waveform (see 6.4.4.2.8 and 6.4.4.2.9).

6.4.4.1.5   If the test frequency selected is higher than 1 Hz, then the maximum frequency shall be below the level at which dynamic mass effects begin to affect the maximum load value or the waveform.

6.4.4.1.6   During the course of the cyclic A-P and M-L tests, specified parts shall be 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. All such replacements shall be recorded in the test report.

6.4.4.1.7   All test samples that successfully complete a cyclic test shall, at the request of the submitter, be visually examined at $\times$ 4 magnification or greater, and the presence and nature of any cracks recorded in the test report.

6.4.4.1.8   All test samples that successfully complete a cyclic test shall be subjected to a final static test force $F_f = F_{sp}$ (see 6.4.4.2.17).

6.4.4.2   Cyclic A-P and M-L test procedure

NOTE   The measurements specified in 6.4.4.2.1 to 6.4.4.2.5 may be carried out with the test sample mounted either in the test equipment or in a special jig which applies the stabilizing test force, F_{stab}, and/or the maximum test force, F_{max}.

6.4.4.2.1   Prepare and align the test sample in accordance with clause 5 and the test submission document.

At zero load, set the knee and hip offsets (f'_K, f'_H, o'_K and o'_H) and the test sample segment lengths (u'_K - u'_{BK}, u'_H - u'_K and u'_{TH} - u'_H) in accordance with the values for the relevant test loading condition and test loading level, specified in 7.2.1 and Table 3.

Measure and record

a) f'_K, f'_H, o'_K and o'_H, and

b) $u'_K - u'_{BK}$, $u'_H - u'_K$ and $u'_{TH} - u'_H$.

6.4.4.2.2   Apply to the test sample 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.

Allow the sample to rest at zero load for a period of at least 15 min before proceeding with 6.4.4.2.3.

6.4.4.2.3   Apply to the test sample the stabilizing test force F_{stab} specified in Table 4.

6.4.4.2.4   In accordance with the values for the relevant test loading condition and test loading level, specified in Table 3, adjust the bottom and top application levers until the knee and hip offsets (f'_K, f'_H, o'_K, and o'_H) are correct at the stabilizing test force F_{stab}.

6.4.4.2.5   Apply and maintain the stabilizing test force F_{stab} until the measurements specified below are completed.

Measure and record

a) f'_K, f'_H, o'_K and o'_H

b) L_K and L_H, and

c) the distance L_{BK-TH} as L_6 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_6.

NOTE   If the measurements of a) and b) have been carried out with the test sample placed in a special jig, the stabilizing test force F_{stab} has to be removed and re-applied by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with c).

6.4.4.2.6   Apply to the test sample the maximum test force F_{max} of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4.

Maintain this force, F_{max}, until the measurements specified below are completed.

Measure and record

a) f'_K, f'_H, o'_K and o'_H,

b) L_K and L_H, and

c)   the distance L_{BK-TH} as L_7 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_7.

NOTE   If the measurements of a) and b) have been carried out with the test sample placed in a special jig, the maximum test force F_{max} has to be removed and re-applied by the test equipment upon transfer of the test sample from the jig to the test equipment before proceeding with c).

6.4.4.2.7   Reduce the test force to the initial test force F_{min} specified in Table 4.

6.4.4.2.8   Maintain the initial test force F_{min} and apply the cyclic test force F_c of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4, at the frequency called for in the test submission document for a series of cycles.

Do not proceed with 6.4.4.2.9 until the test sample and test equipment have settled down and achieved the waveform specified in 6.4.4.1.2 with F_c not deviating by more than 10 % of F_{max}.

Stop the test equipment and record the number of cycles required to settle down in the test report.

NOTE   The number of cycles required for the test to settle down will be determined by the nature of the test sample and the test equipment control mechanism.

6.4.4.2.9   Apply to the test sample the maximum test force F_{max}. Measure and record the initial value of the distance L_{BK-TH} as L_8 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_8.

6.4.4.2.10   Reduce the test force to the initial test force F_{min}.

6.4.4.2.11   Maintain the initial test force F_{min} and apply the cyclic test force F_c of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4, for the number of cycles specified in Table 4 and at the frequency called for in the test submission document.

Inspect the waveform of the applied cyclic test force F_c. Terminate the test if the waveform does not comply with 6.4.4.1.2.

Set the test equipment displacement trip to 5 mm above the value of the initial displacement δ_8 at F_{max} determined in 6.4.4.2.9.

6.4.4.2.12   Examine the test sample for damage if the test equipment has switched off due to excessive displacement.

If the test sample has failed, record that the test sample does not satisfy the requirements of the cyclic A-P or M-L test of this International Standard.

If there is no sign of failure, restart the test from 6.4.4.2.8 and apply the specified number of cycles reduced by the number of cycles completed before the test equipment tripped.

6.4.4.2.13 Measure and record f'_K, f'_H, o'_K and o'_H, L_K and L_H as well as $L_{BK\text{-}TH}$ or displacement δ at F_{min} and F_{max} on the following occasions:

a)   if the number of cycles of load has reached a value at which the exchange of specified parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document (see 6.4.4.1.6);

d)   when the specified number of cycles has been completed.

After the exchange/replacement of specified parts, the test may be restarted from 6.4.4.2.1, 6.4.4.2.2 or 6.4.4.2.8, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

6.4.4.2.14 Record in the test report all occurrences of switch-off, the number of cycles of load applied up to that time, the duration and the reason for switch-off.

6.4.4.2.15 Continue the test until failure occurs or the endurance (number of cycles in the test) specified in Table 4 has been reached. In each case record the total number of cycles of load applied in the test report.

6.4.4.2.16 If a test sample fails, record the nature of failure in the test report.

6.4.4.2.17 In accordance with 6.4.4.1.8, subject all test samples that successfully complete a cyclic test to the final static test force $F_f = F_{sp}$ of the A-P and M-L test loading conditions at the relevant test loading level, specified in Table 4, applied at a rate between 100 N/s and 250 N/s.

To pass the test, the load shall be maintained for 30 s without failure or gross deformation.

6.4.4.3   Failure criteria for cyclic A-P and M-L tests

6.4.4.3.1   If any one sample tested at a frequency of less than 3 Hz does not achieve the minimum endurance specified in Table 4, the component is deemed not to satisfy the requirements of the cyclic A-P or M-L test of this International Standard.

6.4.4.3.2   If a sample tested at a frequency of 3 Hz or higher fails, then at least one further sample shall be tested at less than 3 Hz in the same test loading condition and at the same test loading level. If any further sample fails, the component is deemed not to satisfy the requirements of the cyclic A-P or M-L test of this International Standard.

6.4.4.3.3   If a sample fails to sustain the final static force $F_f = F_{sp}$ for a period of 30 s, the component is deemed not to satisfy the requirements of the cyclic A-P or M-L test of this International Standard.

6.5   Torsional test procedures

6.5.1   General

Carry out the test in one direction of loading only. For asymmetrical test samples apply the torque in the direction tending to rotate the knee internally relative to the hip.

A hip extension moment may be applied in addition to the applied torque if this is necessary to maintain the structural integrity of the test sample when the torque is applied. This should, however, be agreed between the manufacturer/submitter and the test laboratory/facility.

Record the application of a hip extension moment in the test report together with its approximate value.

6.5.2 Static torsional proof test

6.5.2.1 The manufacturer/submitter shall assemble the test sample in accordance with the manufacturer's instructions, taking care in the tightening of bolts which clamp components together. The tightening torques of the bolts shall be stated in the test submission document. All adjustable components shall be set in their midpositions.

The test laboratory/facility shall attach any fixtures necessary for mounting the test sample in the test equipment. The tightening torques of any bolts shall be recorded in the test report.

6.5.2.2 Set up the test sample with the hip unit in full extension and with the effective knee- and hip-joint centres aligned along the u'-axis.

6.5.2.3 Fix one end of the test sample and apply a twisting moment $M_{u'}$ to the other end to generate the settling torsional moment $M_{u'\text{set}}$ specified in Table 4.

Maintain this moment, $M_{u'\text{set}}$, for a period between 10 s and 30 s, and then remove it.

Allow the sample to rest at zero load for a period of at least 15 min before proceeding with 6.5.2.4.

6.5.2.4 Apply to the test sample the twisting moment $M_{u'}$ to generate the stabilizing torsional moment $M_{u'\text{stab}}$ specified in Table 4, and maintain it until the markings and readings of 6.5.2.5 are completed.

6.5.2.5 Mark the initial angular positions at the junctions of all parts.

Measure and record the initial angular positions relevant to twisting about the u'-axis of the bottom and top components of the test sample θ_{b1} and θ_{t1} respectively.

6.5.2.6 Increase the twisting moment $M_{u'}$ smoothly at a rate not exceeding 4 Nm/s to generate the torsional proof moment $M_{u'\text{sp}}$ specified in Table 4. Maintain the torsional proof moment for 30 s and then decrease it to the stabilizing torsional moment $M_{u'\text{stab}}$.

Note and record the time elapsed for testing.

6.5.2.7 Maintain the stabilizing torsional moment $M_{u'\text{stab}}$ until the measurement specified below is completed. Complete the measurement within 15 min.

Measure and record the final angular positions relevant to twisting about the u'-axis of the bottom and top components of the test sample θ_{b2} and θ_{t2} respectively.

Note and record the time elapsed for measuring.

6.5.2.8 Calculate and record the relative angular movement about the u'-axis between the ends of the test sample θ_{r1} as follows:

$$\theta_{r1} = (\theta_{b2} - \theta_{b1}) - (\theta_{t2} - \theta_{t1}) \text{ or } \theta_{r1} = (\theta_{b2} - \theta_{t2}) - (\theta_{b1} - \theta_{t1})$$

6.5.2.9 The test sample shall satisfy the requirements of the static torsional proof test of this International Standard if the relative angular movement between the ends of the test sample θ_{r1} does not exceed 3°, and the hip unit continues to function safely.

If appropriate, use the marking of the initial angular positions at the junctions of all parts specified in 6.5.2.5 to establish where and what amount of slippage has occurred.

6.5.3 Cyclic torsional test

6.5.3.1 General requirements applicable to the cyclic torsional test

6.5.3.1.1   The test equipment shall generate a single pulsating twisting moment $M_{u'}$ oscillating through the range $M_{u'c}$ with the initial twisting moment $M_{u'\text{min}}$ to generate a maximum twisting moment $M_{u'\text{max}}$, where

$$M_{u'\text{max}} = M_{u'\text{min}} + M_{u'c}$$

6.5.3.1.2   The waveform of the pulsating twisting moment $M_{u'}$ shall be sinusoidal (see Figure 3). If it is certified that a sinusoidal form is not possible, then the waveform shall be smooth with no overshoot spikes.

6.5.3.1.3   The test equipment shall switch off if the cyclic twisting moment $M_{u'c}$ deviates by more than 10 % of the maximum twisting moment $M_{u'\text{max}}$.

The test equipment control mechanism used to generate the sinusoidal waveform may require a number of cycles to achieve the required waveform. During this settling-in period the waveform shall be smooth with no overshoot spikes, and the maximum twisting moment applied shall not exceed the maximum twisting moment $M_{u'\text{ max}}$ by more than 10 %.

6.5.3.1.4   The test equipment shall switch off if the relative angular movement about the u'-axis between the ends of the test sample at $M_{u'\text{max}}$ increases by more than 3° from its initial value at $M_{u'\text{max}}$.

The value of initial relative angular movement shall be determined when the test equipment is running at the prescribed load with the prescribed waveform (see 6.5.3.2.6 to 6.5.3.2.8).

6.5.3.1.5   If the test frequency selected is higher than 1 Hz, then the maximum frequency shall be below the level at which dynamic mass effects begin to affect the maximum load value or the waveform.

6.5.3.1.6   During the course of the cyclic torsional test, specified parts shall be 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. All such replacements shall be recorded in the test report.

6.5.3.1.7   All test samples that successfully complete the cyclic torsional test shall, at the request of the submitter, be visually examined at $\times 4$ magnification or greater, and the presence and nature of any cracks recorded in the test report.

6.5.3.1. 8   All test samples that successfully complete the cyclic torsional test shall be subjected to a final static twisting moment $M_{u'f} = M_{u'\text{sp}}$ (see 6.5.3.2.16).

6.5.3.2 Cyclic torsional test procedure

6.5.3.2.1   The manufacturer/submitter shall assemble the test sample in accordance with the manufacturer's instructions, taking care in the tightening of bolts which clamp components together. The tightening torques of the bolts shall be stated in the test submission document. All adjustable components shall be set in their midpositions.

The test laboratory/facility shall attach any fixtures necessary for mounting the test sample in the test equipment. The tightening torques of any bolts shall be recorded in the test report.

6.5.3.2.2   Set up the test sample with the hip unit in full extension and with the effective knee- and hip-joint centres aligned along the u'-axis.

6.5.3.2.3   Fix one end of the test sample and apply a twisting moment $M_{u'}$ to the other end to generate the settling torsional moment $M_{u'\text{set}}$ specified in Table 4.

Maintain this moment, $M_{u'\text{set}}$, for a period between 10 s and 30 s, and then remove it.

Allow the test sample to rest at zero load for a period of at least 15 min before proceeding with 6.5.3.2.4.

6.5.3.2.4 Apply to the test sample the twisting moment $M_{u'}$ to generate the stabilizing torsional moment $M_{u'\text{stab}}$ specified in Table 4, and maintain it until the markings and readings of 6.5.3.2.5 are completed.

6.5.3.2.5 Mark the initial angular positions at the junctions of all parts.

Measure and record the initial angular positions relevant to twisting about the u'-axis of the bottom and top components of the test sample θ_{b3} and θ_{t3} respectively.

6.5.3.2.6 Apply to the test sample the initial twisting moment $M_{u'\text{min}}$ specified in Table 4 and maintain it or maintain the stabilizing twisting moment $M_{u'\text{stab}}$, respectively, and then apply the cyclic twisting moment $M_{u'\text{c}}$ specified in Table 4 at the frequency called for in the test submission document for a series of cycles.

Do not proceed with 6.5.3.2.7 until the test sample and test equipment have settled down and achieved the waveform specified in 6.5.3.1.2 with $M_{u'\text{c}}$ not deviating by more than 10 % of $M_{u'\text{max}}$.

Stop the test equipment and record the number of cycles required to settle down in the test report.

NOTE   The number of cycles required for the test to settle down will be determined by the nature of the test sample and the test equipment control mechanism.

6.5.3.2.7 Apply to the test sample the maximum twisting moment $M_{u'\text{max}}$ specified in Table 4 and maintain it until the measurement specified below is completed.

Measure and record the angular positions relevant to twisting about the u'-axis of the bottom and top components of the test sample θ_{b4} and θ_{t4} respectively.

6.5.3.2.8 Calculate the initial relative angular movement at $M_{u'\text{max}}$ about the u'-axis between the ends of the test sample θ_{r2} as follows:

$$\theta_{r2} = (\theta_{b4} - \theta_{b3}) - (\theta_{t4} - \theta_{t3}) \ \text{ or } \ \theta_{r2} = (\theta_{b4} - \theta_{t4}) - (\theta_{b3} - \theta_{t3})$$

6.5.3.2.9 Reduce the twisting moment $M_{u'}$ to the initial twisting moment $M_{u'\text{min}}$ and maintain it.

6.5.3.2.10 Apply the cyclic twisting moment for the specified number of cycles at the frequency called for in the test submission document. The value of $M_{u'\text{c}}$ and the number of cycles are specified in Table 4.

Inspect the waveform of the applied cyclic twisting moment $M_{u'\text{c}}$. Terminate the test if the waveform does not comply with 6.5.3.1.2.

Set the test equipment displacement trip to the value corresponding to a relative angular movement about the u'-axis between the ends of the test sample of 3° greater than the value of the initial relative angular movement θ_{r2} at $M_{u'\text{max}}$ determined in 6.5.3.2.8.

6.5.3.2.11 Examine the test sample for damage if the test equipment has switched off due to excessive relative angular movement (see 6.5.3.1.4).

If the test sample has failed, record that the test sample does not satisfy the requirements of the cyclic torsional test of this International Standard.

If there is no sign of failure, restart the test from 6.5.3.2.6 and apply the specified number of cycles reduced by the number of cycles completed before the test equipment tripped.

6.5.3.2.12 Measure and record the angular positions of the bottom and top components of the test sample $\theta_{b\text{min}}$ and $\theta_{t\text{min}}$ respectively at $M_{u'\text{min}} / M_{u'\text{stab}}$, and $\theta_{b\text{max}}$ and $\theta_{t\text{max}}$ respectively at $M_{u'\text{max}}$, and calculate and record the related values of relative angular movement about the u'-axis between the ends of the test sample θ_{rx} on the occasions identified in a) and b) as follows:

$$\theta_{rx} = (\theta_{bymax} - \theta_{bymin}) - (\theta_{tymax} - \theta_{tymin}) \text{ or } \theta_{rx} = (\theta_{bymax} - \theta_{tymax}) - (\theta_{bymin} - \theta_{tymin})$$

where $x = 3, 4, 5, ..., n$ and $y = x - 2 = 1, 2, 3, ..., n - 2$

a) if the number of cycles of load has reached the value at which the exchange of parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document (see 6.5.3.1.6);

b) when the specified number of cycles has been completed.

NOTE   After the exchange/replacement of specified parts, the test may be restarted from 6.5.3.2.1, using the original markings specified in 6.5.3.2.5 for resetting up the test sample, from 6.5.3.2.3 or from 6.5.3.2.6, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

6.5.3.2.13   Record in the test report all occurrences of switch-off, the number of cycles of load applied up to that time, the duration and the reason for switch-off.

6.5.3.2.14   Continue the test until failure occurs or the endurance (number of cycles in the test) specified in Table 4 has been reached. In each case record the total number of cycles of load applied in the test report.

6.5.3.2.15   If a test sample fails, record the nature of failure in the test report.

6.5.3.2.16   In accordance with 6.5.3.1.8, subject all test samples that successfully complete the cyclic torsional test to the final static twisting moment $M_{u'f} = M_{u'sp}$ specified in Table 4, applied at a rate not exceeding 4 Nm/s and in the same direction as the cyclic load which has been applied.

To pass the test, the load shall be maintained for 30 s without failure, or slippage at interfaces between adjacent components of the test sample producing a permanent angular displacement greater than 3°.

6.5.3.3   Failure criteria for cyclic torsional test

6.5.3.3.1   If calculation of relative angular movement on the occasion of any occurrence of switch-off shows that slippage at the interface between adjacent components of the test sample has produced a permanent angular displacement θ_{py} at $M_{u'min}$ / $M_{u'stab}$ of more than 3°, the test sample is deemed not to satisfy the requirements of the cyclic torsional test of this International Standard.

If appropriate, use the marking of the initial angular positions at the junctions of all parts specified in 6.5.3.2.5 to establish where and what amount of slippage has occurred.

NOTE θ_{py} is calculated as follows:

$$\theta_{py} = (\theta_{bymin} - \theta_{b3}) - (\theta_{tymin} - \theta_{t3}) \text{ or } \theta_{py} = (\theta_{bymin} - \theta_{tymin}) - (\theta_{b3} - \theta_{t3})$$

θ_{b3} and θ_{t3} are determined in 6.5.3.2.5 and $\theta_{by\,min}$ and θ_{tymin} are determined in 6.5.3.2.13.

6.5.3.3.2   If any one sample tested at a frequency of less than 3 Hz does not achieve the minimum endurance specified in Table 4, the component is deemed not to satisfy the requirements of the cyclic torsional test of this International Standard.

6.5.3.3.3   If a sample tested at a frequency of 3 Hz or higher fails, then at least one further sample shall be tested at less than 3 Hz. If any further sample fails, the component is deemed not to satisfy the requirements of the cyclic torsional test of this International Standard.

6.5.3.3.4   If a sample fails to sustain the final static twisting moment $M_{u'f} = M_{u'sp}$ for a period of 30 s, the component is deemed not to satisfy the requirements of the cyclic torsional test of this International Standard.

6.6   Number of tests required

The minimum number of tests required in order to claim compliance with this International Standard shall be as shown in Table 1. All A-P and M-L tests shall be conducted in the worst case alignment position (see 5.5.3).

Table 1 — Required tests

Type of test	Minimum number of tests required	
	Tests required for all hip units	**Supplementary tests required for hip units with a stride limiter**
Static proof test	1 test in A-P extension and 1 test in M-L	1 test in A-P flexion
Static failure test	1 test in A-P extension and 1 test in M-L	1 test in A-P flexion
Cyclic test	1 test in A-P extension and 1 test in M-L	1 test in A-P flexion
Static torsion test	1 test	
Cyclic torsion test	1 test	

6.7   Restrictions on multiple use of test samples

Test samples that have been subjected to A-P test loading conditions shall not be subjected to M-L test loading conditions or vice versa.

Test samples which have been subjected to the static proof test or the static failure test shall not be used for the cyclic test (but see note 1).

NOTE 1   Test samples which have successfully completed the cyclic test procedure (including the final static load test) may be used for the static proof test or the static failure test after realignment.

NOTE 2   For hip units with a stride limiter, a test sample which has satisfied the requirements for the A-P extension test may be used for the A-P flexion test.

6.8   Accuracy

6.8.1   The test equipment (see 3.4) and any jig used for alignment and/or measurement shall be calibrated at least annually and records of the calibration maintained.

6.8.2   The test equipment and any jig used for alignment and/or measurement under load shall measure the highest load to be applied to an accuracy of within ± 1 %.

6.8.3   The test equipment and any jig used for alignment and/or measurement shall measure linear and/or angular dimensions to an accuracy of within ± 0,1 mm or ± 0,1°, respectively.

6.8.4   For the cyclic tests, the test equipment shall control the frequency of test to an accuracy of within ± 10 %.

6.8.5   Linear dimensions shall be set with a tolerance of ± 1 mm.

6.8.6   Angular dimensions shall be set with a tolerance of ± 1°.

7 Test loading parameters

7.1 Test loads and references

All relevant test loads are listed in Table 2 together with references to the specific subclauses and tables of this International Standard.

Table 2 — Test loads and references

Test load	References	
	Subclause	**Table**
Stabilizing test force $F_{stab} = 50$ N	6.3.2; 6.4.2; 6.4.3; 6.4.4.2	4
Settling test force $F_{set} = 0{,}8 \times F_c$	6.3.2; 6.4.2; 6.4.3; 6.4.4.2	4
Static proof test force of proof test of end attachments $F_{pa} = 1{,}2 \times F_{su,brittle}$	6.3.2	4
Static proof test force $F_{sp} = 1{,}75 \times F_c$	6.4.2; 6.4.4.1; 6.4.4.2; 6.4.4.3	4
Static failure test force — ductile: $F_{su} = 1{,}5 \times F_{sp}$ — brittle: $F_{su} = 2{,}0 \times F_{sp}$	6.4.3	4
Initial test force $F_{min} = 50$ N	6.4.4.1; 6.4.4.2	4
Cyclic test force F_c	6.4.4.1; 6.4.4.2	4
Maximum cyclic test force $F_{max} = F_{min} + F_c$	6.4.4.1; 6.4.4.2	4
Stabilizing twisting moment $M_{u'stab} = 1$ Nm	6.5.2; 6.5.3.2	4
Settling twisting moment $M_{u'set} = 3$ Nm	6.5.2; 6.5.3.2	4
Static proof twisting moment $M_{u'sp}$	6.5.2; 6.5.3.1; 6.5.3.2; 6.5.3.3	4
Initial twisting moment $M_{u'min} = 1$ Nm	6.5.3.1; 6.5.3.2	4
Cyclic twisting moment $M_{u'c}$	6.5.3.1; 6.5.3.2	4
Maximum cyclic twisting moment $M_{u'max} = M_{u'min} + M_{u'c}$	6.5.3.1; 6.5.3.2	4

7.2   Details of loading

7.2.1   Length of test sample

The length of the test samples is determined by the following relationships:

$u'_K - u'_{BK} = 100$ mm

$u'_H - u'_K = 400$ mm

$u'_{TH} - u'_H = 200$ mm

NOTE   For the different u'-levels, see clause 4 and Figure 1.

7.2.2   Load reference points, offsets and effective lever arms

The f'- and o'-coordinates (offsets) of the load reference points on the bottom, knee, hip and top reference planes and the effective lever arms for the A-P and M-L test loading conditions at the different test loading levels shall be in accordance with Table 3.

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Table 3 — Configurations for A-P and M-L tests

Type of test		Reference plane	Reference centre	Offsets[2] mm		Effective lever arms[1], [2] mm
Test loading level A 100	A-P extension	Bottom	P_{BK}	$f'_{BK} = 104$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 67$	$o'_K = 0$	$L_K = 63$
		Hip	P_H	$f'_H = -83$	$o'_H = 0$	$L_H = 78$
		Top	P_{TH}	$f'_{TH} = -159$ [3]	$o'_{TH} = 0$ [3]	
	A-P flexion	Bottom	P_{BK}	$f'_{BK} = -7$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = 0$	$L_K = 0$
		Hip	P_H	$f'_H = 29$	$o'_H = 0$	$L_H = 29$
		Top	P_{TH}	$f'_{TH} = 43$ [3]	$o'_{TH} = 0$ [3]	
	M-L	Bottom	P_{BK}	$f'_{BK} = 0$ [3]	$o'_{BK} = -37$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = -47$	$L_K = 47$
		Hip	P_H	$f'_H = 0$	$o'_H = -86$	$L_H = 86$
		Top	P_{TH}	$f'_{TH} = 0$ [3]	$o'_{TH} = -106$ [3]	
Test loading level A 80	A-P extension	Bottom	P_{BK}	$f'_{BK} = 115$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 75$	$o'_K = 0$	$L_K = 70$
		Hip	P_H	$f'_H = -84$	$o'_H = 0$	$L_H = 78$
		Top	P_{TH}	$f'_{TH} = -163$ [3]	$o'_{TH} = 0$ [3]	
	A-P flexion	Bottom	P_{BK}	$f'_{BK} = -9$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = 0$	$L_K = 0$
		Hip	P_H	$f'_H = 35$	$o'_H = 0$	$L_H = 35$
		Top	P_{TH}	$f'_{TH} = 53$ [3]	$o'_{TH} = 0$ [3]	
	M-L	Bottom	P_{BK}	$f'_{BK} = 0$ [3]	$o'_{BK} = -49$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = -57$	$L_K = 57$
		Hip	P_H	$f'_H = 0$	$o'_H = -91$	$L_H = 90$
		Top	P_{TH}	$f'_{TH} = 0$ [3]	$o'_{TH} = -108$ [3]	
Test loading level A 60	A-P extension	Bottom	P_{BK}	$f'_{BK} = 116$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 77$	$o'_K = 0$	$L_K = 72$
		Hip	P_H	$f'_H = -76$	$o'_H = 0$	$L_H = 71$
		Top	P_{TH}	$f'_{TH} = -153$ [3]	$o'_{TH} = 0$ [3]	
	A-P flexion	Bottom	P_{BK}	$f'_{BK} = -10$ [3]	$o'_{BK} = 0$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = 0$	$L_K = 0$
		Hip	P_H	$f'_H = 41$	$o'_H = 0$	$L_H = 41$
		Top	P_{TH}	$f'_{TH} = 62$ [3]	$o'_{TH} = 0$ [3]	
	M-L	Bottom	P_{BK}	$f'_{BK} = 0$ [3]	$o'_{BK} = -63$ [3]	
		Knee	P_K	$f'_K = 0$	$o'_K = -67$	$L_K = 67$
		Hip	P_H	$f'_H = 0$	$o'_H = -83$	$L_H = 83$
		Top	P_{TH}	$f'_{TH} = 0$ [3]	$o'_{TH} = -92$ [3]	

1) For 'offset' and 'effective lever arm' see 4.7.1 and 4.7.2.

The given values are rounded to the integer mm - values nearest to the exact values calculated from the relevant components of loading acting on the effective knee and hip joint centre (see also Annex B).

3) Offsets in the bottom and top reference planes are only for guidance in aligning test samples.

7.2.3 Test loads and endurance

The test loads and endurance for the A-P, M-L and torsional test loading conditions at the different test loading levels shall be in accordance with Table 4.

Table 4 — Test loads and endurance

Type of test	Symbol	Test load		
		Value for		
		level A100	level A 80	level A 60
A-P and M-L loading condition				
Proof test of end attachments	F_{pa}	5 376 N	4 410 N	3 780 N
All tests	F_{stab} F_{set}	50 N 1 024 N	50 N 840 N	50 N 720 N
Static tests	F_{sp} $F_{su,ductile}$ $F_{su,brittle}$	2 240 N 3 360 N 4 480 N	1 838 N 2 756 N 3 675 N	1 575 N 2 363 N 3 150 N
Cyclic test Number of cycles: 2×10^6	F_{min} F_c F_{max}	50 N 1 280 N 1 330 N	50 N 1 050 N 1 100 N	50 N 900 N 950 N
Torsional loading condition				
All tests	$M_{u'stab}$ $M_{u'set}$	1 Nm 3 Nm		
Static torsional test	$M_{u'sp}$	50 Nm		
Cyclic torsional test Number of cycles: 2×10^6	$M_{u'min}$ $M_{u'c}$ $M_{u'max}$	1 Nm 30 Nm 31 Nm		

8 Test submission document

8.1 Document need

The test submission document shall accompany each item submitted for testing in accordance with clauses 5, 6 and 7. It shall provide the information specified in 8.2 to 8.4.

8.2 General requirements

8.2.1 The manufacturer/submitter shall prepare the test submission document with any associated information and shall provide at least one copy with every item submitted for test.

8.2.2 The manufacturer/submitter shall clearly indicate a name and address for communication purposes. If appropriate, the identity of the original equipment manufacturer shall be provided.

8.2.3 A unique and traceable identification for the test submission document shall be provided by the manufacturer/submitter who shall maintain a record of such identification. This identification shall also be applied to the test sample.

8.2.4 The test laboratory/facility required to conduct the test shall be clearly indicated.

8.2.5 The date of submission or dispatch to the test laboratory/facility shall be clearly indicated.

8.3 Information required for test samples

8.3.1 All test samples

The following information, attributable to a fully traceable identification for each test sample, shall be included in the test submission document:

a) manufacturer's name or other means of identification (for each component if a test sample consists of parts from different manufacturers);

b) manufacturer's model identification name and/or number (for each component if a test sample consists of parts from different manufacturers);

c) type of test sample in accordance with 5.1;

d) if appropriate, any certifications from the manufacturer which states that the test sample has been taken from normal production and which gives details of the method of selection in accordance with 5.3;

e) identification of effective centrelines and effective centres in accordance with 5.2.2 and 5.5.2;

f) record of any load application levers and their static alignment in accordance with 5.2.4;

g) any special alignment instructions for the test sample and/or attachments in accordance with 5.2.5;

h) tightening torque settings for connecting bolts (particularly applicable to test samples for torsional tests in accordance with 6.5.2.1 and 6.5.3.2.1).

8.3.2 Test samples for all A-P and M-L tests

Identification of the worst-case alignment position in accordance with 5.5.3.

8.4 Information required for tests

8.4.1 General

For each test sample, the information specified in 8.4.2 to 8.4.6 shall be included in the test submission document.

8.4.2 For all tests

Specify

a) the particular test requested, with reference to the relevant subclauses of clauses 6 and 7;

b) the particular set-up dimensions and the loads to be applied during the test in accordance with 6.3.1 and clause 7.

8.4.3 For all A-P and M-L tests

Specify the worst-case alignment position in accordance with 6.4.1.1.

8.4.4 For all torsional tests

Specify identification of the midpositions of all adjustable components in accordance with 6.5.2.1.

8.4.5 For all cyclic tests

Specify

a) replacement intervals of specified parts in accordance with 6.4.4.1.6 and 6.5.3.1.6;

b) if appropriate, request for visual examination of the test sample after successful completion of the cyclic test in accordance with 6.4.4.1.7 and 6.5.3.1.7;

c) the test frequency called for in accordance with 6.4.4.2.11 and 6.5.3.2.11.

8.4.6 For A-P and M-L static failure tests

If appropriate, request for continuation of the test until failure actually occurs in accordance with the last paragraph of 6.4.3.7. This request shall include instructions concerning the documentation of test results.

9 Test report

9.1 General requirements

9.1.1 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.

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

9.1.3 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.

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

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

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

9.1.7 All records called for in the relevant subclauses of clause 6 shall be copied into the test report.

9.2 Records required for all test samples

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

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 5.1;

c) the load application levers used in accordance with 5.2.4;

d) the alignment of the sample in accordance with 5.2.4, 5.2.6 and 5.5;

e) tightening torque settings for connecting bolts (particularly applicable to test samples for torsional tests in accordance with 6.5.2.1 and 6.5.3.2.1).

9.3 Records required for all tests

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

a) the particular test carried out in accordance with the relevant subclauses of clauses 6 and 7. In special cases reference to the test submission document will be necessary;

b) the particular set-up dimensions and the loads applied during the test in accordance with 6.3.1 and clause 7;

c) proof test of attachments (if required) in accordance with 6.3.2;

d) any particular arrangement in accordance with the second paragraph of 6.4.1.2 and the notes following 6.4.1.3, 6.4.4.2.8 and/or 6.5.3.2.6;

e) accuracy of test equipment and individual measurements in accordance with 6.8.

9.4 Records required for results of A-P and M-L tests

9.4.1 General

For each test sample, the information specified in 9.4.2 to 9.4.4 shall be included in the test report.

9.4.2 Results of static A-P and M-L proof tests

Include records of

a) measurements of offsets, effective lever arms, and lengths or displacements in accordance with 6.4.2.1, 6.4.2.5 and 6.4.2.8 and calculation of deformation in accordance with 6.4.2.9;

b) examination/inspection of function in accordance with 6.4.2.11;

c) load at, and nature of, any failure in accordance with 6.4.2.12.

9.4.3 Results of static A-P and M-L failure tests

Include records of

a) measurements of offsets and effective lever arms in accordance with 6.4.3.1 and 6.4.3.5;

b) the ultimate test force F_{su} in accordance with 6.4.3.6 and 6.4.3.7;

c) at the request of the manufacturer/submitter, results of the continuation of test until failure actually occurs in accordance with the last paragraph of 6.4.3.7;

d) the mode of failure in accordance with 6.4.3.8.

9.4.4 Results of cyclic A-P and M-L tests

Include records of

a) measurements of offsets, effective lever arms, and lengths or displacements in accordance with 6.4.4.2.1, 6.4.4.2.5, 6.4.4.2.6, 6.4.4.2.9 and 6.4.4.2.13;

b) the number of cycles for the test to settle down in accordance with 6.4.4.2.8.

c) the test frequency in accordance with 6.4.4.2.11;

d) the details of all switch-off occurrences in accordance with 6.4.4.2.14;

e) the replacement parts in accordance with 6.4.4.1.6;

f) the number of cycles at failure or the endurance in accordance with 6.4.4.2.15;

g) the nature of any failure in accordance with 6.4.4.2.16;

h) at the request of the manufacturer/submitter, the presence and nature of any cracks detected by visual examination in accordance with 6.4.4.1.7;

i) results of the final static test to proof loading level in accordance with 6.4.4.1.8 and 6.4.4.2.17.

9.5 Records required for results of torsional tests

9.5.1 Inclusion of records

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

9.5.2 Results of static torsional test

Include records of

a) the tightening torque of any joint-clamping bolts in accordance with 6.5.2.1;

b) measurements of the initial and final angular positions of the bottom and top components of the test sample in accordance with 6.5.2.5 or 6.5.2.7, respectively;

c) the time elapsed for testing and for measuring the final angular positions of the bottom and top components of the test sample in accordance with 6.5.2.6 and 6.5.2.7;

d) calculation of the relative angular movement between the ends of the test sample in accordance with 6.5.2.8.

9.5.3 Results of cyclic torsional test

Include records of

a) the tightening torque of any joint-clamping bolts in accordance with 6.5.2.1;

b) measurements of angular positions of the bottom and top components of the test sample in accordance with 6.5.3.2.5, 6.5.3.2.7 and 6.5.3.2.12;

c) calculation of the relative angular movement between the ends of the test sample in accordance with 6.5.3.2.8 and 6.5.3.2.12;

d) the number of cycles for the test to settle down in accordance with 6.5.3.2.6;

e) the test frequency in accordance with 6.5.3.2.10;

f) the details of all switch-off occurrences in accordance with 6.5.3.2.13;

g) the replacement of specified parts in accordance with 6.5.3.1.6;

h) the number of cycles at failure or the endurance in accordance with 6.5.3.2.14;

i) the nature of any failure in accordance with 6.5.3.2.15;

j) at the request of the manufacturer/submitter, the presence and nature of any cracks detected by visual examination in accordance with 6.5.3.1.7;

k) results of the final static test to proof loading level in accordance with 6.5.3.1.8 and 6.5.3.2.16.

Annex A
(normative)

Description of internal loads and their effects

A.1 General

The test loading conditions specified in this International Standard are based on internal reference loads consisting of an axial force (axial compression), bending moments and a twisting moment described in A.3.

The reference forces and moments act respectively along and about reference lines. The moment reference lines are specified in A.2.

A.2 Moment reference lines

A.2.1 General

The moment reference lines are those lines about which the moments specified in A.3 act. They are specified as follows using the elements of the geometric system described in clause 4.

A.2.2 Knee moment reference lines

A.2.2.1   The knee moment reference line $K_{f'}$ is the line of intersection of the knee reference plane (K) with the f'-u'-plane.

A.2.2.2   The knee moment reference line $K_{o'}$ is the line of intersection of the knee reference plane (K) with the o'-u'-plane.

A.2.3 Hip moment reference lines

A.2.3.1   The hip moment reference line $H_{f'}$ is the line of intersection of the hip reference plane (H) with the f'-u'-plane.

A.2.3.2   The hip moment reference line $H_{o'}$ is the line of intersection of the hip reference plane (H) with the o'-u'-plane.

A.3 Internal loads

A.3.1 General

The internal forces and moments are indicated in the following subclauses, together with anatomical descriptions of their effects. Table A.1 contains a list of these, together with alternative descriptions for the movements which positive forces and moments tend to cause.

For a left-sided application, the axial force, all bending moments and the twisting moment $M_{u'}$ are positive as illustrated in Figure A.1.

For a right-sided application, the mirror image applies (see 4.1 and Figure 1). As a consequence the bending moments $M_{Kf'}$, $M_{Hf'}$ and the twisting moment $M_{u'}$ are positive in the opposite direction (see Figure A.1).
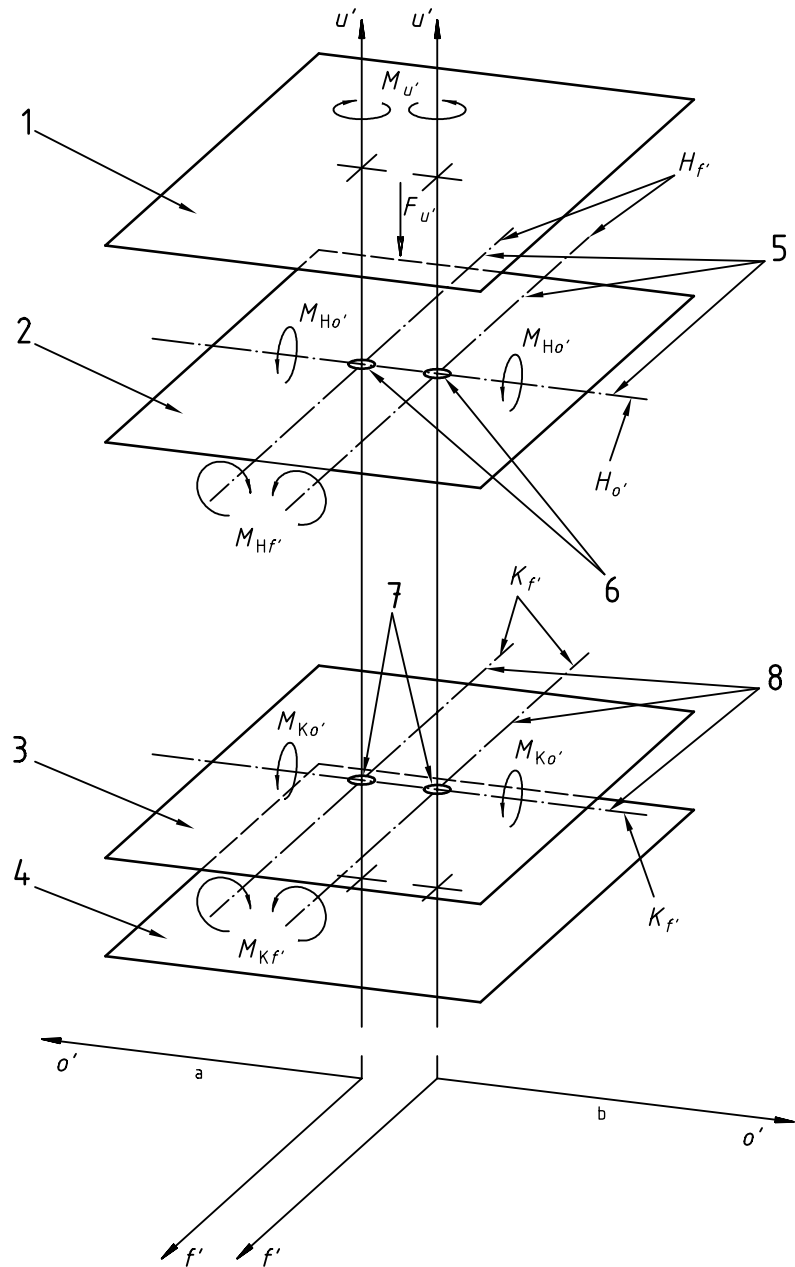
Key

1 Top reference plane, TH
2 Hip reference plane, H
3 Knee reference plane, K
4 Bottom reference plane, BK
5 Hip moment reference line
6 Effective hip joint centre
7 Effective knee joint centre
8 Knee moment reference line
a Right
b Left

Figure A.1 — Coordinate system according to 4.2, illustrating positive directions of internal (reaction) loads, comprising axial force $F_{u'}$ and bending moments $M_{Ko'}$, $M_{Kf'}$, $M_{Ho'}$ and $M_{Hf'}$, generated in the upper (proximal) part of the test piece by the lower (distal) part through the load actions applied in the bottom reference plane

A.3.2 Axial force $F_{u'}$ (axial compression)

The axial force $F_{u'}$ is the force component along the u'-axis of the coordinate system according to 4.2. Positive $F_{u'}$ tends to compress the thigh segment of the hip disarticulation prosthesis in its longitudinal direction.

A.3.3 Moments

A.3.3.1 Knee bending moment, $M_{\mathrm{K}o'}$

The knee bending moment $M_{\mathrm{K}o'}$ is the moment about the knee moment reference line $\mathrm{K}_{o'}$. Positive $M_{\mathrm{K}o'}$ tends to cause extension at the knee joint.

A.3.3.2 Knee bending moment, $M_{\mathrm{K}f'}$

The knee bending moment $M_{\mathrm{K}f'}$ is the moment about the knee moment reference line $\mathrm{K}_{f'}$. Positive $M_{\mathrm{K}f'}$ tends to cause a lateral movement of the knee relative to the hip.

A.3.3.3 Hip bending moment, $M_{\mathrm{H}o'}$

The hip bending moment $M_{\mathrm{H}o'}$ is the moment about the hip moment reference line $\mathrm{H}_{o'}$. Positive $M_{\mathrm{H}o'}$ tends to cause flexion at the hip joint.

A.3.3.4 Hip bending moment, $M_{\mathrm{H}f'}$

The hip bending moment $M_{\mathrm{H}f'}$ is the moment about the hip moment reference line $\mathrm{H}_{f'}$. Positive $M_{\mathrm{H}f'}$ tends to cause adduction at the hip joint.

A.3.3.5 Twisting moment (torque), $M_{u'}$

The twisting moment $M_{u'}$ is the moment about the u'-axis of the coordinate system according to 4.2. Positive $M_{u'}$ tends to cause internal rotation of the distal end of the thigh segment of the hip disarticulation prosthesis relative to the proximal end.

Table A.1 — Positive internal force and moments with descriptions of their effects

Internal load		Anatomical description	Alternative description
		Positive load tends to	
Axial force	$F_{u'}$	compress the thigh in its longitudinal direction	
Knee moment	$M_{\mathrm{K}o'}$	cause extension at the knee joint	straighten the knee
Knee moment	$M_{\mathrm{K}f'}$	cause a lateral movement at the knee relative to the hip	move the knee in an outward direction relative to the hip
Hip moment	$M_{\mathrm{H}o'}$	cause flexion at the hip joint	move the thigh in a forward direction
Hip moment	$M_{\mathrm{H}f'}$	cause adduction at the hip joint	move the thigh in an inward direction
Twisting moment	$M_{u'}$	cause internal rotation of the distal end of the thigh relative to the proximal end	twist the thigh to turn the front side of the knee inwards

Annex B
(informative)

Reference data for the specification of the A-P, M-L and torsional test loading conditions at different test loading levels

B.1 Background statement on test loading levels

Since the start of the work by ISO Technical Committee ISO/TC 168, some countries have established an adverse event reporting system. At the time of publication, this has shown a low field failure rate associated with testing, based on the data of all users, to a single test loading level.

The test loading level A100 according to the categorization of 6.2.3 is based on this single test loading level and, additionally, on a statistical analysis of data included in the final report of a recent international study concerned with the acquisition of loads exerted on hip disarticulation prostheses by amputees during daily use in indoor and outdoor environment (see the Bibliography).

Test loading levels A80 and A60 according to the categorization of 6.2.3 are based on a statistical analysis of the data referred to in the foregoing paragraph and require validation by field experience.

B.2 Specification of the A-P, M-L and torsional test loading conditions

The data referred to in clause B.1 establishes the basis from which to specify the parameters and values for the A-P, M-L and torsional test loading conditions at the different test loading levels according to the categorization of 6.2.3.

Table B.1 contains the values of the knee and hip bending moments M_K and M_H as specified in annex A and the test force F for the A-P and M-L test loading conditions.

Table B.2 contains the values of the twisting moment $M_{u'}$.

Table B.3 gives formulae for calculating the axial force $F_{u'}$ as specified in annex A from given values of test force F, knee and hip bending moments M_K and M_H and distance u'_H - u'_K.

Table B.4 gives formulae for calculating effective lever arms and offsets from given values of test force F, axial force $F_{u'}$ and knee and hip bending moments M_K and M_H.

Table B.5 gives formulae for calculating offsets at any height (see Table 3).

Table B.1 — Values of knee and hip bending moments M_K and M_H and test force F for A-P and M-L test loading conditions

Test load			Test load level	Test loading conditions		
				A-P extension	A-P flexion	M-L
Test force	F	N	A 100	1 280	1 280	1 280
			A 80	1 050	1 050	1 050
			A 60	900	900	900
Knee bending moment	$M_{Ko'}$	Nm	A 100	80	0	0
			A 80	73	0	0
			A 60	65	0	0
Hip bending moment	$M_{Ho'}$	Nm	A 100	−100	37	0
			A 80	−82	37	0
			A 60	−64	37	0
Knee bending moment	$M_{Kf'}$	Nm	A 100	0	0	60
			A 80	0	0	60
			A 60	0	0	60
Hip bending moment	$M_{Hf'}$	Nm	A 100	0	0	110
			A 80	0	0	95
			A 60	0	0	75

Table B.2 — Values of twisting moment $M_{u'}$

Test loading condition			Static test	Cyclic test
Axial torsion	$M_{u'}$	Nm	50	30

Table B.3 — Formulae for calculating the axial force $F_{u'}$ from given values of test force F, knee and hip bending moments M_K and M_H and distance $u'_H - u'_K$

A-P test loading conditions:	$F_{u'} = \sqrt{F^2 - \left(\dfrac{M_{Ho'} - M_{Ko'}}{u'_H - u'_K} \right)^2}$
M-L test loading conditions:	$F_{u'} = \sqrt{F^2 - \left(\dfrac{M_{Hf'} - M_{Kf'}}{u'_H - u'_K} \right)^2}$

Table B.4 — Formulae for calculating effective lever arms and offsets from given values of test force F, axial force $F_{u'}$ and knee and hip bending moments M_K and M_H

Level	A-P test loading conditions		M-L test loading conditions	
	effective lever arms mm	offsets mm	effective lever arms mm	offsets mm
Knee	$L_K = \dfrac{M_{Ko'}}{F}$	$f'_K = \dfrac{M_{Ko'}}{F_{u'}}$	$L_K = \dfrac{M_{Kf'}}{F}$	$o'_K = \dfrac{M_{Kf'}}{F_{u'}}$
Hip	$L_H = \dfrac{M_{Ho'}}{F}$	$f'_H = \dfrac{M_{Ho'}}{F_{u'}}$	$L_H = \dfrac{M_{Hf'}}{F}$	$o'_H = \dfrac{M_{Hf'}}{F_{u'}}$

Table B.5 — Formulae for calculating offsets at any height, u_x

A-P extension test loading condition

$$f'_x = f'_K + \frac{\left(f'_H - f'_K\right)\left(u'_x - u'_K\right)}{\left(u'_H - u'_K\right)} \quad \text{or} \quad f'_x = f'_H + \frac{\left(f'_H - f'_K\right)\left(u'_x - u'_H\right)}{\left(u'_H - u'_K\right)}$$

A-P flexion test loading condition

$$f'_x = \frac{f'_H\left(u'_x - u'_K\right)}{\left(u'_H - u'_K\right)} \quad \text{or} \quad f'_x = f'_H + \frac{f'_H\left(u'_x - u'_H\right)}{\left(u'_H - u'_K\right)}$$

M-L test loading condition

$$o'_x = o'_K + \frac{\left(o'_H - o'_K\right)\left(u'_x - u'_K\right)}{\left(u'_H - u'_K\right)} \quad \text{or} \quad o'_x = o'_H + \frac{\left(o'_H - o'_K\right)\left(u'_x - u'_H\right)}{\left(u'_H - u'_K\right)}$$

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