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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.

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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.

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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.

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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

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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).

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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}.

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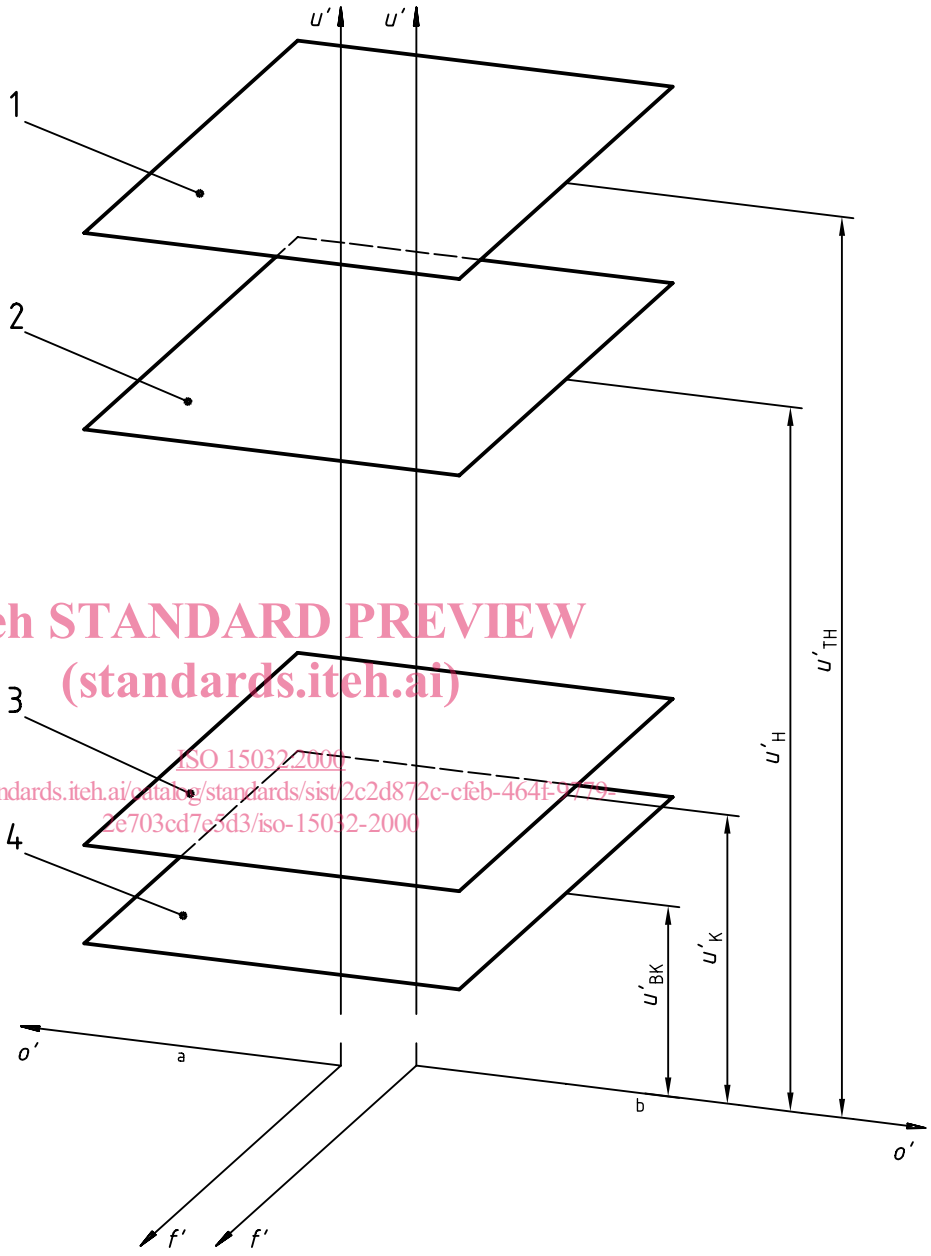

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Key

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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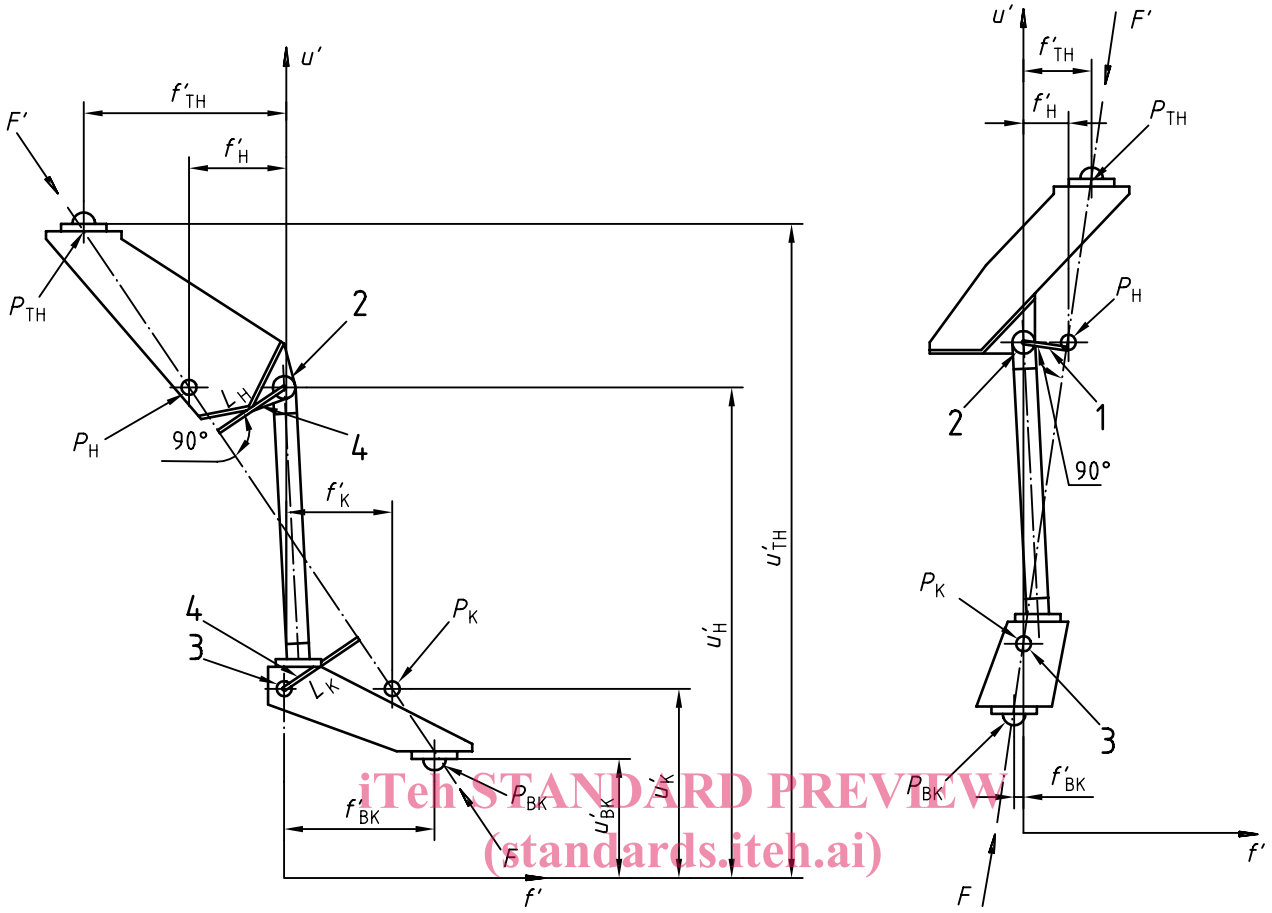

a) A-P ext. test loading condition

b) A-P flex. test loading condition

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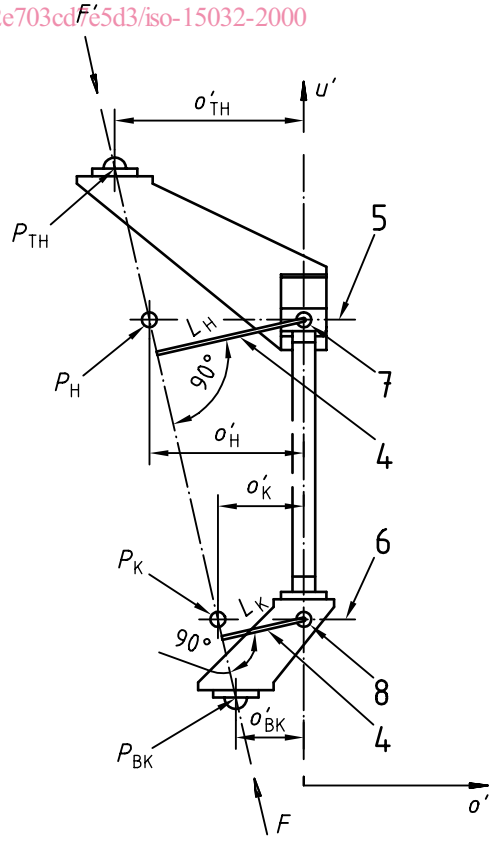

c) M-L test loading condition

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

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

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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.

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4.7 Reference distances

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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