INTERNATIONAL STANDARD

ISO 10328-1

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Prosthetics — Structural testing of lower-limb prostheses —

Part 1:
Test configurations

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs

Partie 1: Configurations d'essai

Reference number
ISO 10328-1:1996(E)

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.

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.

International Standard ISO 10328-1 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

ISO 10328 consists of the following parts, under the general title *Prosthetics — Structural testing of lower-limb prostheses*:

— *Part 1: Test configurations*

— *Part 2: Test samples*

— *Part 3: Principal structural tests*

— *Part 4: Loading parameters of principal structural tests*

— *Part 5: Supplementary structural tests*

— *Part 6: Loading parameters of supplementary structural tests*

— *Part 7: Test submission document*

— *Part 8: Test report*

Annex A of this part of ISO 10328 is for information only.

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Introduction

Throughout all parts of ISO 10328, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent or deficient limb segment.

As a result of concern in the international community about the need to provide prostheses that are safe in use, and also because of an awareness that test standards would assist the development of better prostheses, a series of meetings was held under the aegis of the International Society for Prosthetics and Orthotics (ISPO). The final meeting was held in Philadelphia, PA, USA in 1977, at which a preliminary consensus was reached on methods of testing and the required load values. From 1979 onwards this work was continued by ISO Technical Committee 168, leading to the development of this series of International Standards. The test procedures may not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subject to a series of load actions, each varying individually with time. The test methods specified in ISO 10328 use static and cyclic strength tests in which, with one exception, compound loadings are produced by the application of a single test force.

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. ISO 10328 specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of lower-limb prostheses and their components requires controlled field trials in addition to the laboratory tests specified in the different parts of ISO 10328.

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 user 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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Prosthetics — Structural testing of lower-limb prostheses —

Part 1:
Test configurations

1 Scope

ISO 10328 specifies procedures for static and cyclic strength tests of lower-limb prostheses where, with one exception, compound loadings are produced by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.

The tests described in ISO 10328 apply to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses.

NOTE — The tests may be performed on complete structures, on partial structures, or on individual components.

This part of ISO 10328 specifies the test configurations by defining

— the coordinate systems;

— the location of a test sample within each of the coordinate systems;

— the position of the line of application of the test force within each of the coordinate systems.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 10328. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 10328 are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO 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.*

ISO 10328-2:1996, *Prosthetics — Structural testing of lower-limb prostheses — Part 2: Test samples.*

3 Definitions

For the purposes of this part of ISO 10328, the definitions given in ISO 8549-1 apply.

4 Test configurations

4.1 For ease in interpretation and presentation, 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 in asymmetrically designed prosthetic components.

4.2 Each test configuration shall be a three-dimensional, rectangular coordinate system (see figure 1), containing a geometric system of planes, lines and points (see figures 2 and 3).

4.3 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.

5 Axes

5.1 The axes of each of the coordinate systems have an origin at ground level and are specified in 5.2 to 5.4 in relation to a prosthesis which is standing on the ground in a vertical position.

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

5.2 The *u*-axis is a line extending from the origin and passing through the effective ankle joint centre and the effective knee joint centre (see ISO 10328-2:1996, 7.2 and 7.4 and figures 1 and 2). Its positive direction is upwards (in the proximal direction).

5.3 The *o*-axis is perpendicular to the *u*-axis and parallel to the effective knee joint centreline (see ISO 10328-2:1996, 7.3 and figure 1). 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.

5.4 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).

6 Reference planes

The reference planes (see figures 2 and 3) shall be parallel planes perpendicular to the *u*-axis. They are specified in 6.1 to 6.4.

6.1 Bottom reference plane, B

The bottom reference plane (B) is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see clause 7).

6.2 Ankle reference plane, A

The ankle reference plane (A) is located at a distance $u = u_A$ from the origin. It contains the effective ankle joint centre (see ISO 10328-2:1996, 7.2).

6.3 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 ISO 10328-2:1996, 7.4).

6.4 Top reference plane, T

The top reference plane (T) is located at a distance $u = u_T$ from the origin. It contains the top load application point P_T (see clause 7).

NOTE — The reference planes specified in 6.1 to 6.4 also contain reference lines which relate to ISO 10328-3:1996, annex A.

7 Reference points

The reference points shall be the points of intersection of the load line (see clause 9) with the reference planes. The coordinates of the reference points are as follows:

— bottom load application point, $P_B(f_B,o_B,u_B)$;

— ankle load reference point, $P_A(f_A,o_A,u_A)$;

— knee load reference point, $P_K(f_K,o_K,u_K)$;

— top load application point, $P_T(f_T,o_T,u_T)$.

NOTE — In the subsequent parts of ISO 10328, the *f*- and *o*-coordinates are also referred to as offsets.

8 Test force

The test force F is a single compressive load applied to the bottom and top load application points P_B and P_T specified in clause 7.

9 Load line

The load line shall be the line of application of the test force F. The load line passes through the reference points specified in clause 7.

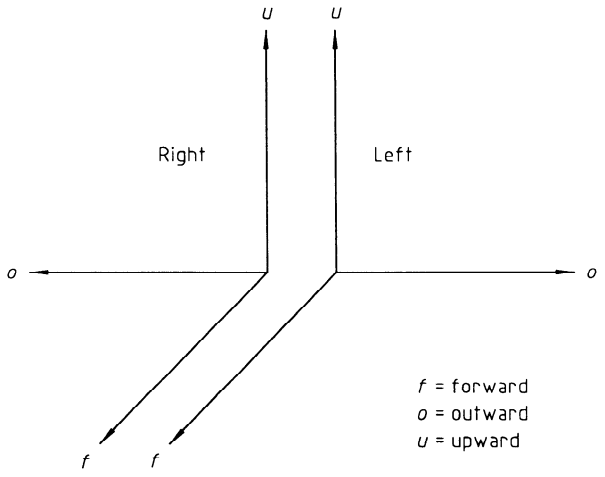


Figure 1 — Coordinate systems for right- and left-sided application

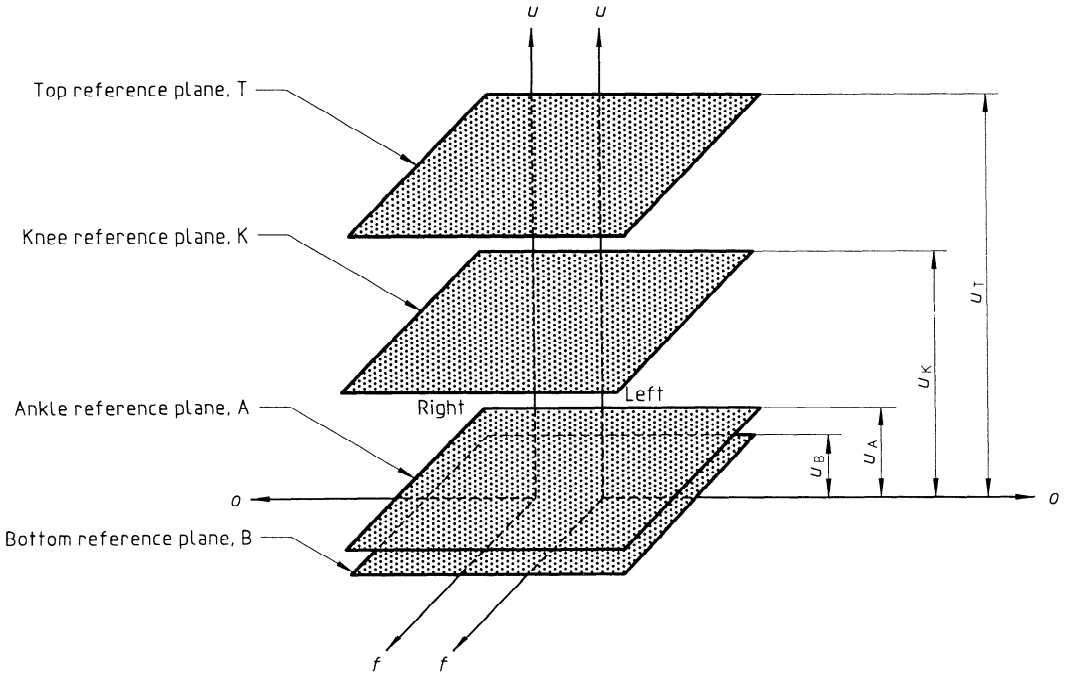
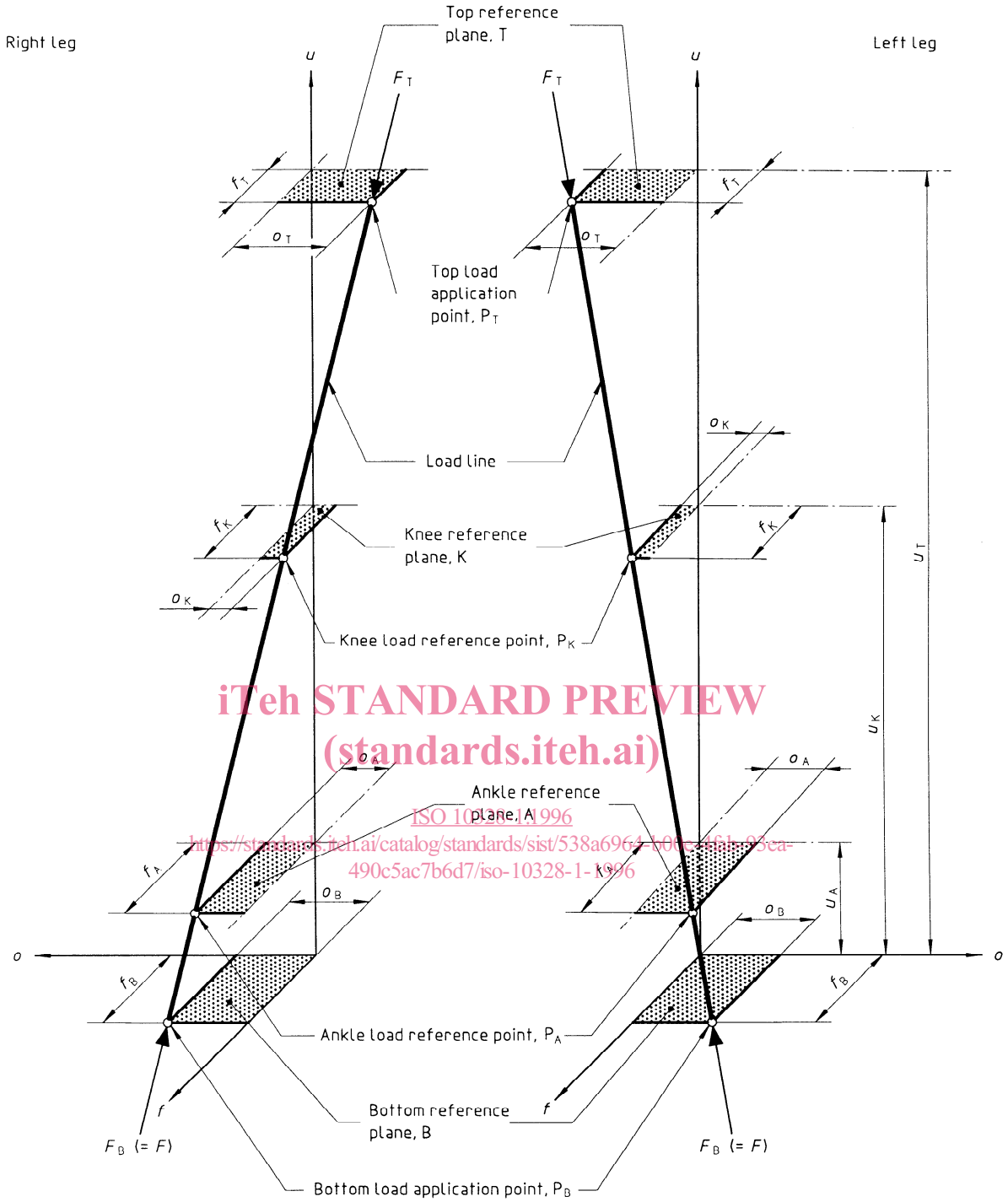


Figure 2 — Coordinate systems with reference planes



NOTE — This figure illustrates a typical test loading condition that occurs in normal gait. It does not illustrate the test loading conditions I and II specified in ISO 10328-3:1996, subclause 4.3.

Figure 3 — Specific configuration with $u_B = 0$, showing coordinate systems with reference planes, reference lines, reference points and test force F