
**Prosthetics — Structural testing
of lower-limb prostheses —
Requirements and test methods**

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai

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Contents

	Page
Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Designations and symbols of test forces and moments	2
5 Strength and related performance requirements and conditions of use	3
6 Coordinate systems and test configurations	5
6.1 General.....	5
6.2 Axes of coordinate systems.....	5
6.3 Reference planes.....	5
6.3.1 General.....	5
6.3.2 Top reference plane, T.....	5
6.3.3 Knee reference plane, K.....	5
6.3.4 Ankle reference plane, A.....	6
6.3.5 Bottom reference plane, B.....	6
6.4 Reference points.....	7
6.5 Test force.....	8
6.6 Load line.....	8
6.7 Longitudinal axis of the foot and effective joint centres and centrelines.....	8
6.7.1 General.....	8
6.7.2 Longitudinal axis of the foot.....	8
6.7.3 Effective ankle-joint centre.....	8
6.7.4 Effective ankle-joint centreline.....	10
6.7.5 Effective knee-joint centreline.....	10
6.7.6 Effective knee-joint centre.....	11
6.8 Reference distances.....	11
6.8.1 Offsets.....	11
6.8.2 Combined offsets.....	11
6.8.3 Effective lever arms L_A and L_K	11
6.8.4 Distance L_{BT}	11
7 Test loading conditions and test loading levels	11
7.1 Test loading conditions.....	11
7.1.1 General.....	11
7.1.2 Test loading conditions of principal structural tests.....	12
7.1.3 Test loading conditions of separate structural tests.....	12
7.2 Test loading levels.....	12
8 Values of test loads, dimensions and cycles	13
9 Compliance	20
9.1 General.....	20
9.2 Selection of tests required to claim compliance with this International Standard.....	21
9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this International Standard.....	21
9.3.1 General.....	21
9.3.2 Particular arrangements concerning the ankle-foot device or foot unit.....	21
9.3.3 Particular arrangements and requirements concerning the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure.....	21
9.4 Number of tests and test samples required to claim compliance with this International Standard.....	22
9.5 Multiple use of test samples.....	22

9.5.1	General	22
9.5.2	Restriction	22
9.6	Testing at particular test loading levels not specified in this International Standard	23
10	Test samples	25
10.1	Selection of test samples	25
10.1.1	General	25
10.1.2	Selection of ankle-foot devices and foot units of appropriate size of foot	26
10.2	Types of test samples	27
10.2.1	Complete structure	27
10.2.2	Partial structure	29
10.2.3	Any other structure	29
10.3	Preparation of test samples	29
10.4	Identification of test samples	30
10.5	Alignment of test samples	31
10.5.1	Test samples for principal tests and separate tests on knee locks	31
10.5.2	Test samples for separate tests on ankle-foot devices and foot units	31
10.5.3	Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts	31
10.5.4	Test samples for separate tests on knee locks	32
10.6	Worst-case alignment position of test samples	32
11	Responsibility for test preparation	33
12	Test submission document	34
12.1	General requirements	34
12.2	Information required for test samples	35
12.2.1	All test samples	35
12.2.2	Test samples for tests on ankle-foot devices and foot units	35
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts	35
12.3	Information required for tests	35
12.3.1	General	35
12.3.2	For all tests	35
12.3.3	For static tests in torsion and on ankle-foot devices and foot units	36
12.3.4	For static ultimate strength tests	36
12.3.5	For cyclic tests	36
12.3.6	For tests in torsion	36
12.3.7	For tests on ankle-foot devices and foot units	36
13	Equipment	37
13.1	General	37
13.2	Equipment for the principal tests specified in 16.2 and 16.3	37
13.2.1	End attachments	37
13.2.2	Jig (optional)	39
13.2.3	Test equipment	40
13.3	Equipment for the separate static test in torsion specified in 17.1	42
13.3.1	Test equipment	42
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2	42
13.4.1	Test equipment	42
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3	46
13.5.1	Extension pieces	46
13.5.2	Test equipment to perform static compression loading – (Compression testing machine or other equipment)	46
13.6	Equipment for the separate tests on knee locks specified in 17.4	46
13.6.1	End attachments	46
13.6.2	Jig (optional)	46
13.6.3	Test equipment	46
14	Accuracy	47

14.1	General	47
14.2	Accuracy of equipment	47
14.3	Accuracy of procedure	47
15	Test principles	48
15.1	General	48
15.2	Static test procedure	48
15.3	Cyclic test procedure	48
16	Test procedures – Principal structural tests	48
16.1	Test loading requirements	48
16.1.1	Preparation for test loading	48
16.1.2	Application of test loading	48
16.2	Principal static test procedure	50
16.2.1	Principal static proof test	50
16.2.2	Principal static ultimate strength test	55
16.3	Principal cyclic test procedure	59
16.3.1	General requirements	59
16.3.2	Test method	59
16.3.3	Performance requirements	63
16.3.4	Compliance conditions	64
17	Test procedures — Separate structural tests	68
17.1	Separate static test in torsion	68
17.1.1	General	68
17.1.2	Purpose of test	68
17.1.3	Test method	68
17.1.4	Performance requirements	70
17.1.5	Compliance conditions	70
17.2	Separate tests on ankle-foot devices and foot units	72
17.2.1	General	72
17.2.2	Purpose of tests	72
17.2.3	Separate static proof test for ankle-foot devices and foot units	72
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units	76
17.2.5	Separate cyclic test for ankle-foot devices and foot units	81
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts	86
17.3.1	General	86
17.3.2	Purpose of test	86
17.3.3	Applicability of the test to specific test samples	86
17.3.4	Test method	87
17.3.5	Performance requirement	88
17.3.6	Compliance conditions	88
17.4	Separate tests on knee locks	89
17.4.1	General	89
17.4.2	Purpose of tests	90
17.4.3	Separate static proof test for knee locks	90
17.4.4	Separate static ultimate strength test for knee locks	94
17.4.5	Separate cyclic test for knee locks	96
18	Test laboratory/facility log	105
18.1	General requirements	105
18.2	Specific requirements	105
19	Test report	105
19.1	General requirements	105
19.2	Specific requirements	106
19.3	Options	106
20	Classification and designation	106
20.1	General	106

20.2	Examples of classification and designation.....	106
21	Labelling	107
21.1	General.....	107
21.2	Use of mark “*”) and warning symbol.....	108
21.3	Examples of label layout.....	108
21.4	Label placement.....	108
Annex A	(informative) Description of internal loads and their effects	110
Annex B	(informative) Reference data for the specification of test loading conditions and test loading levels of principal cyclic tests	114
Annex C	(informative) Guidance on the application of an alternative static ultimate strength test	118
Annex D	(normative) Guidance on the application of an additional test loading levels P6, P7 and P8	119
Annex E	(informative) Summary of the records to be entered in the test laboratory/facility log 122	
Annex F	(informative) Background information on the loading profiles generated by test equipment according to 13.4.1.2 for separate cyclic tests for ankle-foot devices and foot units according to 17.2.5.1	137
Annex G	(informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142	139
Bibliography	140

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics*.

This second edition cancels and replaces the first edition ISO 10328:2006 which has been technically revised with the following changes:

- a) Test loading levels P7 and P8 have been introduced in [Table B.1](#), [Table B.2](#), [Table B.3](#), [Table 4.1](#), [Table D.1](#), [Table D.2](#), [Table D.3](#) and the clauses pointing at these tables have been updated. Additional information on P7 and P8 is given in Annex B.1;
- b) [Table 9](#) has been revised;
- c) [Annex D](#) has changed from informative to normative.

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.

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 one 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 ISO 10328:1996. The test procedures may not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subjected to a series of load actions, each varying individually with time. The test methods specified in this International Standard use static and cyclic strength tests which typically produce compound loadings 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. 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 lower-limb 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 user activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be determined.

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of lower limb prosthetic devices/structures with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE 1). Prosthetic ankle-foot devices and foot units on the market, which have demonstrated their compliance with the strength requirements specified in 4.4 of ISO 22523:2006 through submission to the relevant tests of ISO 10328:2006, need not be retested to ISO 22675:2016.

WARNING — This International Standard is *not suitable* to serve as a guide for the selection of a specific lower limb prosthetic device/structure in the prescription of an individual lower limb prosthesis! Any disregard of this warning can result in a safety risk for amputees.

This International Standard specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 2) which typically produce compound loadings 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 this International Standard comprise

- principal static and cyclic tests for all components;
- a separate static test in torsion for all components;
- separate static and cyclic tests on ankle-foot devices and foot units for all ankle-foot devices as single components including ankle units or ankle attachments and all foot units as single components;
- a separate static ultimate strength test in maximum knee flexion on knee joints and associated parts for all knee units or knee-shin-assemblies and adjacent components that normally provide the flexion stop on a complete prosthesis;
- separate static and cyclic tests on knee locks for all mechanisms which lock the knee joint in the extended position of the knee unit or knee-shin-assembly.

The tests described in this International Standard apply to specific types of ankle-disarticulation prostheses (see NOTE 2), to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses and to the distal (lower) part of hip-disarticulation and hemi-pelvectomy prostheses (see NOTE 3).

NOTE 1 The tests can be performed on complete structures, on part structures or on individual components.

NOTE 2 The tests only apply to ankle-disarticulation prostheses which include (foot) components of prosthetic ankle-foot devices taken from the normal production line.

NOTE 3 The distal part comprises the knee unit, the ankle-foot device and all parts between. Tests on hip units are described in ISO 15032.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8549-1:1989, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

ISO 22523:2006, *External limb prostheses and external orthoses — Requirements and test methods*

ISO 22675:2016, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions in ISO 8549-1:1989 and the following definitions apply.

3.1 proof strength

static load representing an occasional severe event, which can be sustained by the prosthetic device/structure and still allow it to function as intended

3.2 ultimate strength

static load representing a gross single event, which can be sustained by the prosthetic device/structure but which could render it thereafter unusable

3.3 fatigue strength

cyclic load which can be sustained by the prosthetic device/structure for a given number of cycles

3.4 batch

set of test samples of a prosthetic device/structure submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this International Standard

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4 Designations and symbols of test forces and moments

The designations and symbols of all relevant test forces and moments are listed in [Table 1](#).

Table 1 — Designations and symbols of test forces and moments

Designation	Symbol
Test forces; twisting moments	$F, F_1, F_2; M_u$
Proof test force of end attachments	F_{pa}
Stabilizing test force	F_{stab}
Settling test force	F_{set}
Static proof test force	F_{sp}
Static proof test force on heel/forefoot	F_{1sp}, F_{2sp}
Static ultimate test force	F_{su}
Static ultimate test force on heel/forefoot	F_{1su}, F_{2su}
NOTE Further details of the test forces and moments listed are given in Table 3 .	

Table 1 (continued)

Designation	Symbol
Minimum test force	F_{cmin}
Maximum test force	F_{cmax}
Range of pulsating test force	F_{cr}
Mean test force	F_{cmean}
Amplitude of pulsating test force	F_{ca}
Pulsating test force	$F_c(t)$
Final static test force	F_{fin}
Minimum test force on heel/forefoot	F_{1cmin}, F_{2cmin}
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}
Mean test force on heel/forefoot	F_{1cmean}, F_{2cmean}
Amplitude of pulsating test force on heel/forefoot	F_{1ca}, F_{2ca}
Pulsating test force on heel/forefoot	$F_{1c}(t), F_{2c}(t)$
Final static test force on heel/forefoot	F_{1fin}, F_{2fin}
Stabilizing twisting moment	M_{u-stab}
Settling twisting moment	M_{u-set}
Maximum twisting moment	M_{u-max}
NOTE	Further details of the test forces and moments listed are given in Table 3.

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5 Strength and related performance requirements and conditions of use

5.1 According to ISO 22523:2006, 4.4.1, a lower limb prosthetic device/structure “... shall have the strength to sustain the loads occurring during use by amputees [...] in the manner intended by the manufacturer for that device according to his written instructions on its intended use”.

For the assessment of the conformity of lower limb prosthetic devices/structures with the above requirement (see also Scope), this International Standard provides a means of determining the three categories of strength defined in 3.1 to 3.3 and, in addition, the static strength in torsion and the security against slipping of clamped components.

All of these are listed in Table 2, together with the related performance requirements and the test methods for their verification.

5.2 In order to satisfy the general requirement in 5.1 for a specific lower limb prosthetic device/structure, the following safety concept shall apply.

The device/structure shall

- a) comply with the requirements of this International Standard (see 9.1, 9.2 and 9.3) for a specific test loading level (see 7.2)

and

- b) be used in accordance with the body mass limit specified by the manufacturer in consideration of the intended use of that device (see NOTE).

The conditions in a) and b) are regarded in **both** the classification and designation of prosthetic devices/structures according to [Clause 20](#) and their labelling according to Clause 21.

NOTE The statement of the body mass limit not to be exceeded by amputees is part of the conditions of use to be specified, with justification, by the manufacturer in his written instructions on the intended use of a specific lower limb prosthetic device/structure, taking account of all other factors affecting the loads expected to be exerted on that lower limb prosthetic device/structure by amputees (see [Clause B.1](#)).

Table 2 — Categories of strength addressed in this International Standard, together with the related performance requirements and test methods for their verification

Category of strength	Related performance requirement ^a	Test method for verification
Proof strength (see 3.1)	Structure shall sustain static loading by proof test forces at prescribed values for prescribed times	Principal static proof test (16.2.1), separately applied in two test configurations, separate static proof test for ankle-foot devices and foot units (17.2.3), successively applied in heel and forefoot loading, separate static proof test for knee locks (17.4.3), applied in a single test configuration.
	Permanent deformation of structure shall not exceed prescribed values in any loading condition	Principal static proof test (16.2.1), separate static proof test for knee locks (17.4.3)
Ultimate strength (see 3.2)	Structure shall sustain static loading by ultimate test forces at prescribed values	Principal static ultimate strength test (16.2.2), separately applied in two test configurations, separate static ultimate strength test for ankle-foot devices and foot units (17.2.4), separately applied in heel and forefoot loading, separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (17.3), separate static ultimate strength test for knee locks (17.4.4), applied in a single test configuration
Fatigue strength (see 3.3)	Structure shall sustain successively 1) static loading by maximum test forces at prescribed values for prescribed times; 2) cyclic loading by pulsating test forces at prescribed values for prescribed numbers of cycles; 3) final static loading by final test forces at prescribed values for prescribed times	Principal cyclic test (16.3), separately applied in two test configurations, separate cyclic test for ankle-foot devices and foot units (17.2.5), separately applied in heel and forefoot loading, separate cyclic test for knee locks (17.4.5), applied in a single test configuration
Static strength in torsion	Structure shall sustain static loading by static test force at prescribed value for prescribed time	Separate static test in torsion (17.1), applied in two opposite directions of twisting
Security against slippage of clamped components	Relative angular movement between ends of structure shall not exceed prescribed value	

^a The performance requirements related to a specific category of strength are specified in full length in an individual subclause following the subclause in which the test method for their verification is specified.

6 Coordinate systems and test configurations

6.1 General

6.1.1 For ease in interpretation and presentation, two test configurations are specified, one for right-sided and a mirror image for left-sided application. This measure makes it possible to apply 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.

6.1.2 Each test configuration shall be defined in a three-dimensional, rectangular coordinate system (see [Figure 1](#)), having an origin 0 and containing a geometric system of planes, lines and points (see [Figures 2](#) and [3](#)).

6.1.3 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.

6.2 Axes of coordinate systems

6.2.1 The axes of each of the coordinate systems are specified in [6.2.2](#) to [6.2.4](#) in relation to a prosthesis which is standing on the ground in an upright position.

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

6.2.2 The u -axis extends from the origin 0 of the coordinate systems (see [Figure 1](#)) and passes through the effective ankle-joint centre and the effective knee-joint centre (see [6.7.3](#) and [6.7.6](#) as well as [Figure 6](#)). Its positive direction is upwards (in the proximal direction).

6.2.3 The o -axis extends from the origin 0 perpendicular to the u -axis (see [Figure 1](#)) and parallel to the effective knee-joint centreline (see [6.7.5](#) and [Figure 6](#)). 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.

6.2.4 The f -axis extends from the origin 0 perpendicular to both the o -axis and the u -axis (see [Figure 1](#)). Its positive direction is forward towards the toe (in the anterior direction).

6.3 Reference planes

6.3.1 General

The reference planes (see [Figures 2](#) and [3](#)) shall be parallel planes perpendicular to the u -axis. They are specified in [6.3.2](#) to [6.3.5](#).

NOTE The reference planes specified in [6.3.2](#) to [6.3.5](#) also contain reference lines which relate to [Annex B](#).

6.3.2 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 [6.4](#)).

6.3.3 Knee reference plane, K

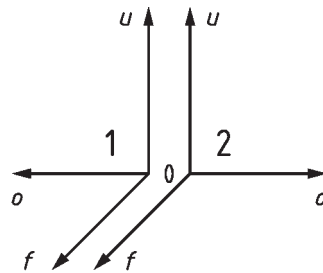
The knee reference plane, K, is located at a distance $u = u_K$ from the origin. It contains the knee load reference point P_K (see [6.4](#)) and the effective knee-joint centre (see [6.7.6](#)).

6.3.4 Ankle reference plane, A

The ankle reference plane, A, is located at a distance $u = u_A$ from the origin. It contains the ankle load reference point P_A (see 6.4) and the effective ankle-joint centre (see 6.7.3).

6.3.5 Bottom reference plane, B

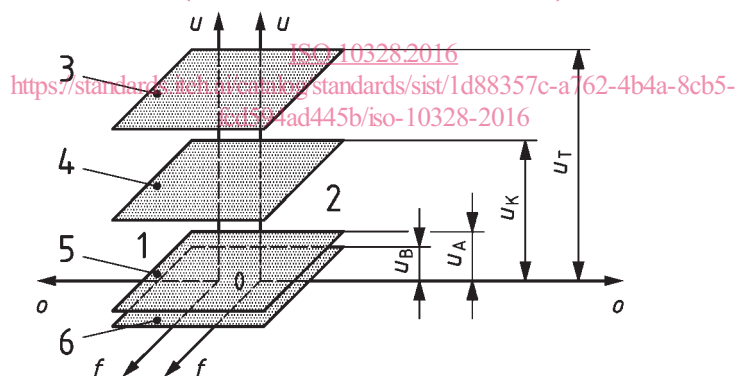
The bottom reference plane, B, is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see 6.4).



Key

- | | | | |
|---|--------|---|---------|
| 1 | right | f | forward |
| 2 | left | o | outward |
| 0 | origin | u | upward |

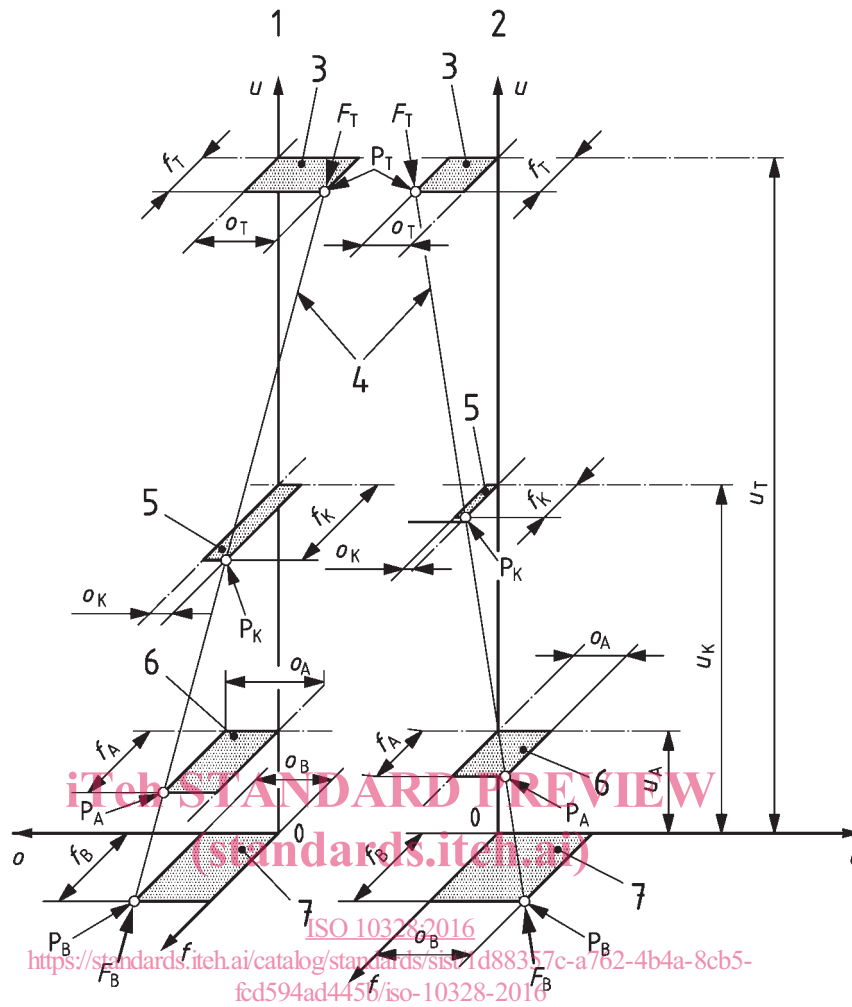
Figure 1 — Coordinate systems for right and left-sided application (standards.iteh.ai)



Key

- | | | | |
|---|------------------------|---|---------------------------|
| 1 | right | 4 | knee reference plane, K |
| 2 | left | 5 | ankle reference plane, A |
| 3 | top reference plane, T | 6 | bottom reference plane, B |

Figure 2 — Coordinate systems according to Figure 1 with reference planes



Key

- | | | | | | |
|---|------------------------|---|---------------------------|-------|-------------------------------|
| 1 | right leg | 5 | knee reference plane, K | P_T | top load application point |
| 2 | left leg | 6 | ankle reference plane, A | P_K | knee load reference point |
| 3 | top reference plane, T | 7 | bottom reference plane, B | P_A | ankle load reference point |
| 4 | load line | | | P_B | bottom load application point |

NOTE This figure illustrates a typical test loading condition representative of the condition of forefoot loading during the stance phase of normal walking. It does not illustrate the test loading conditions defined in 7.1.2.

Figure 3 — Specific configuration with $u_B = 0$, showing coordinate systems with reference planes (see Figures 1 and 2), reference lines, reference points and test force, F , for right and left-sided application

6.4 Reference points

The reference points are the points of intersection of the load line (see 6.6) with the reference planes (see Figure 3). The coordinates of the reference points are as follows:

- top load application point, $P_T (f_T, o_T, u_T)$
- knee load reference point, $P_K (f_K, o_K, u_K)$
- ankle load reference point, $P_A (f_A, o_A, u_A)$