

BS EN ISO 10328:2016



BSI Standards Publication

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods (ISO 10328:2016)

bsi.

AVA Documents
Document Sharing Hub

National foreword

This British Standard is the UK implementation of EN ISO 10328:2016. It supersedes BS EN ISO 10328:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/168, Prosthetics and orthotics.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016. Published by BSI Standards Limited 2016

ISBN 978 0 580 92522 1

ICS 11.040.40

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2016.

Amendments issued since publication

Date	Text affected
------	---------------

English Version

Prosthetics - Structural testing of lower-limb prostheses -
Requirements and test methods (ISO 10328:2016)

Prothèses - Essais portant sur la structure des
prothèses de membres inférieurs - Exigences et
méthodes d'essai (ISO 10328:2016)

Prothetik - Prüfung der Struktur von Prothesen der
unteren Gliedmaßen - Anforderungen und
Prüfverfahren (ISO 10328:2016)

This European Standard was approved by CEN on 12 May 2016.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 10328:2016) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products for persons with disability" the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 10328:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10328:2016 has been approved by CEN as EN ISO 10328:2016 without any modification.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk has to be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
9.1	5	With respect to use in combination with other devices or equipment.
9.1	20 and 21	With respect to any restrictions on use which shall be indicated on the label or in the instructions for use.
12.7.1	5, 7, 8, 9, 10, 15, 16, 17 and 18	Only covered for mechanical strength.
13.1	5, 20, and 21.4	Essential requirement 13.1 is not fully covered here; only the aspects of classification are addressed.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.3 b)	21	Only covered for classification of the use of the device.
13.3 k)	21.2	Only covered for limitations due to body mass limit and specific activities undertaken by the user.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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 .	

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

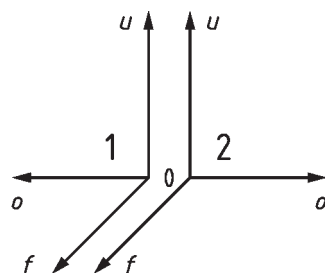
The knee reference plane, K, is located at a distance $u = u_K$ from the origin. It contains the knee load reference point P_K (see [6.4](#)) and the effective knee-joint centre (see [6.7.6](#)).

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

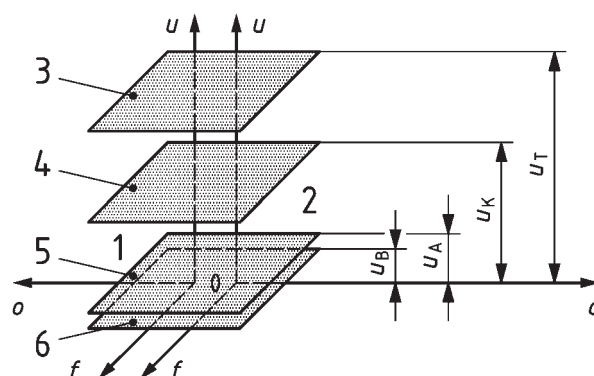
The bottom reference plane, B, is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see 6.4).



Key

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

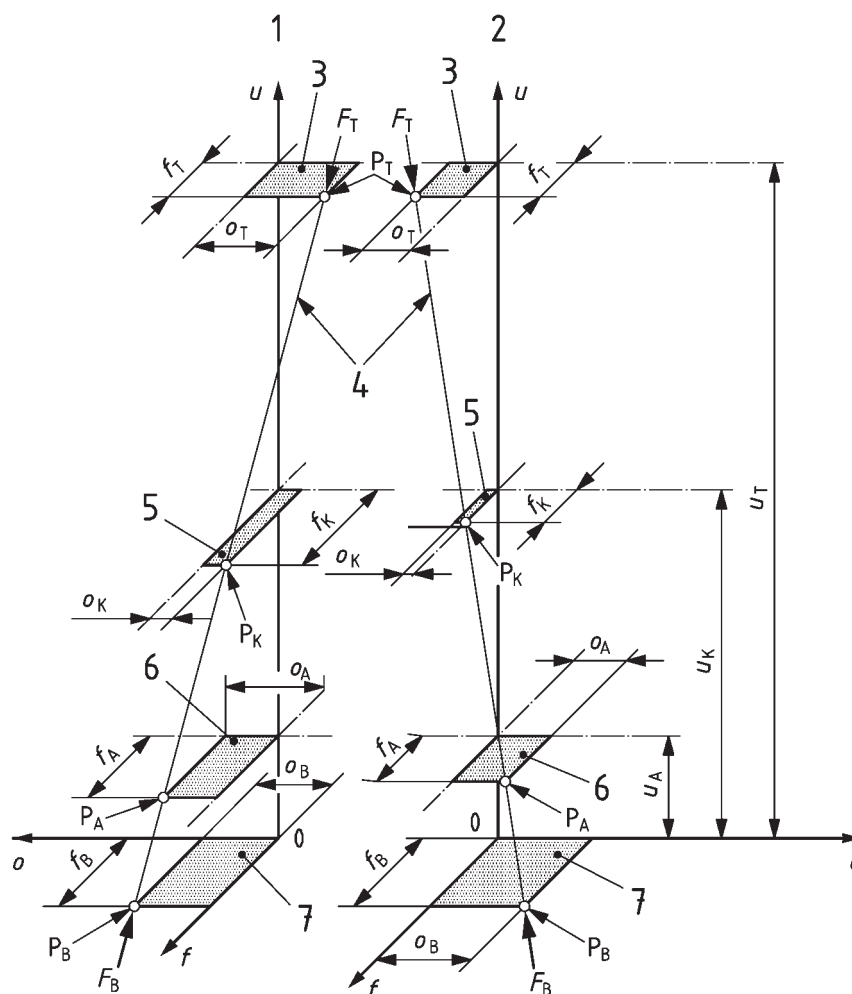
Figure 1 — Coordinate systems for right and left-sided application



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, $P_A (f_A, o_A, u_A)$

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

IMPORTANT — In the subsequent clauses of this International Standard, the *f*- and *o*-coordinates are also referred to as OFFSETS (see also [6.8.1](#)).

6.5 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 [6.4](#).

6.6 Load line

The load line is the line of application of the test force, F . It passes through the reference points specified in [6.4](#).

6.7 Longitudinal axis of the foot and effective joint centres and centrelines

6.7.1 General

In order to align the test sample within the appropriate coordinate system (see [6.1](#) to [6.3](#)) it is necessary to locate

- a) the longitudinal axis of the foot (see [6.7.2](#));
- b) the effective ankle-joint centre (see [6.7.3](#));
- c) the effective ankle-joint centreline (see [6.7.4](#));
- d) the effective knee-joint centreline (see [6.7.5](#));
- e) the effective knee-joint centre (see [6.7.6](#)).

If the location of the longitudinal axis of the foot or any effective joint centre or effective joint centreline is not straightforward, the manufacturer/submitter shall provide a diagram or instructions, with justification, identifying its location in relation to the test sample.

6.7.2 Longitudinal axis of the foot

Unless otherwise specified by the manufacturer/submitter, the longitudinal axis of the foot shall be taken to pass through the centre of the widest part of the forefoot and equidistant between the medial and lateral borders of the foot at a quarter of the length of the foot from the most posterior part of the foot with the foot placed as specified in [6.7.3.3](#) and illustrated in [Figure 4](#).

6.7.3 Effective ankle-joint centre

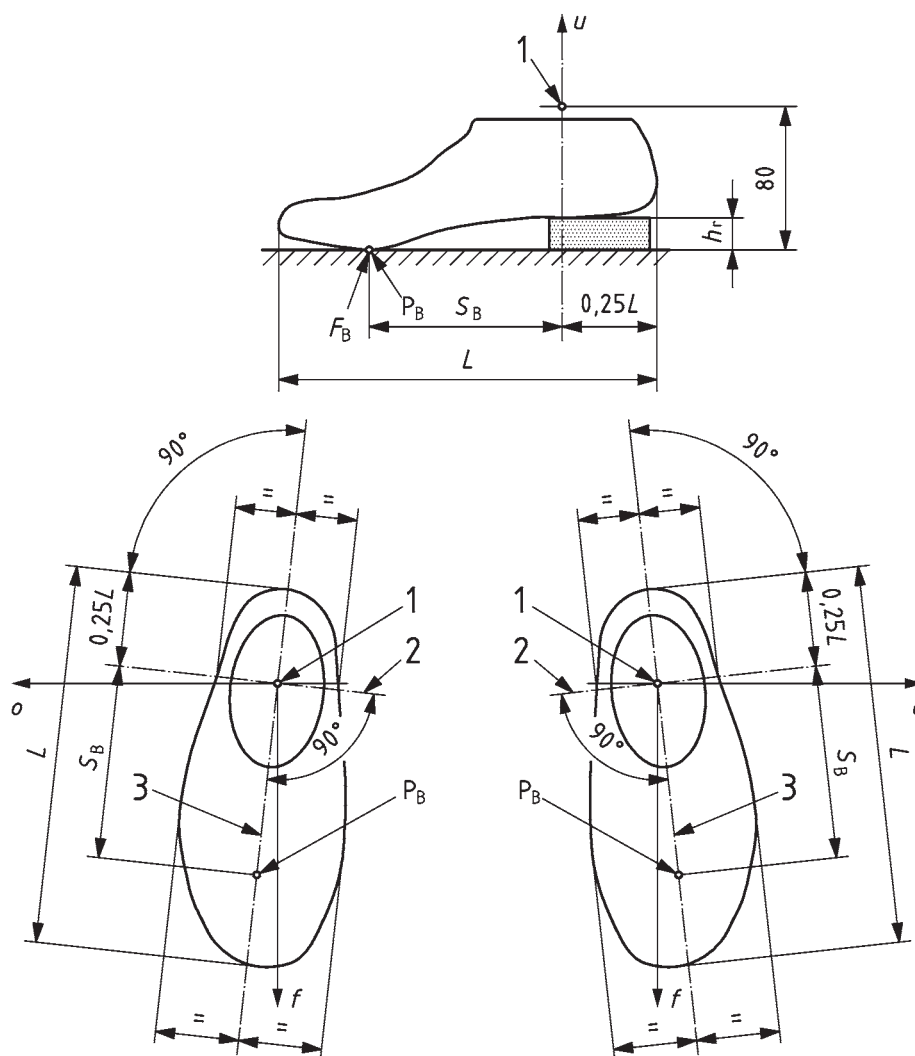
6.7.3.1 Locate the effective ankle-joint centre as described in [6.7.3.2](#) to [6.7.3.4](#).

NOTE The position of a mechanical axle for plantar- and dorsiflexion (if present) is irrelevant to the alignment of the test sample within the appropriate coordinate system.

6.7.3.2 Locate the longitudinal axis of the foot as described in [6.7.2](#) or in accordance with any specific instruction from the manufacturer/submitter.

6.7.3.3 Place the foot on a horizontal surface with a block of the manufacturer's/submitter's recommended heel height h_r placed under the heel of the foot (see [Figure 4](#)).

Dimensions in millimetres



Key

- | | | | |
|-------|--|-------|--|
| 1 | effective ankle-joint centre | L | foot length |
| 2 | effective ankle-joint centreline | P_B | bottom load application point on forefoot (test loading condition II) |
| 3 | longitudinal axis of foot corresponding to 6.7.2 | S_B | combined bottom offset of bottom load application point P_B on forefoot from u -axis |
| h_r | heel height | | |

NOTE The recommended heel height for the ankle-foot device or foot unit under test is taken as $h_r = 20$ mm unless otherwise specified by the manufacturer/submitter.

Figure 4 — Determination of longitudinal axis of foot (see 6.7.2), effective ankle-joint centre (see 6.7.3) and effective ankle-joint centreline (see 6.7.4) for test loading conditions I and II and of combined bottom offset S_B (see 6.8.2) for test loading condition II [see 7.1.2 b)]

6.7.3.4 The effective ankle-joint centre lies

- in a vertical plane passing through the longitudinal axis of the foot;
- in the ankle reference plane located 80 mm above the bottom reference plane, i.e. 80 mm above the horizontal line passing through P_B ;

c) a quarter of the length of the foot from the most posterior part of the foot.

6.7.4 Effective ankle-joint centreline

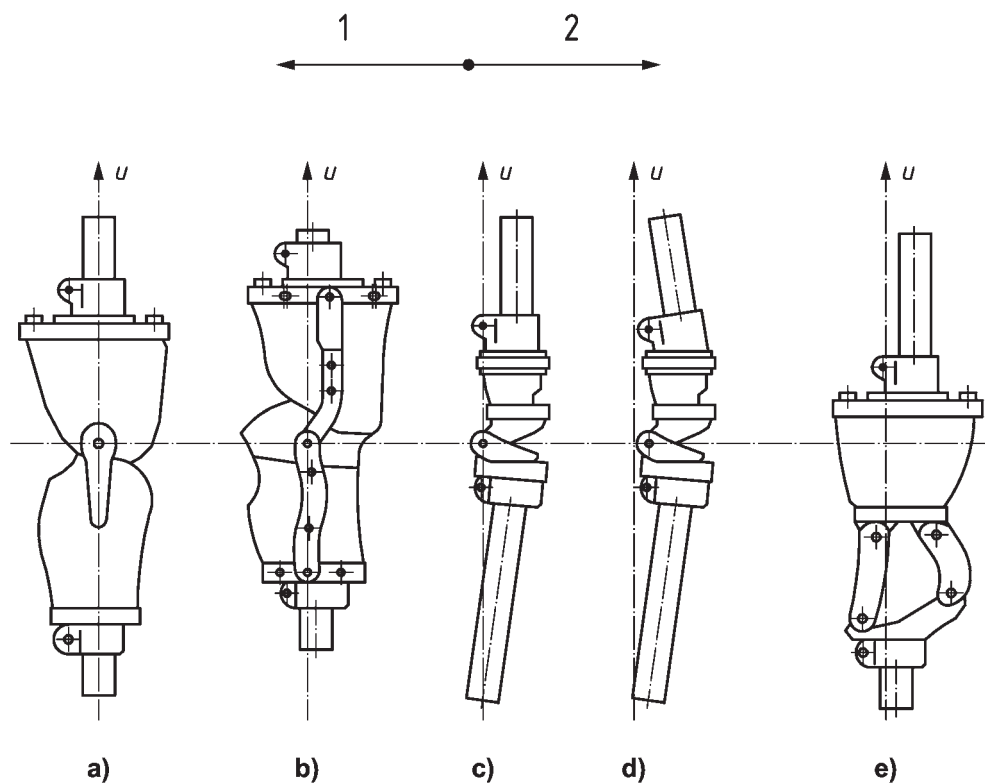
The effective ankle-joint centreline shall be the horizontal line passing through the effective ankle-joint centre (see 6.7.3) perpendicular to the longitudinal axis of the foot (see 6.7.2).

6.7.5 Effective knee-joint centreline

6.7.5.1 For a monocentric knee unit which has no knee lock or stance phase control mechanism, the effective knee-joint centreline shall coincide with the joint flexion axis [see Figure 5 a), b) and c)].

This shall also apply to a monocentric knee unit with a knee lock or a stance phase control mechanism which allows walking when these are disengaged.

6.7.5.2 For all knee units not covered by 6.7.5.1, the effective knee-joint centreline shall be established from the manufacturer's/submitter's written alignment instructions for the knee unit [see Figure 5 d) and e)].



Key

- 1 orientation 1 = posterior (toward the rear)
- 2 orientation 2 = anterior (toward the front)

a), b), c) are examples with the effective knee-joint centreline as specified in 6.7.5.1.

d), e) are examples with the effective knee-joint centreline as specified in 6.7.5.2.

Figure 5 — Position of effective knee-joint centreline for prosthetic knee units of different types

6.7.6 Effective knee-joint centre

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

6.7.6.2 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.

6.7.6.3 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.

6.8 Reference distances

6.8.1 Offsets

The offsets shall be the perpendicular distances of the reference points specified in 6.4 from the $o-u$ plane and the $u-f$ plane of the coordinate systems specified in 6.1 and 6.2. Their values are identical with the corresponding f - and o -coordinates of these reference points.

6.8.2 Combined offsets

The combined offsets S_B , S_A , S_K and S_T shall be the perpendicular distances of the reference points P_B , P_A , P_K and P_T specified in 6.4 from the u -axis of the coordinate systems specified in 6.1 and 6.2.

NOTE S_B is also addressed in 10.1.2 and illustrated in Figures 4 and 6 for test loading condition II defined in 7.1.2 b).

6.8.3 Effective lever arms L_A and L_K

The effective lever arms are the perpendicular distances of the effective joint centres from the load line, where L_A represents the ankle effective lever arm length and L_K the knee effective lever arm length.

6.8.4 Distance L_{BT}

L_{BT} shall be the distance between the bottom load application point P_B and the top load application point P_T (see 6.4).

7 Test loading conditions and test loading levels

7.1 Test loading conditions

7.1.1 General

The complexity of the load actions to which a lower-limb prosthesis is actually subjected during use by the amputee cannot be simulated by a single test procedure. Therefore, several types of static and cyclic strength tests are specified in the two categories "Principal structural tests" (Clause 16) and "Separate structural tests" (Clause 17), each type of test applying a single or two different test loading condition(s) (see 7.1.2 and 7.1.3).

Each test loading condition is characterized by a specific test load acting along or about a specific line of load application and producing axial compression, shear forces, bending moments and/or torque as single components of loading or compound loadings.

The test loading condition(s) for each type of test are addressed in Table 16 and specified in the relevant Tables 3 to 14. Further details are given in the relevant test procedures, specified in Clauses 16 and 17.

NOTE For further information see also Annexes A and B.

7.1.2 Test loading conditions of principal structural tests

The loading of the static and cyclic principal structural tests specified in [16.2](#) and [16.3](#) shall be applied in two different test loading conditions I and II relating to the maxima occurring at different instants during the stance phase of normal walking as described in a) and b). For both test loading conditions the position of the line of load application (see [7.1.1](#)) within the coordinate system (see [6.1](#) and [6.2](#)) shall be three-dimensional (see [Figures 3, 6](#) and [11](#)). The specific values of offsets, combined offsets and test forces for each test loading condition and each principal structural test are specified in [Tables 6, 7](#) and [8](#).

- a) Test loading condition I is related to the instant of maximum loading occurring early in the stance phase of walking.
- b) Test loading condition II is related to the instant of maximum loading occurring late in the stance phase of walking.

7.1.3 Test loading conditions of separate structural tests

7.1.3.1 Test loading condition of the separate static test in torsion

The loading of the separate static test in torsion specified in [17.1](#) shall be applied as torque about the u -axis (see [6.2.2](#)) first in one direction and then in the other direction. The specific values of torque are specified in [Table 9](#).

7.1.3.2 Test loading conditions of the separate tests on ankle-foot devices and foot units

The loading of the separate static and cyclic tests on ankle-foot devices and foot units specified in [17.2](#) shall be applied in two different test loading conditions simulating heel loading in the direction determined by the angle α and forefoot loading in the direction determined by the angle β . For both test loading conditions the position of the line of load application (see [7.1.1](#)) within the coordinate system (see [6.1](#) and [6.2](#)) shall be two-dimensional (see [Figure 7](#)). The specific values of angles and forces for each test loading condition and each test are specified in [Tables 10](#) and [11](#).

7.1.3.3 Test loading condition of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts

The loading of the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts specified in [17.3](#) shall be applied in a single test loading condition simulating kneeling or squatting (deep knee bend). The position of the line of load application (see [7.1.1](#)) within the coordinate system (see [6.1](#) and [6.2](#)) shall be two-dimensional (see [Figure 8](#)). The specific values of length and test force are specified in [Table 12](#).

7.1.3.4 Test loading condition of the separate tests on knee locks

The loading of the separate static and cyclic tests on knee locks specified in [17.4](#) shall be applied in a single test loading condition simulating a situation in which heel loading tends to flex the knee while it is locked in full extension. The position of the line of load application (see [7.1.1](#)) within the coordinate system (see [6.1](#) and [6.2](#)) shall be two-dimensional. The specific values of offsets and test forces are specified for each test in [Tables 13](#) and [14](#).

7.2 Test loading levels

7.2.1 The load actions referred to in the first paragraph of [7.1.1](#) vary with individual physical parameters, locomotion characteristics of the amputee and other factors. For these reasons different

categories of prostheses are needed and, consequently, different test loading levels are required, each being specified by individual values of dimensions and loads.

The series P test loading levels designated as given in 7.2.3 shall apply to lower limb prostheses for adults.

NOTE For further information see Annex B.

7.2.2 The specification of the test loading conditions of each of the test loading levels listed in 7.2.3 is governed by a safety concept, characterized in the following manner (see also Tables 3 and 8).

- The values of test force, F_{cr} , of the principal cyclic test according to 16.3.2 are set at a level which covers the full range of load actions disclosed by the locomotion data acquired from the group of amputees representative of the relevant test loading level (see Annex B); the values of the test forces, F_{1cr} and F_{2cr} , of the separate cyclic test for ankle-foot devices and foot units according to 17.2.5 and the test force, F_{cr} , of the separate cyclic test for knee locks according to 17.4.5 are set correspondingly.
- The corresponding values of the test forces, F_{sp} and F_{su} , of the principal static tests according to 16.2.1 and 16.2.2, the test forces, F_{1sp}/F_{2sp} and F_{1su}/F_{2su} , of the separate static tests for ankle-foot devices and foot units according to 17.2.3 and 17.2.4 and the test forces, F_{sp} and F_{su} , of the separate static tests for knee locks according to 17.4.3 and 17.4.4 are calculated by application of factors as specified in Table 3; the values of the twisting moment, M_{umax} , of the separate static test in torsion according to 17.1 and the test force, F_{su} , of the separate static ultimate strength test in maximum knee flexion according to 17.3 are set correspondingly.
- The specification of all test forces takes account of records on component failures of lower limb prostheses, taken in clinical or technical service.

7.2.3 Designation of test loading levels for adults is given below.

Test loading levels: P3, P4, P5, P6, P7 and P8

NOTE 1 Field experience has shown that there is a need for lower limb prostheses which sustain loads above the level covered by test loading level P5. In order to allow the structural testing of such prostheses on a uniform basis, test loading levels P6, P7 and P8 have been developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units (see Annex D).

NOTE 2 The values of the dimensions and loads of test loading levels P3, P4 and P5 are specified in separate tables in Clause 8. It is suggested that the values of the dimensions and loads specified in D.3 and D.4 and Tables D.2 and D.3 are appropriate for test loading level P6 and as an interim measure, pending validation, P7 and P8. Further test loading levels will be defined, if necessary.

8 Values of test loads, dimensions and cycles

Forces and twisting moments; segmental lengths, offsets and angles; prescribed number of cycles are addressed.

Tables 3 to 13 describe and/or specify the values of

- test forces and twisting moments,
- dimensions such as segmental lengths, offsets and angles and
- cycles (prescribed number of loading cycles).

Table 3 — Test loads and relevant references

Test force ^a or moment		Reference		
		Clause	Table	Test descrip- tor ^b
Proof test force on end attachments	$F_{pa} = 1,2 F_{su, \text{upper level}}$	13	4, D.1	A
Stabilizing test force	F_{stab}	13, 16, 17	4, 8, 14, D.2	A, 1, 2, 3, 9, 10, 11
Settling test force	$F_{set} = 0,8 F_{cr}$	13, 16, 17	4, 8, 14, D.2	A, 1, 2, 3, 9, 10, 11
Static proof test force	$F_{sp} = 1,75 F_{cr}$	16, 17	8, 14, D.2	1, 9
Static proof test force on heel	$F_{1sp} = 1,75 F_{1cr}$	17	11, D.3	5
Static proof test force on forefoot	$F_{2sp} = 1,75 F_{2cr}$	17	11, D.3	5
Static ultimate test force	$F_{su, \text{lower level}} = 1,5 F_{sp}$	16	8, D.2	2
– lower level	$F_{su, \text{upper level}} = 2,0 F_{sp}$	16	8, D.2	2
– upper level				
Static ultimate test force	F_{su}	17	12	8
Static ultimate test force	$F_{su} = 2,0 F_{sp}$	17	14	10
Static ultimate test force on heel	$F_{1su, \text{lower level}} = 1,5 F_{1sp}$	17	11, D.3	6
– lower level	$F_{1su, \text{upper level}} = 2,0 F_{1sp}$	17	11, D.3	6
– upper level				
Static ultimate test force on forefoot	$F_{2su, \text{lower level}} = 1,5 F_{2sp}$	17	11, D.3	6
– lower level	$F_{2su, \text{upper level}} = 2,0 F_{2sp}$	17	11, D.3	6
– upper level				
NOTE To simplify application of this International Standard, all relevant test loads are listed in this table together with references to the specific clauses, tables and test procedures.				
^a The test forces F_{set} , F_{pa} , F_{sp} and F_{su} are determined using appropriate factors.				
^b Test descriptors				
A: Proof test of end attachments (apparatus)				
1: Principal static proof test				
2: Principal static ultimate strength test				
3: Principal cyclic test				
4: Separate static test in torsion				
5: Separate static proof test for ankle-foot devices and foot units				
6: Separate static ultimate strength test for ankle-foot devices and foot units				
7: Separate cyclic test for ankle-foot devices and foot units				
8: Separate static ultimate strength test in maximum knee flexion				
9: Separate static proof test for knee locks				
10: Separate static ultimate strength test for knee locks				
11: Separate cyclic test for knee locks				

Table 3 (continued)

Test force ^a or moment		Clause	Reference	
			Table	Test descrip- tor ^b
Minimum test force	F_{cmin}	13, 16, 17	8, 14, D.2	3, 11
Maximum test force	F_{cmax}	13, 16, 17	8, 14, D.2	3, 11
Range of pulsating test force	F_{cr}	13, 16, 17	8, 14, D.2	3, 11
Mean test force	$F_{cmean} = 0,5 (F_{cmin} + F_{cmax})$	13	8, 14, D.2	3, 11
Amplitude of pulsating test force	$F_{ca} = 0,5 F_{cr}$	13	8, 14, D.2	3, 11
Pulsating test force	$F_c(t)$	13, 16, 17		3, 11
Final static test force	$F_{fin} = F_{sp}$	16, 17	8, 14, D.2	3, 11
Minimum test force on heel/forefoot	F_{1cmin}, F_{2cmin}	13, 17	11, D.3	7
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}	13, 17	11, D.3	7
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}	13, 17	11, D.3	7
	F_{1cmean}, F_{2cmean}	13	11, D.3	7
Mean test force on heel/forefoot	F_{1ca}, F_{2ca}	13	11, D.3	7
Amplitude of pulsating test force on heel/forefoot	$F_{1c}(t), F_{2c}(t)$	13, 17		7
Pulsating test force on heel/forefoot	F_{1fin}, F_{2fin}	17	11, D.3	7
Final static test force on heel/forefoot				
Stabilizing twisting moment	M_{u-stab}	17	9	4
Settling twisting moment	M_{u-set}	17	9	4
Maximum twisting moment	M_{u-max}	17	9	4
NOTE To simplify application of this International Standard, all relevant test loads are listed in this table together with references to the specific clauses, tables and test procedures.				
^a The test forces F_{set} , F_{pa} , F_{sp} and F_{su} are determined using appropriate factors.				
^b Test descriptors				
A: Proof test of end attachments (apparatus)				
1: Principal static proof test				
2: Principal static ultimate strength test				
3: Principal cyclic test				
4: Separate static test in torsion				
5: Separate static proof test for ankle-foot devices and foot units				
6: Separate static ultimate strength test for ankle-foot devices and foot units				
7: Separate cyclic test for ankle-foot devices and foot units				
8: Separate static ultimate strength test in maximum knee flexion				
9: Separate static proof test for knee locks				
10: Separate static ultimate strength test for knee locks				
11: Separate cyclic test for knee locks				

Table 4 — Test forces of the proof test of end attachments for test loading levels P5, P4 and P3 (see 13.2.1.2)

End attachments for			Stabilizing test force, F_{stab}	Settling test force, F_{set}	Proof test force, F_{pa}
Test procedure	Test loading level	Test loading condition	N	N	N
Principal structural tests ^a	P5	I	50	1 024	5 376
		II		920	4 830
	P4	I		944	4 956
		II		828	4 348
	P3	I		736	3 864
		II		638	3 348
Separate tests on knee locks	P5, P4, P3		50	800	4 200

NOTE For the additional test loading levels P6, P7 and P8 the test forces are specified in [Table D.1](#).

^a End attachments that satisfy the stiffness requirements of the proof test of end attachments for proof test forces $F_{pa} = 1,2 F_{su, upper level}$ of a specific test loading level specified in this table are suitable for all static and cyclic tests of this International Standard carried out at this specific test loading level and at all lower levels.

For sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard and/or to the specific requirements of the prosthetic device/structure submitted for test, particular conditions apply (see the option described in 13.2.1.2.1).

Table 5 — Total length and segmental lengths of different types of test samples for principal tests and separate tests on knee locks, for all test loading conditions and test loading levels (see also [10.2](#), [10.3](#), [16.2](#), [16.3](#), [17.4](#) and [Figure 2](#))

Dimensions in millimetres

Reference plane level	Typical combinations of segmental lengths of test samples ^{a,b}		
	A	B	C
u_T	— $(u_T - u_K) = 150^b$	— $(u_T - u_K) = 150^b$	—
u_K	— $(u_K - u_A) = 420$	—	$(u_T - u_A) = 570$
u_A	— $(u_A - u_B) = 80$	$(u_K - u_B) = 500$	—
u_B	—	—	$(u_A - u_B) = 80$
Total length $(u_T - u_B)^{a,b}$	650	650	650

NOTE The total length and the segmental lengths also apply to the additional test loading levels P6, P7 and P8 specified in [Annex D](#) [see [D.3 a](#)].

^a The total length of 650 mm can be achieved by different combinations of segmental lengths. Examples of the combinations of segment lengths specified in columns A, B and C, typical of the different types of test sample, are shown below.

- Complete structure: A
- Partial structure: A, B, C
- Any other structure: A, B, C

^b For the testing of samples of prosthetic structures including knee-disarticulation or transfemoral (above-knee) sockets (see 10.3.3), the value of 150 mm specified in columns A and B for the segment length $(u_T - u_K)$ and the value of 570 mm specified in column C for the segment length $(u_T - u_A)$ are too short and need to be increased as required, by increasing the total length $(u_T - u_B)$. In this case the values of the offsets f_T and o_T , specified in [Table 6](#), need to be replaced by new values adapted to the increased total length $(u_T - u_B)$, to be calculated using the formulae in [Figure 12](#) (see also footnote b in [Table 6](#)).

Table 6 — Values of offsets for all principal tests
(see 16.2 and 16.3)

Dimensions in millimetres

Reference plane	Direction and location ^b	Offset ^a					
		Numerical value					
		mm					
		Test loading condition					
Top ^c	f_T	Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
	f_T	82	55	89	51	81	51
	o_T	– 79	– 40	– 74	– 44	– 85	– 49
Knee	f_K	52	72	56	68	49	68
	o_K	– 50	– 35	– 48	– 39	– 57	– 43
Ankle	f_A	– 32	120	– 35	115	– 41	115
	o_A	30	– 22	25	– 24	24	– 26
Bottom ^c	f_B	– 48	129	– 52	124	– 58	124
	o_B	45	– 19	39	– 22	39	– 23

NOTE The offsets specified for P5 also apply to the additional test loading levels P6, P7 and P8 specified in Annex D [see D.3 a)].

^a See 6.8.1.

^b For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 5, the offsets f_T and o_T specified in this table need to be adapted, using the formulae in Figure 12 [see also footnote b in Table 5].

^c Only for guidance in aligning test samples.

Table 7 — Values of combined offsets related to the values of offsets listed in Table 6
(see 10.1.2 and 13.2.1.2.3)

Dimensions in millimetres

Reference plane	Dimension and location ^b	Combined offsets $S_x = \sqrt{f_x^2 + o_x^2}$ ^a					
		Numerical value					
		mm					
		Test loading condition					
Top	S_T	Test loading level P5		Test loading level P4		Test loading level P3	
		I	II	I	II	I	II
	S_T	114	68	116	67	117	71
Knee	S_K	72	80	74	78	75	81
Ankle	S_A	44	122	43	118	48	118
Bottom	S_B	66	130	65	126	70	126

NOTE The combined offsets specified for P5 also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

^a For the determination of the size of prosthetic feet and the setting of the length of load application levers, specific values of combined offsets (see 6.8.2) may be required. This table states values of combined offsets related to the values of offsets listed in Table 6.

^b For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 5, the combined offset S_T specified in this table needs to be adapted, using the formulae in the heading [see also footnote b in Table 5].

Table 8 — Test forces of all principal tests and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3
(see 16.2 and 16.3)

Test procedure and test load			Unit	Test loading level (P_x) and test loading condition (I; II)					
				P5		P4		P3	
				I	II	I	II	I	II
Static and cyclic test procedures	Stabilizing test force	F_{stab}	N	50					
	Settling test force	F_{set}	N	1 024	920	944	828	736	638
Static test procedure	Proof test force	F_{sp}	N	2 240	2 013	2 065	1 811	1 610	1 395
	Ultimate static test force	$F_{su, lower level}$	N	3 360	3 019	3 098	2 717	2 415	2 092
		$F_{su, upper level}$	N	4 480	4 025	4 130	3 623	3 220	2 790
Cyclic test procedure	Minimum test force	F_{cmin}	N	50					
	Cyclic range	F_{cr}	N	1 280	1 150	1 180	1 035	920	797
	Maximum test force	F_{cmax} $F_{cmax} = F_{cmin} + F_{cr}$	N	1 330	1 200	1 230	1 085	970	847
	Mean test force	F_{cmean} $F_{cmean} = 0,5 (F_{cmin} + F_{cmax})$	N	690	625	640	568	510	449
	Cyclic amplitude	F_{ca} $F_{ca} = 0,5 F_{cr}$	N	640	575	590	518	460	399
	Final static force	F_{fin} $F_{fin} = F_{sp}$	N	2 240	2 013	2 065	1 811	1 610	1 395
	Prescribed number of cycles		1	3×10^6					

NOTE For the additional test loading levels P6, P7 and P8 the values of the test forces and the prescribed number of cycles are specified in Table D.2.

Table 9 — Twisting moments of the separate static test in torsion
(see 17.1)

Test loading level	Static test load		
	N·m		
	Settling twisting moment, M_{u-set}	Stabilizing twisting moment, M_{u-stab}	Maximum twisting moment, M_{u-max}
P5, P4, P3	3	1	50

NOTE The specified test loads also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Table 10 — Angles of directions of loading of all separate tests on ankle-foot devices and foot units, for test loading levels P5, P4 and P3
(see 17.2 and Figure 7)

Angles	Degrees
α	15
β	20
γ	7

NOTE The specified directions of loading also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Table 11 — Test forces of all separate tests on ankle-foot devices and foot units and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3
(see 17.2)

Test procedure and test load			Unit	Test loading level (P_x) and test loading condition ($F_{1x}; F_{2x}$)					
				P5		P4		P3	
				Heel load-ing, F_{1x}	Fore-foot load-ing, F_{2x}	Heel load-ing, F_{1x}	Fore-foot load-ing, F_{2x}	Heel load-ing, F_{1x}	Fore-foot load-ing, F_{2x}
Static test procedure	Proof test force	F_{1sp}, F_{2sp}	N	2 240	2 240	2 065	2 065	1 610	1 610
	Ultimate static test force	F_{1su} , lower level, F_{2su} , lower level	N	3 360	3 360	3 098	3 098	2 415	2 415
		F_{1su} , upper level, F_{2su} , upper level	N	4 480	4 480	4 130	4 130	3 220	3 220
Cyclic test procedure	Minimum test force	F_{1cmin}, F_{2cmin}	N	50					
	Cyclic range	F_{1cr}, F_{2cr}	N	1 280	1 280	1 180	1 180	920	920
	Maximum test force	F_{1cmax}, F_{2cmax} $F_{xcmax} = F_{xcmin} + F_{xcr}$	N	1 330	1 330	1 230	1 230	970	970
	Mean test force	F_{1cmean}, F_{2cmean} $F_{xcmean} = 0,5 (F_{xcmin} + F_{xcmax})$	N	690	690	640	640	510	510
	Cyclic amplitude	F_{1ca}, F_{2ca} $F_{xca} = 0,5 F_{xcr}$	N	640	640	590	590	460	460
	Final static force	F_{1fin}, F_{2fin} $F_{xfin} = F_{xsp}$	N	2 240	2 240	2 065	2 065	1 610	1 610
	Prescribed number of cycles		1	2×10^6					

NOTE For the additional test loading levels P6, P7 and P8 the values of the test forces and the prescribed number of cycles are specified in Table D.3.

Table 12 — Loading parameters of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts
(see 17.3 and Figure 8)

Test loading level	Length, L_e mm	Ultimate static test force, F_{su} N
P5, P4, P3	400	1 750

NOTE The specified loading parameters also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

**Table 13 — Offsets of all separate tests on knee locks,
for test loading levels P5, P4 and P3**
(see 17.4)

Reference Plane	Offset ^a	
	Direction	Numerical value mm
Knee	f_K	- 50
	o_K	0
Ankle	f_A	- 50
	o_A	0
NOTE The specified offsets also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.		
^a See 6.8.1.		

**Table 14 — Test forces of all separate tests on knee locks and prescribed number of cycles
of the cyclic test, for test loading levels P5, P4 and P3**
(see 17.4)

Test procedure and test load			Unit	Test loading level (P _x) P5, P4, P3
Static and cyclic test procedures	Stabilizing test force	F_{stab}	N	50
	Settling test force	F_{set}	N	800
Static test procedure	Proof test force	F_{sp}	N	1 750
	Ultimate static test force	F_{su}	N	3 500
Cyclic test procedure	Minimum test force	F_{cmin}	N	50
	Cyclic range	F_{cr}	N	1 000
	Maximum test force	F_{cmax} $F_{cmax} = F_{cmin} + F_{cr}$	N	1 050
	Mean test force	$F_{cmean} = 0,5 (F_{cmin} + F_{cmax})$	N	550
	Cyclic amplitude	F_{ca} $F_{ca} = 0,5 F_{cr}$	N	500
	Final static force	F_{fin} $F_{fin} = F_{sp}$	N	1 750
	Prescribed number of cycles		1	1×10^6
NOTE The specified test forces and the prescribed number of cycles also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.				

9 Compliance

9.1 General

In order to claim compliance with this International Standard for a prosthetic device/structure submitted for test, a prescribed number of test samples of this structure from the allowed batch, specified in Table 16, shall satisfy the relevant requirements of Clauses 9, 10, 16 and 17 and the relevant

test loading conditions and test loading levels of [Clauses 7](#) and [8](#). Any claim of compliance shall state the test loading level at which tests were conducted.

Compliance of a prosthetic device/structure submitted for test with the performance requirements of a specific test of this International Standard required (see [9.2](#)) shall be certified by the test laboratory/facility only for the specific prosthetic assembly and alignment simulated in the set-up of the batch of test samples of the prosthetic device/structure which have been subjected to this test (see [9.4](#)).

NOTE The manufacturer/submitter may claim compliance also for other prosthetic assemblies and/or alignments in which the prosthetic device/structure submitted for test can be used, provided it can be certified that these lie within the range of loading covered by the most adverse assembly and the worst-case alignment simulated in the test sample set-up of the prosthetic device/structure submitted for test.

9.2 Selection of tests required to claim compliance with this International Standard

The different combinations of principal and separate structural tests, required to be completed on test samples of prosthetic structures submitted for test representing complete assemblies, partial assemblies or individual components (see [Clause 10](#)) to claim their compliance with this International Standard, are indicated in [Table 15](#).

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

9.3.1 General

For batches of test samples of prosthetic structures submitted for test including an ankle-foot device or foot unit, the claim of compliance with this International Standard requires that the ankle-foot device or foot unit satisfy the requirements of the separate tests on ankle-foot devices and foot units specified in [17.2](#), independent of other tests required to claim compliance with this International Standard, which also may involve/load the ankle-foot device or foot unit.

9.3.2 Particular arrangements concerning the ankle-foot device or foot unit

In order to claim compliance with this International Standard, for a prosthetic structure submitted for test including an ankle-foot device or foot unit that is detachable:

- samples of this ankle-foot device or foot unit from the permitted batch (see [Table 16](#)) shall be subjected only to the separate tests on ankle-foot devices and foot units specified in [17.2](#)

while

- the samples of the remainder of the prosthetic structure shall be subjected to the principal structural tests specified in [16.2](#) and [16.3](#) with the ankle-foot device or foot unit replaced by a rigid lever arm (bottom load application lever).

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

9.3.3.1 In order to claim compliance with this International Standard for a prosthetic structure submitted for test including an ankle-foot device or foot unit that is detachable, batches of the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base, shall be tested in either of the ways specified in 9.3.3.2 and 9.3.3.3.

9.3.3.2 If the manufacturer/submitter intends to claim compliance with this International Standard for a specific assembly of connecting part and ankle-foot device or foot unit or for specified assemblies of the connecting part and several types of ankle-foot device or foot unit, then batches of samples of each specific assembly shall be subjected to the separate tests on ankle-foot devices and foot units specified in [17.2](#).

9.3.3.3 If the manufacturer/submitter intends to claim compliance with this International Standard for assemblies of the connecting part and any type of ankle-foot device or foot unit in accordance with the NOTE in [9.1](#), then batches of samples of this part shall be subjected to the principal structural tests specified in [16.2](#) and [16.3](#) in a test sample set-up in which the foot unit is replaced by a rigid lever arm, in order to apply the longest effective lever arm possible corresponding to the requirements of 10.3.4.

9.4 Number of tests and test samples required to claim compliance with this International Standard

The minimum number of tests required for each type of test in the prescribed loading conditions in order to claim compliance with this International Standard is shown in [Table 16](#).

The tests shall be conducted on test samples from the batch specified in [Table 16](#) for each type of test.

The minimum number indicates how many test samples of a prosthetic device/structure submitted for test shall complete the tests without failing.

All tests shall be conducted in the worst-case alignment position of the test samples (see [10.6](#)) and, if these include partial structures according to 10.2.2 which can be used in various prosthetic assemblies, in the most adverse prosthetic assembly possible (see 10.3.4).

NOTE The total number of test samples actually needed for the conduct of a selection of specific types of tests relevant to the prosthetic device/structure submitted for test may differ from the total calculated by addition of the number of test samples specified in [Table 16](#) for each of the types of tests selected, since the number of substitutes needed may vary, and since test samples that have completed a specific test without failing may be used for another test (see [9.5](#), [16.2.1.1.2](#), [16.2.2.1.2](#), [17.2.3.1.2](#), [17.2.4.1.2](#), [17.4.3.1.2](#) and [17.4.4.1.2](#)).

9.5 Multiple use of test samples

9.5.1 General

Test samples, which have demonstrated compliance with the performance requirements of any of the tests specified in this International Standard, may be subjected to other tests of this International Standard, except as stated in [9.5.2](#).

Any decision on the multiple use of test samples shall be based on a corresponding indication in the test submission document (see [Clause 12](#)) and/or the agreement between the manufacturer/submitter and the test laboratory/facility.

As a general rule, any failure occurring during a test on a test sample that has previously been subjected to another test justifies the repetition of the failed test on a substitute test sample (see [Table 16](#)).

NOTE The multiple use of test samples is specifically addressed in the principal static tests ([16.2.1](#) and [16.2.2](#)), the separate static tests for ankle-foot devices and foot units ([17.2.3](#) and [17.2.4](#)) and the separate static tests for knee locks ([17.4.3](#) and [17.4.4](#)) – (see also references in the NOTE in [9.4](#)).

Unless otherwise indicated in the test submission document and/or agreed between the manufacturer/submitter and the test laboratory/facility, this International Standard does not stipulate that the tests required to claim compliance for the prosthetic device/structure submitted for test be conducted in a particular order, with the exception of the restriction specified in [9.5.2](#).

9.5.2 Restriction

Compliance of any test sample with the performance requirements of any of the cyclic tests of this International Standard cannot be claimed if the test sample has previously been subjected to any of the static ultimate strength tests of this International Standard.

9.6 Testing at particular test loading levels not specified in this International Standard

For different reasons the intended use of a particular design of a lower limb prosthetic device/structure may require the tests of this International Standard to be applied at a particular test loading level not specified in this International Standard, derived from the next lower regular test loading level of this International Standard by increasing its test loads by $x\%$.

In this case compliance with this International Standard cannot be claimed for that particular test loading level.

However, compliance with this International Standard can be claimed for the next lower regular test loading level of this International Standard, from which that particular test loading level has been derived.

Reference to this International Standard may also be given by stating that the prescribed batch (or batches) of test samples of a prosthetic device/structure submitted for test has (have) been tested a) following this International Standard or in a more specific manner b) by applying the tests of this International Standard at test loads set $x\%$ above test loading level P_y .

Table 15 — Tests required to claim compliance with this International Standard for prosthetic structures representing complete assemblies, partial assemblies or individual components

Examples of prosthetic structures submitted for test ^a	Principal structural tests ^b	Separate structural tests			
		Test in torsion ^c	Tests on ankle-foot devices and foot units ^d	Test in maximum knee flexion ^e	Tests on knee locks ^f
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis with foot unit	x (see 9.3)	x	x (see 9.3)	x	x
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis without foot unit	x	x		x	x
Complete structure of transtibial prosthesis with foot unit	x (see 9.3)	x	x (see 9.3)		
Complete structure of transtibial prosthesis without foot unit	x	x			
Partial structure including knee unit and ankle-foot device or foot unit	x (see 9.3)	x	x (see 9.3)	x	x
Partial structure including knee unit but not ankle-foot device or foot unit	x	x		x	x
^a Examples of the different types of test samples of prosthetic structures submitted for test are specified in 10.2. ^b Tests required for test samples of all prosthetic structures except samples of single ankle-foot devices or foot units. ^c Test required for test samples of all prosthetic structures. ^d Tests required for test samples of prosthetic structures including an ankle-foot device or foot unit, independent of other tests required to claim compliance with this International Standard, which also may involve/load the ankle-foot device or foot unit. ^e Test required for test samples of prosthetic structures including a knee unit which, under real conditions of use as a member of a finished lower limb prosthesis, will be loaded at its physical boundaries of angular movement in the position of maximum knee flexion of that prosthesis. (This need not happen in every case, as the position of maximum knee flexion may be determined by other parts of the prosthesis which come into contact first.) ^f Tests required for test samples of prosthetic structures including a knee unit which can be locked in the extended position.					

Table 15 (continued)

Examples of prosthetic structures submitted for test ^a	Principal structural tests ^b	Separate structural tests			
		Test in torsion ^c	Tests on ankle-foot devices and foot units ^d	Test in maximum knee flexion ^e	Tests on knee locks ^f
Partial structure including ankle-foot device or foot unit but not knee unit	×	×	×		
Partial structure without knee unit and without ankle-foot device or foot unit	×	×			
Ankle-foot device or foot unit (e.g. of ankle-disarticulation prosthesis) only		×	×		
^a Examples of the different types of test samples of prosthetic structures submitted for test are specified in 10.2 . ^b Tests required for test samples of all prosthetic structures except samples of single ankle-foot devices or foot units. ^c Test required for test samples of all prosthetic structures. ^d Tests required for test samples of prosthetic structures including an ankle-foot device or foot unit, independent of other tests required to claim compliance with this International Standard, which also may involve/load the ankle-foot device or foot unit. ^e Test required for test samples of prosthetic structures including a knee unit which, under real conditions of use as a member of a finished lower limb prosthesis, will be loaded at its physical boundaries of angular movement in the position of maximum knee flexion of that prosthesis. (This need not happen in every case, as the position of maximum knee flexion may be determined by other parts of the prosthesis which come into contact first.) ^f Tests required for test samples of prosthetic structures including a knee unit which can be locked in the extended position.					

Table 16 — Number of tests and test samples required to claim compliance with this International Standard

Type of test	Test loading condition and manner of application	Minimum ^a number of tests required	Batch ^b of test samples allowed for each type of test		
			Regular test samples	No. ^c	Reference
Principal structural tests					
Static proof test (see 16.2.1.1)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2	2	1	16.2.1.1.12
		2	2	1	
Static ultimate strength test (see 16.2.2.1)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2	2	1	16.2.2.1.9 and 16.2.2.1.10 (option)
		2	2	1	
Cyclic test ^d (see 16.3.2)	Test loading condition I [7.1.2 a)] and Test loading condition II [7.1.2 b)]	2	2	1	16.3.2.22
		2	2	1	
Separate test in torsion					
Static test (see 17.1.3)	Two opposite directions of loading, successively applied to each test sample (7.1.3.1)	2	2	—	—
Separate tests on ankle-foot devices and foot units					
a The term <i>minimum</i> indicates that repetition of tests on permitted substitute test samples may be necessary to satisfy the compliance conditions. b For the definition of <i>batch</i> see 3.4. c The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed in the reference column applies. d All cyclic tests are followed by final static tests, applied in the same test loading conditions (directions of loading).					

Table 16 (continued)

Type of test	Test loading condition and manner of application	Minimum ^a number of tests required	Batch ^b of test samples allowed for each type of test		
			Regular test samples	Possible substitute test samples No. ^c	Reference
Static proof test (see 17.2.3.1)	Direction of loading at angle α and direction of loading at angle β , successively applied to each test sample (7.1.3.2)	2	2	1	17.2.3.1.11
Static ultimate strength test (see 17.2.4.1)	Direction of loading at angle α	2	2	1	17.2.4.1.15 and 17.2.4.1.17 (option)
	and Direction of loading at angle β (7.1.3.2)	2	2	1	17.2.4.1.15 and/or 17.2.4.1.16 and 17.2.4.1.17 (option)
Cyclic test ^d (see 17.2.5.1)	Direction of loading at angle α and direction of loading at angle β , alternately applied to each test sample (7.1.3.2)	2	2	—	—
Separate static ultimate strength test in maximum knee flexion on knee joints and associated parts					
Static test (see 17.3.4)	Single condition (7.1.3.3)	2	2	—	—
Separate tests on knee locks					
Static proof test (see 17.4.3.1)	Single condition (7.1.3.4)	2	2	1	17.4.3.1.12
Static ultimate strength test (see 17.4.4.1)	Single condition (7.1.3.4)	2	2	1	17.4.4.1.9
Cyclic test ^d (see 17.4.5.1)	Single condition (7.1.3.4)	2	2	1	17.4.5.1.22
^a The term <i>minimum</i> indicates that repetition of tests on permitted substitute test samples may be necessary to satisfy the compliance conditions. ^b For the definition of <i>batch</i> see 3.4. ^c The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed in the reference column applies. ^d All cyclic tests are followed by final static tests, applied in the same test loading conditions (directions of loading).					

10 Test samples

10.1 Selection of test samples

10.1.1 General

The test samples of prosthetic devices/structures selected for test shall be taken from normal production. Details of the selection shall be recorded in the test submission document (see [Clause 12](#)). If the manufacturer/submitter supplies a certificate stating that the test sample has been taken from the normal production line, this certificate shall be included in the test submission document, together with details of the sampling method.

NOTE Test samples of prosthetic devices/structures may also be submitted for specific tests by any interested party.

10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot

10.1.2.1 For principal structural tests on samples of prosthetic structures including an ankle-foot device or a foot unit that forms an integral part of the structure and cannot be detached (see 9.3), the size of the foot selected shall allow the application of load in accordance with the combined bottom offset S_B specified for the test (see 6.8.2, Table 7 and Figures 4 and 6), S_B being determined by the formula

$$S_B = \sqrt{f_B^2 + o_B^2} \quad (1)$$

where f_B and o_B are the f - and o -offsets of the bottom load application point P_B .

The selection of the size of the foot and possible subsequent adaptations of the test force shall be carried out as follows:

- select a size that gives the correct combined bottom offset, S_B ;
- if a correct size foot is not available, use the next larger size;
- if the foot available is shorter than the correct length, then increase the applied test force F to F' where:

$$F' = F \left(\frac{S_{B\text{spec}}}{S_{B\text{act}}} \right) \quad (2)$$

and where

$S_{B\text{spec}}$ is the specified combined bottom offset;

$S_{B\text{act}}$ is the actual combined bottom offset.

10.1.2.2 For separate structural tests on ankle-foot devices and foot units on samples of prosthetic structures including an ankle-foot device or a foot unit that can be detached or on samples comprising an ankle-foot device or a foot unit as a single component, the size of the foot selected shall provide the worst-case loading (see note) that is possible for that type of foot when subjected to the heel and forefoot loading specified for the test (see Tables 10 and 11).

The size of foot providing the worst-case loading shall be determined by the manufacturer/submitter (see NOTE) and shall be stated, with justification, in the test submission document (see Clause 12).

NOTE The determination of the size of foot providing the worst-case loading may be based on design features, on findings of risk management and/or on the results of appropriate preliminary tests conducted on feet of different size.

An appropriate measure for the worst-case loading is the direction and magnitude of the ankle (A-P) bending moment (see Annex A), generated by the test forces applied to the heel and forefoot of the ankle-foot device or foot unit and determined by the lengths of the effective lever arms on which these test forces act.

Although there is a fundamental relationship between the lengths of the effective lever arms and the size of the foot, the worst-case loading need not necessarily be provided in each case by the largest size of foot available for the test loading level to be applied, but can also be influenced by other design parameters.

10.2 Types of test samples

10.2.1 Complete structure

10.2.1.1 For a knee-disarticulation or a transfemoral (above-knee) prosthesis, a complete structure consists of a knee unit and ankle unit or ankle attachment with all parts between. It may also contain parts above the knee unit, including the socket (see [10.2.1.4](#)), and below the ankle unit or ankle attachment, including the foot unit.

10.2.1.2 For the distal part of a hip-disarticulation (or hemi-pelvectomy) prosthesis, a complete structure consists of a knee unit and ankle unit or ankle attachment with all parts between. It may also contain parts below the ankle unit or ankle attachment, including the foot unit.

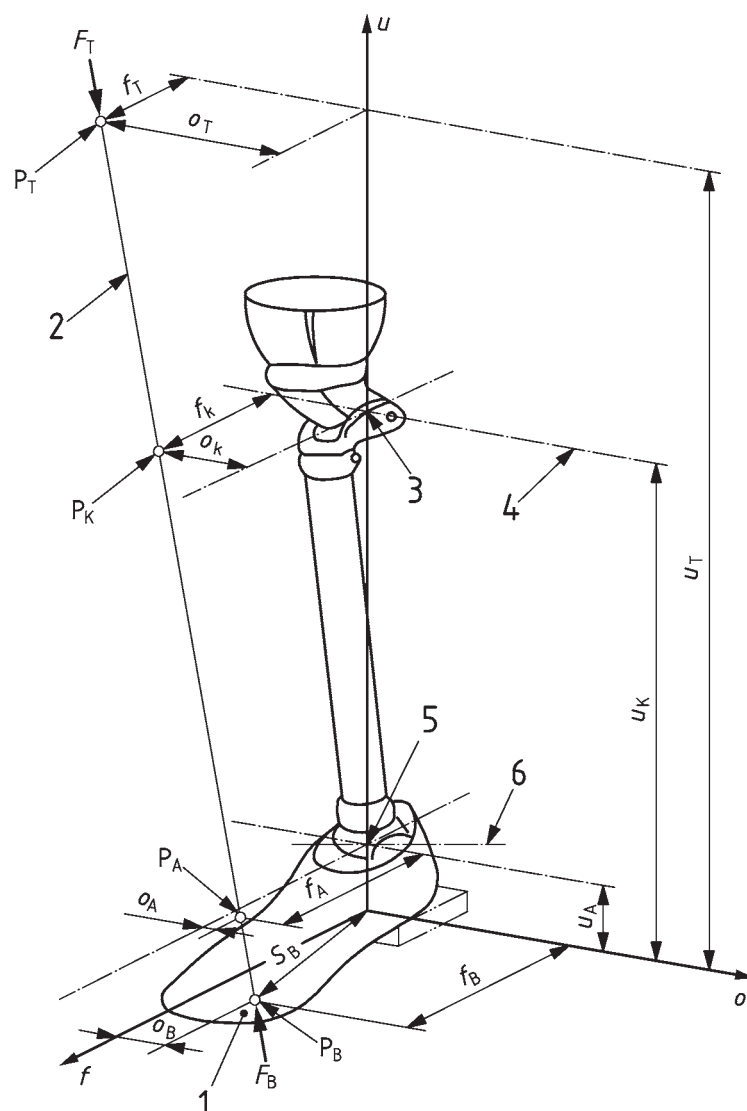
NOTE Tests of components of hip-disarticulation (or hemi-pelvectomy) prostheses which are above the level of the knee are specified in ISO 15032.

10.2.1.3 For a transtibial (below-knee) prosthesis, a complete structure consists of the ankle unit or ankle attachment and the socket attachment with all parts between. It may also contain parts above the socket attachment, including the socket (see [10.2.1.4](#)), and below the ankle unit or ankle attachment, including the foot unit.

10.2.1.4 The mechanical connection between a transtibial (below-knee), knee-disarticulation or transfemoral (above-knee) socket and the distal shin-socket or knee-socket attachment is a critical region of a prosthetic structure.

In order to demonstrate that this connection has the strength required to sustain the loads expected to occur during use by amputees in the manner intended, manufacturers shall submit complete structures, including the socket or a socket dummy, for test in accordance with the relevant requirements of this International Standard.

10.2.1.5 An example of a complete structure of a left transfemoral (above-knee) prosthesis and its alignment within the coordinate system is shown in [Figure 6](#).



Key

- 1 left foot
- 2 load line
- 3 effective knee-joint centre
- 4 effective knee-joint centreline
- 5 effective ankle-joint centre
- 6 effective ankle-joint centreline
- P_K knee load reference point
- P_A ankle load reference point
- P_B bottom load application point
- P_T top 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 corresponds to test loading condition II defined in [7.1.2 b](#)).

Figure 6 — Application of a specific test configuration with $u_B = 0$ to a left-sided sample specified in [10.2.1](#)

10.2.2 Partial structure

For any type of prosthesis, a partial structure is less than a complete structure and may be a single component, such as a knee unit or an ankle-foot device.

A specific example of a partial structure is a test sample of a foot unit or the structural parts of a foot unit used in specific types of ankle-disarticulation prostheses.

When a partial structure is tested, the end connections shall have mechanical characteristics similar to those of the intended adjacent components, unless otherwise specified in this International Standard.

10.2.3 Any other structure

If the design of a leg structure does not allow it to be tested as a test sample in accordance with [10.2.1](#) or [10.2.2](#), then a special test set-up may be used for testing. For example, such a leg could be a one-piece flexible plastic structure that includes the foot.

If the manufacturer/submitter and the test laboratory/facility certify in writing in the test submission document (see [Clause 12](#)) and the test report (see [Clause 19](#)), that the effective geometry of the test sample and the test loading conditions comply with the requirements of [Clauses 7, 8 and 16](#) or [17](#), as appropriate, then testing may be carried out and a test report issued in accordance with [Clause 19](#), in which this compliance is specifically addressed.

If the test sample satisfies the requirements of the relevant clauses of this International Standard, then compliance with these clauses can be claimed. The claim shall clearly indicate that the test sample complies with [10.2.3](#) of this International Standard.

If the geometry of the test sample cannot be so certified, then compliance with these clauses cannot be claimed.

10.3 Preparation of test samples

10.3.1 The samples shall include all parts normally fitted.

10.3.2 Any cosmetic components shall be omitted from the sample, unless they contribute to the structural strength.

10.3.3 Where any test sample includes a socket or socket dummy, the preparation of the test sample shall include the measures listed in a) to c).

- a) The distal portion of the socket or socket dummy, into which the distal socket attachment device extends, shall either be a void or be filled with foam or soft materials, in order to allow this portion to deform freely under load.
- b) The remaining proximal portion of the socket or socket dummy shall be connected rigidly to the top end attachment, consisting of the extension piece, as required, and the top load application lever.

The use of a mandrel as extension piece, anchored within the socket or socket dummy by means of rigid foam, has been found to be suitable.

- c) For a transtibial (below-knee) socket or socket dummy, the position of the effective knee-joint centre and the direction of the effective knee-joint centreline shall be identified, based on anatomical features derived from the socket shape. This is necessary to allow the alignment of the socket as required (see [10.5](#) and [10.6](#)).

It has been found to be suitable to transfer the effective knee-joint centreline to the socket by drilling holes through the medial and lateral socket wall in the direction of the effective knee-joint centreline, the holes to serve as guide for alignment pins of a jig.

10.3.4 Where any test sample includes a partial structure according to [10.2.2](#) which can be used in different prosthetic assemblies, then the test sample set-up shall be prepared in accordance with a) and b) and the test submission document (see [Clause 12](#)).

- a) If the partial structure is intended to be allowed for free use in any prosthetic assembly, then the test sample set-up shall be prepared to represent the most adverse prosthetic assembly possible.
- b) If the partial structure is intended to be allowed for limited use in specified prosthetic assemblies, then the test sample set-up shall be prepared to represent each prosthetic assembly specified.

10.3.5 Where any test sample includes any end fittings, then it shall be assembled in accordance with [Clause 11](#) and the test submission document.

10.3.6 For the principal structural tests (see [Clause 16](#)) and the separate structural tests on knee locks (see 17.4), all test sample types according to [10.2](#) shall be given a fixed total length, using end attachments consisting of extension pieces and the load application levers.

The fixed total length shall be determined by the dimension $u_T - u_B$ and shall be achieved by selecting either one of the combinations specified in [Table 5](#) for different types of test sample (see [10.2](#)) or any other relevant combination. The combination of segment lengths selected shall be recorded.

10.3.7 For the separate tests on ankle-foot devices and foot units, the ankle-foot device or foot unit, selected in accordance with [10.1.2](#), shall be submitted assembled by the manufacturer/submitter to the part connected to the remainder of the prosthesis such as an ankle unit, alignment device, pylon base, compliant structure or exoskeletal member. The type and identification of the part connected shall be recorded.

10.3.8 For the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (see [17.3.4](#)), the test sample shall consist of the assembly of knee unit and associated parts that normally provides the knee flexion stop on a complete prosthesis, comprising

- sub-assemblies of knee units and adjacent components normally required for their attachment to the proximal and distal part of a prosthesis and/or their alignment within a prosthesis, and
- knee-shin-assemblies, including adjacent components required for their attachment to the proximal part of a prosthesis and/or their alignment within a prosthesis.

Parts outside the specific assembly may be substituted. The form of the specific assembly and any substituted parts shall be recorded.

If a specific knee unit or knee-shin-assembly can be used in conjunction with different attachment/alignment components, then the test sample set-up shall represent the assembly where the knee flexion stop point is nearest to the axis of rotation (monocentric design) or nearest to the instantaneous centre of rotation (polycentric design) of the knee unit or knee-shin-assembly at maximum knee flexion of the test sample. (This is in accordance with [10.3.4](#)).

10.3.9 For the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, all test samples shall have extension pieces attached above and below the knee unit, to represent wholly or in part the thigh and shin portion (for details see [10.5.3.1](#)). The lengths of these extension pieces shall be recorded.

10.4 Identification of test samples

The test laboratory/facility shall apply to each test sample an indelible, unique and traceable identification.

10.5 Alignment of test samples

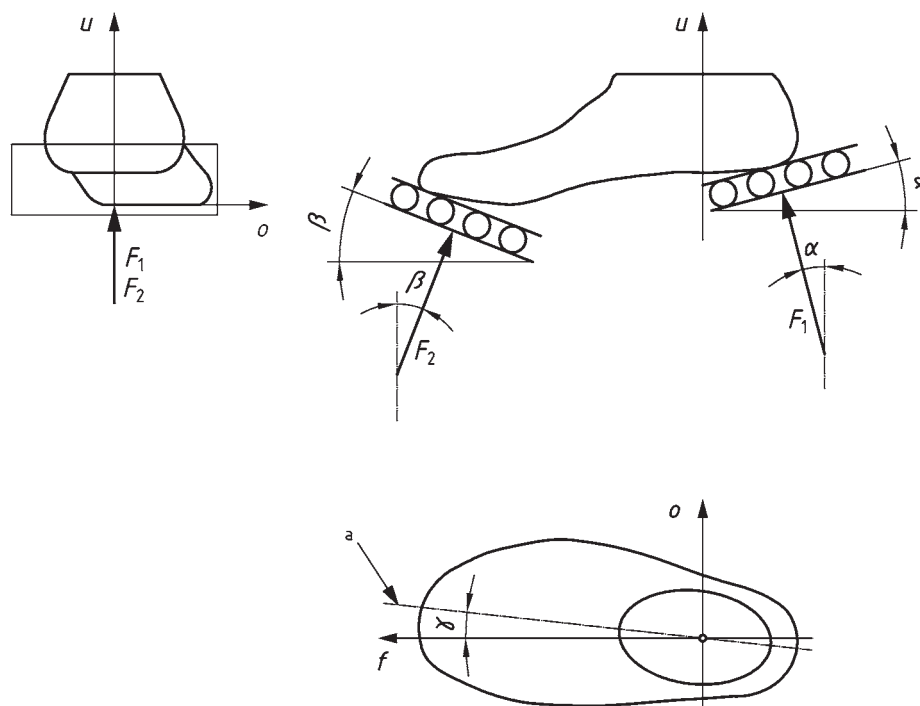
10.5.1 Test samples for principal tests and separate tests on knee locks

10.5.1.1 For the principal structural tests (see [Clause 16](#)) and the separate structural tests on knee locks (see [17.4](#)), all test sample types specified in [10.2](#) shall be aligned within the appropriate coordinate system in accordance with [6.1](#) to [6.3](#), [6.7.3](#) to [6.7.6](#), [10.6](#), [14.3](#) a) to d), [Tables 5](#) and [6](#) or [13](#) and the test submission document (see [Clause 12](#)).

10.5.2 Test samples for separate tests on ankle-foot devices and foot units

10.5.2.1 Test samples of an ankle-foot device or foot unit shall be aligned within the appropriate coordinate system in accordance with [6.1](#) to [6.3](#), [6.7.2](#) to [6.7.4](#), [14.3](#) a) and d), [Table 10](#) and the test submission document (see [Clause 12](#)).

The longitudinal axis of the foot (see [6.7.2](#)) shall be turned by $\gamma = 7^\circ$ as shown in [Figure 7](#) and specified in [Table 10](#) to give a “toe out” position of the ankle-foot device or foot unit.



a Longitudinal axis of foot corresponding to [6.7.2](#).

NOTE The test mechanism used to apply F_1 and F_2 , each should allow low-friction motion in both tangential directions, realized e.g. by ball bearings.

Figure 7 — Position of foot in test equipment
(see [10.5.2](#), [13.4](#) and [17.2](#))

10.5.3 Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts

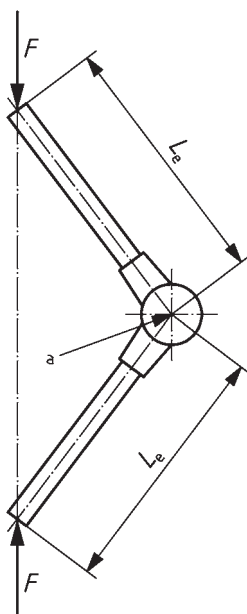
10.5.3.1 In the initial test sample set-up with the knee unit fully extended, the extension pieces attached above and below the knee unit to represent wholly or in part the thigh and shin portion shall be aligned on the u -axis and perpendicular to the effective knee-joint centreline and shall provide a length, L_e , of

400 mm, measured from the effective knee-joint centre, in accordance with [6.2.2](#), [6.7.5](#), [6.7.6](#), [10.3.9](#), [14.3](#) a) and b), [Table 12](#) and [Figure 8](#)).

10.5.3.2 If the alignment of the test sample is adjustable, it shall be set in the worst-case alignment position in accordance with [10.6](#).

10.5.4 Test samples for separate tests on knee locks

If the lock position is adjustable or alignment adjustment of the test sample moves the lock in relation to the centre of rotation, then the test sample shall be set so that the lock is as close as possible to the effective knee-joint centre (see [6.7.6](#)).



Key

- L_e length of thigh and shin portion
- a Effective knee-joint centre.

Figure 8 — Test configuration for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts
(see [10.5.3.1](#), [13.5](#) and [17.3.4](#))

10.6 Worst-case alignment position of test samples

10.6.1 All tests shall be conducted in the worst-case alignment position of the test samples as defined by the criteria specified in [10.6.2](#) to [10.6.4](#).

10.6.2 The structurally worst alignment position shall, if possible, be defined by the manufacturer/submitter in the test submission document (see [Clause 12](#)). It shall lie within the limitations of the manufacturer's written instructions for the alignment of the limb as supplied with every component of the type.

10.6.3 Where the structurally worst position cannot be defined as required in [10.6.2](#), then the 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 (see [6.8.3](#)).

10.6.4 For samples for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts, the worst-case alignment position is when the perpendicular distance of the axis of rotation (monocentric design) or the instantaneous centre of rotation (polycentric design) of the knee unit from the load line at maximum knee flexion of the test sample assembly reaches its maximum value (but see NOTE).

In order to ensure that the test sample reaches the highest possible value of knee flexion that can occur in a normal prosthesis, the structures representing the thigh and shin portion (including the extension pieces) shall be designed and/or arranged so that their posterior contour/shape and extension keep within the “reference” contour/shape determined by the smallest dimensions that are possible in accordance with the manufacturer’s instructions for the intended application(s) of the knee unit or knee-shin-assembly taking account of

- the type(s) of prosthesis (knee-disarticulation, transfemoral or hip-disarticulation prosthesis);
- the attachment of these assemblies to the proximal and distal part of the prosthesis;
- the alignment of the knee joint within the prosthesis;
- the intended use of these assemblies within a complete prosthesis by the envisaged group(s) of amputees.

NOTE In order to enlarge the free space on the posterior side of the test sample to allow the maximum value of knee flexion to be reached, it may be appropriate or necessary to start the adjustment of the alignment with the knee unit placed in a position of posterior displacement relative to the longitudinal axis of the structure representing the thigh and shin portion, which would have the opposite effect on the distance referred to in the first paragraph of [10.6.4](#), and then to re-adjust the alignment in a way which moves the knee unit from the position of posterior displacement in the anterior direction so as to increase this distance.

11 Responsibility for test preparation

11.1 The manufacturer/submitter shall be responsible for the selection and assembly of the components to be tested including screw connection torque settings in accordance with the manufacturer’s written instructions for the assembly of components as supplied with every component of the type.

Correct tightening torque setting is of particular importance for the bolts of clamped connections regarding security against slippage, which is tested in the separate static test in torsion (see [17.1.3.1](#)).

11.2 The manufacturer/submitter shall be responsible for the provision with the test sample of specified parts to be replaced when the number of cycles of the principal cyclic test and the separate cyclic test for knee locks has reached a value at which such replacement is indicated [see 16.1.3.2/[16.3.2.16](#), [17.2.5.1.2](#) a)/[17.2.5.1.9](#) and [17.4.5.1.1](#) b)/[17.4.5.1.16](#)].

11.3 The manufacturer/submitter shall be responsible for preparing the test submission document in accordance with [Clause 12](#).

11.4 The manufacturer/submitter or the test laboratory/facility shall be responsible for the attachment of the end attachments required for the principal structural tests and the separate tests on knee locks (see [13.2.1](#) and [13.6.1](#)) and the extension pieces required for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts (see [13.5.1](#)).

Whoever assembles them shall be responsible for their static alignment in accordance with

- [10.5.1](#) for the principal structural tests;
- [10.5.3](#) for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts;

- [10.5.1](#) and [10.5.4](#) for the separate tests on knee locks.

11.5 The test laboratory/facility shall be responsible for the verification that the test sample is assembled in accordance with [Clause 10](#), the test submission document (see [Clause 12](#)) and the manufacturer's/submitter's written instructions supplied with every component of the type.

If the test sample assembly is not correct the test laboratory/facility shall, in consultation with the manufacturer/submitter, alter it to the specified configuration.

11.6 The test laboratory/facility shall be responsible for adjustment of the alignment to give the correct offsets and effective lever arms during test, in accordance with

- [10.5.1](#) for the principal structural tests (see also [16.2.1.1.2/16.2.1.1.5](#), [16.2.2.1.2/16.2.2.1.5](#) and [16.3.2.2/16.3.2.5](#));
- [10.5.3](#) for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts (see also [17.3.4.1](#));
- [10.5.1](#) and [10.5.4](#) for the separate tests on knee locks (see also [17.4.3.1.2/17.4.3.1.5](#), [17.4.4.1.2/17.4.4.1.5](#) and [17.4.5.1.2/17.4.5.1.5](#)).

12 Test submission document

12.1 General requirements

12.1.1 The manufacturer/submitter shall prepare the test submission document with any associated information and shall provide at least one copy with the batch of test samples of every prosthetic device/structure submitted for test.

12.1.2 The manufacturer/submitter shall, if appropriate, state in the test submission document which of the measurements and recordings of the ankle and knee offsets f_A , f_K , o_A and o_K and/or effective lever arms L_A and L_K , indicated at various stages of the principal structural tests (see [16.2](#) and [16.3](#)) and the separate structural tests on knee locks (see [17.4](#)), shall be carried out.

NOTE Although these data may provide interesting and useful information particularly on the deformation of test samples under load, they are irrelevant to the performance requirements to be satisfied according to the compliance conditions of each of these tests. For this reason, the measurements and recordings referred to will be carried out only if requested by the manufacturer/submitter.

12.1.3 The manufacturer/submitter shall, if appropriate, state in the test submission document which of the information to be recorded in the test log in accordance with this International Standard shall be included in the test report in addition to the information required to be included according to [Clause 19](#).

12.1.4 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.

12.1.5 The manufacturer/submitter shall provide a unique and traceable identification for the test submission document which shall also be indelibly marked on the test sample. The manufacturer/submitter shall maintain a record of such identification.

12.1.6 The manufacturer/submitter shall clearly indicate the test laboratory/facility required to conduct the test.

12.1.7 The manufacturer/submitter shall clearly indicate the date of submission or dispatch to the test laboratory/facility.

12.2 Information required for test samples

12.2.1 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 and model identification and/or number or other means of identification;
- b) type of sample in accordance with [10.2.1](#), [10.2.2](#) or [10.2.3](#);
- c) any certification 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 [10.1.1](#);
- d) any special assembly instructions for the test sample and/or attachments in accordance with [10.3](#);
- e) if not straightforward, identification of the position of effective centres ([6.7.3](#) and [6.7.6](#)) and/or effective centrelines ([6.7.4](#) and [6.7.5](#)) in accordance with [10.5](#);
- f) identification of the worst-case alignment position in accordance with [10.6](#);
- g) tightening torque values for connecting bolts in accordance with [11.1](#);
- h) record of the supply of any replacement parts provided in accordance with [11.2](#);
- i) record of any end attachments and/or extension pieces and their static alignment in accordance with [10.3](#), [10.5](#) (and [11.3](#)).

12.2.2 Test samples for tests on ankle-foot devices and foot units

The manufacturer/submitter shall include in the test submission document

- a) a record of any agreement on the identification of the longitudinal axis of the foot in accordance with [6.7.2](#);
- b) information relating to the arrangements for tests on samples of prosthetic structures including ankle-foot devices and foot units, addressed in [9.3](#);
- c) a statement, with justification, of the size of foot providing the worst-case loading, in accordance with [10.1.2.2](#).

12.2.3 Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts

The manufacturer/submitter shall include in the test submission document a specification of the location/position of the knee flexion stop on each type of prosthesis for which the knee unit or knee-shin-assembly can be used according to their intended application, together with an identification of associated parts that are involved in the provision of the knee flexion stop, in accordance with [10.3.4](#) and [10.3.8](#).

12.3 Information required for tests

12.3.1 General

The information addressed in [12.3.2](#) to [12.3.7](#) for each test sample shall be included in the test submission document.

12.3.2 For all tests