



DPC: 25/30475251 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000

Fax: +44 (0)20 8996 7400

www.bsigroup.com

Date: 17 June 2025

Origin: European

Latest date for receipt of comments: 10 August 2025

Project No. 2023/01286

Responsible committee: CH/168 Prosthetics and orthotics

Interested committees:

Title: Draft BS EN ISO 10328 Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

- i) has any issues related to 3rd party IPR, patent or copyright
- ii) affects other national standard(s)
- iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 10 August 2025

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop <http://shop.bsigroup.com> or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from <https://standardsdevelopment.bsigroup.com/>.

Responsible Committee Secretary: Committee Service Centre (BSI)

Direct tel: 020 8996 7009

E-mail: csc@bsigroup.com

Full document details: 25/30475251 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
------------------	------------------------

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 10328

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

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

ICS: 11.040.40

ISO/TC 168

Secretariat: **DIN**

Voting begins on:
2025-06-17

Voting terminates on:
2025-09-09

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 10328:2025(en)

Full document details: 25/30475251 DC

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

© ISO 2025



Documents

Document Sharing Hub



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	vii
Introduction	ix
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Symbols	2
5 Strength and related performance requirements and conditions of use	3
6 Coordinate systems and test configurations	4
6.1 General	4
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	5
6.3.5 Bottom reference plane, B	6
6.4 Reference points	8
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	12
6.8.3 Effective lever arms L_A and L_K	12
6.8.4 Distance L_{BT}	12
7 Test loading conditions and test loading levels	12
7.1 Test loading conditions	12
7.1.1 General	12
7.1.2 Test loading conditions of principal structural tests	12
7.1.3 Test loading conditions of separate structural tests	13
7.2 Test loading levels and Test Ranges (R)	13
8 Values of test loads, dimensions and cycles	14
9 Compliance	20
9.1 General	20
9.2 Selection of tests required to claim compliance with this document	20
9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this document	20
9.3.1 General	20
9.3.2 Particular arrangements concerning the ankle-foot device or foot unit	20
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 document	21
9.5 Multiple use of test samples	21
9.5.1 General	21

9.5.2	Restriction	22
9.6	Testing at particular test loading levels not specified in this document.....	22
10	Test samples	24
10.1	Selection of test samples.....	24
10.1.1	General.....	24
10.1.2	Selection of ankle-foot devices and foot units of appropriate size of foot.....	25
10.2	Types of test samples.....	25
10.2.1	Complete structure.....	25
10.2.2	Partial structure.....	28
10.2.3	Any other structure.....	28
10.3	Preparation of test samples.....	28
10.4	Identification of test samples.....	29
10.5	Alignment of test samples.....	30
10.5.1	Test samples for principal tests and optional separate tests on knee locks.....	30
10.5.2	Test samples for separate tests on ankle-foot devices and foot units.....	30
10.5.3	Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts.....	30
10.6	Worst-case alignment position of test samples.....	31
11	Responsibility for test preparation	32
12	Test submission document.....	33
12.1	General requirements.....	33
12.2	Information required for test samples.....	34
12.2.1	All test samples.....	34
12.2.2	Test samples for tests on ankle-foot devices and foot units.....	34
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts	34
12.3	Information required for tests.....	34
12.3.1	General.....	34
12.3.2	For all tests.....	34
12.3.3	For static tests in torsion and on ankle-foot devices and foot units.....	35
12.3.4	For static ultimate strength tests.....	35
12.3.5	For cyclic tests.....	35
12.3.6	For tests in torsion.....	35
12.3.7	For tests on ankle-foot devices and foot units.....	35
13	Equipment.....	35
13.1	General.....	35
13.2	Equipment for the principal tests specified in 16.2 and 16.3	36
13.2.1	End attachments.....	36
13.2.2	Jig (optional).....	38
13.2.3	Test equipment.....	38
13.3	Equipment for the separate static test in torsion specified in 17.1	40
13.3.1	Test equipment.....	40
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2	40
13.4.1	Test equipment.....	40
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3	44
13.5.1	Extension pieces.....	44
13.5.2	Test equipment to perform static compression loading – (Compression testing machine or other equipment).....	44
13.6	Equipment for the optional separate tests on knee locks specified in 17.4	44
13.6.1	End attachments.....	44
14	Accuracy.....	44
14.1	General.....	44
14.2	Accuracy of equipment.....	45
14.3	Accuracy of procedure.....	45
15	Test principles.....	45

15.1	General.....	45
15.2	Static test procedure.....	45
15.3	Cyclic test procedure.....	49
16	Test procedures – Principal structural tests.....	49
16.1	Test loading requirements.....	49
16.1.1	Preparation for test loading.....	49
16.1.2	Application of test loading.....	50
16.2	Principal static test procedure.....	51
16.2.1	Principal static proof test.....	51
16.2.2	Principal static ultimate strength test.....	56
16.3	Principal cyclic test procedure.....	58
16.3.1	General requirements.....	58
16.3.2	Test method.....	59
16.3.3	Performance requirements.....	63
16.3.4	Compliance conditions.....	63
17	Test procedures — Separate structural tests.....	67
17.1	Separate static test in torsion.....	67
17.1.1	General.....	67
17.1.2	Purpose of test.....	67
17.1.3	Test method.....	67
17.1.4	Performance requirements.....	69
17.1.5	Compliance conditions.....	69
17.2	Separate tests on ankle-foot devices and foot units.....	71
17.2.1	General.....	71
17.2.2	Purpose of tests.....	71
17.2.3	Separate static proof test for ankle-foot devices and foot units.....	71
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units.....	75
17.2.5	Separate cyclic test for ankle-foot devices and foot units.....	78
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts.....	84
17.3.1	General.....	84
17.3.2	Purpose of test.....	84
17.3.3	Applicability of the test to specific test samples.....	84
17.3.4	Test method.....	85
17.3.5	Performance requirement.....	86
17.3.6	Compliance conditions.....	86
17.4	Separate optional tests on knee locks.....	87
17.4.1	General.....	87
17.4.2	Purpose of tests.....	87
18	Test laboratory/facility log.....	87
18.1	General requirements.....	87
18.2	Specific requirements.....	87
19	Test report.....	87
19.1	General requirements.....	87
19.2	Specific requirements.....	88
19.3	Options.....	88
20	Classification and designation.....	88
20.1	General.....	88
20.2	Examples of classification and designation.....	89
21	Compliance with this document.....	89
21.1	General.....	89
21.2	Example of identifier layout.....	89
21.3	Identifier placement.....	90
	Annex A (informative) Description of internal loads and their effects.....	91

Annex B (informative) Reference data for the specification of test loading conditions and test loading levels and Test Ranges (R) of principal cyclic tests	95
Annex C (informative) Guidance on the application of an alternative static ultimate strength test.....	99
Annex D (informative) Summary of the records to be entered in the test laboratory/facility log	100
Annex E (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.....	110
Annex F (informative) Background Data (reduced) of the six-minute walk test for Adults (see [5])	112
Annex G (informative) Guidance on the application of an additional test loading level P2	113
Annex H (informative) Alternative test geometry for loading condition I and II derived from recent biomechanical studies	118
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	120
Bibliography	123

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).

ISO draws attention to the possibility that the implementation of this document may involve the use of patent. ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of patents which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

This third edition cancels and replaces the second edition (ISO 10328:2016), which has been technically revised.

The main changes are as follows:

- Offsets for P3 and P4 are combined into the test offset for P5 in [Table 7](#) and have been removed from document. Outward offset at bottom reference plane has been changed from -19 mm to +19 mm to align with results from modern gait analysis. Outwards offsets knee and ankle have been adjusted accordingly.
- Test load levels P6 through P8 previously in former [Annex D](#) have been included in [Tables 5, 9](#) and [12](#) and the Annex removed from the document. Former [Annex E](#) and [F](#) have been renamed to [Annex D](#) and [E](#) and references updated. Former [Annex G](#) has been removed. New [Annex F](#), [Annex G](#), [Annex H](#) and [Annex ZA](#) have been added.
- Test Ranges (R) for the strength test have been introduced, related to the intended use of the device. The ranges differ by different loading factors, while tests load levels remain unchanged apart from rounding and accommodation to changed offsets (see below).
- Test forces in [Table 12](#) have been adjusted for P3 and P4.
- A method to analyse shock absorption capacity has been added, which eliminates the difficulty to decide whether a device passes or fails above the ultimate static lower load level.
- Separate tests on knee locks are now optional tests and the test methods on separate tests on knee locks have been removed from the document.
- Test geometry of this document is limited to 150mm above knee-joint centre.
- [Section 21](#) has been renamed to Compliance to Standard and reference to Labelling has been removed from the document.

ISO/DIS 10328:2025(en)

- [Table 2](#), [Table 5](#), [Table 6](#), [Table 7](#), [Table 8](#), [Table 9](#), [Table 10](#), [Table 11](#) and [Table 12](#) have been updated and forces adjusted for new unified offsets.
- [Table B.1](#), [Table B.2](#), [Table B.3](#) and [Table B.4](#) have been updated.
- The rate of loading of between 100 N/s and 10 kN/s is now normative.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Throughout this document, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent 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 document 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 document 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 document.

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

WARNING — This document 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 document 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.

This document specifies Test Ranges (R) by specifying locomotion profiles for the cyclic test in relation to the intended use. According to the concept of the tests of this document, each sample of lower limb prosthetic device / structure submitted for test is, nevertheless, free to develop its individual performance under load.

The tests described in this document 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;
- optional separate 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 document 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). The test geometry described in this standard is only intended to be used up to a level of 150 mm above the knee-joint centre.

This document 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). Lower limb prosthetic devices/structures 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 22523:2006, need not be retested to this document.

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 are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 22675:2024, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

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

IEC 60417, *Graphical symbols for use on equipment*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at <https://www.iso.org/obp>

— IEC Electropedia: available at <https://www.electropedia.org/>

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 conformity with requirements

3.5

shock absorption capacity

capacity of a specimen to absorb energy by deflection without a proportional increase of force

3.6

test force

force applied to a sample under test

4 Symbols

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}
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 4 .	

5 Strength and related performance requirements and conditions of use

5.1 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 in accordance with ISO 22523:2006, 4.4.1. Based on the written instructions for use, the manufacturer/submitter assigns a Test Range (R) that is appropriate to test the strength of the device for the intended use. The manufacturer / supplier is responsible for the instructions for use and the related assignment. National or international classification schemes are independent to the instructions and the related assignment. For the assessment of the strength to sustain loads occurring during use, this document provides a means of determining the four categories of strength. These are listed in [Table 2](#), together with the related performance requirements and the test methods for their verification.

5.2 In order to demonstrate the strength to sustain the loads occurring during use by amputees of a specific lower limb prosthetic device/structure, the following safety concept shall apply.

The device/structure shall

- a) comply with the requirements in [9.1](#), [9.2](#) and [9.3](#) and for a specific test loading level the requirements in [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).

and

c) be used solely for the intended use as described in the instructions for use..

The conditions in a), b) and c) are regarded in both the classification and designation of prosthetic devices/structures according to [Clause 20](#) and their identification 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 document, 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	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
	Permanent deformation of structure shall not exceed prescribed values in any loading condition	Principal static proof test (16.2.1)
Ultimate strength	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)
Fatigue strength	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,
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, with the related mirrored values, 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](#)).

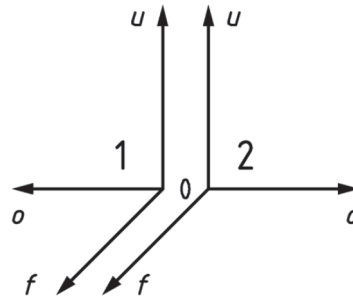
6.3.4 Ankle reference plane, A

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](#)).

NOTE Connectors or ankle-joint units, connecting the ankle-foot unit to proximal elements, can be located in positions different to the effective ankle-joint centre.

6.3.5 Bottom reference plane, B

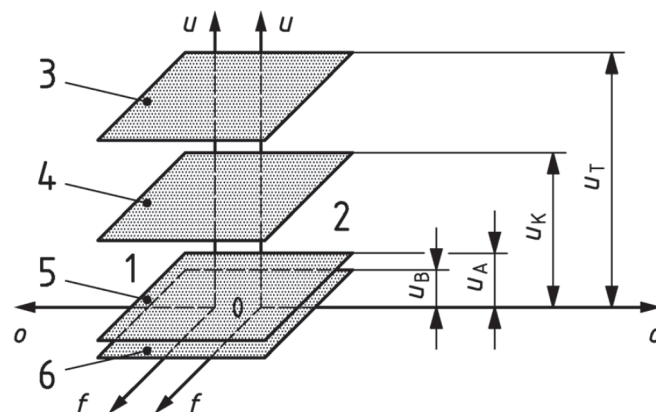
The bottom reference plane, B, is located at a distance $u = u_B$ from the origin. It contains the bottom load application point P_B (see 6.4).



Key

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

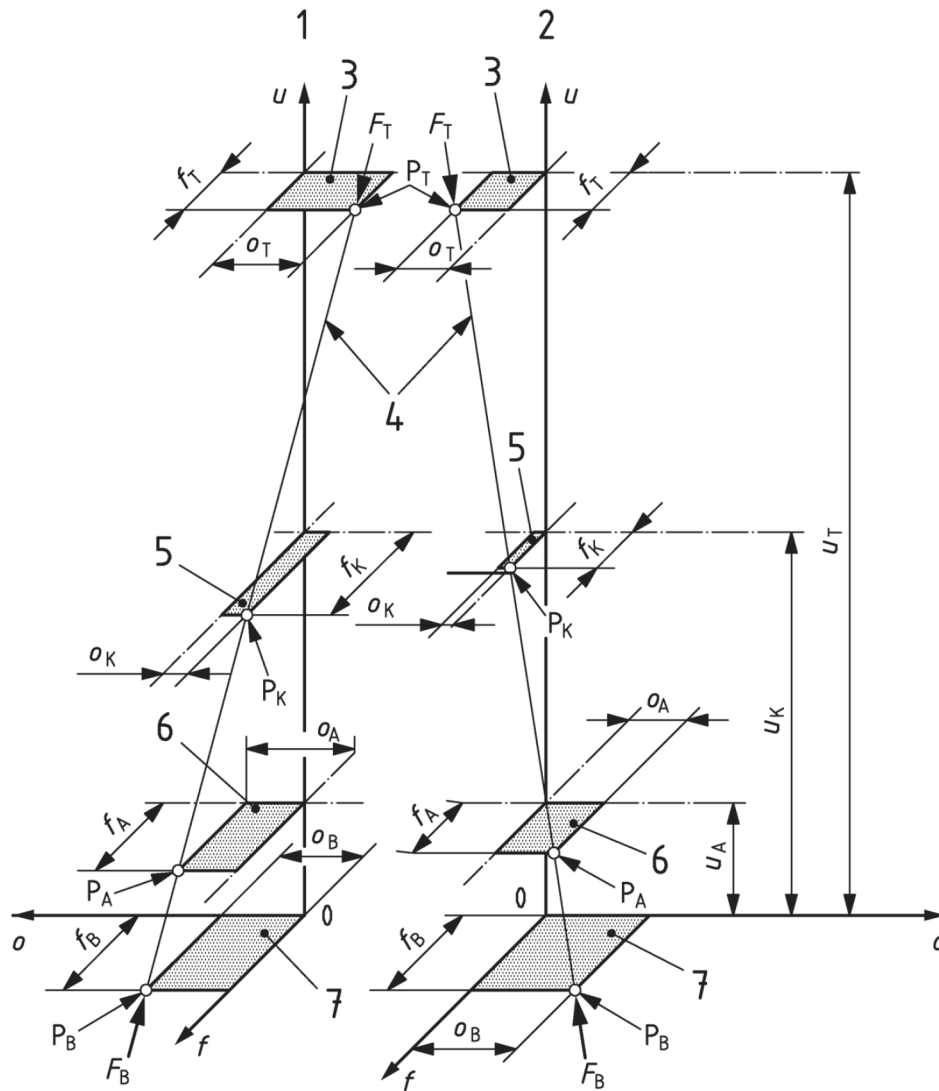
Figure 1 — Coordinate systems for right and left-sided application



Key

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

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



Key

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

In the subsequent clauses of this document, 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 obvious, 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

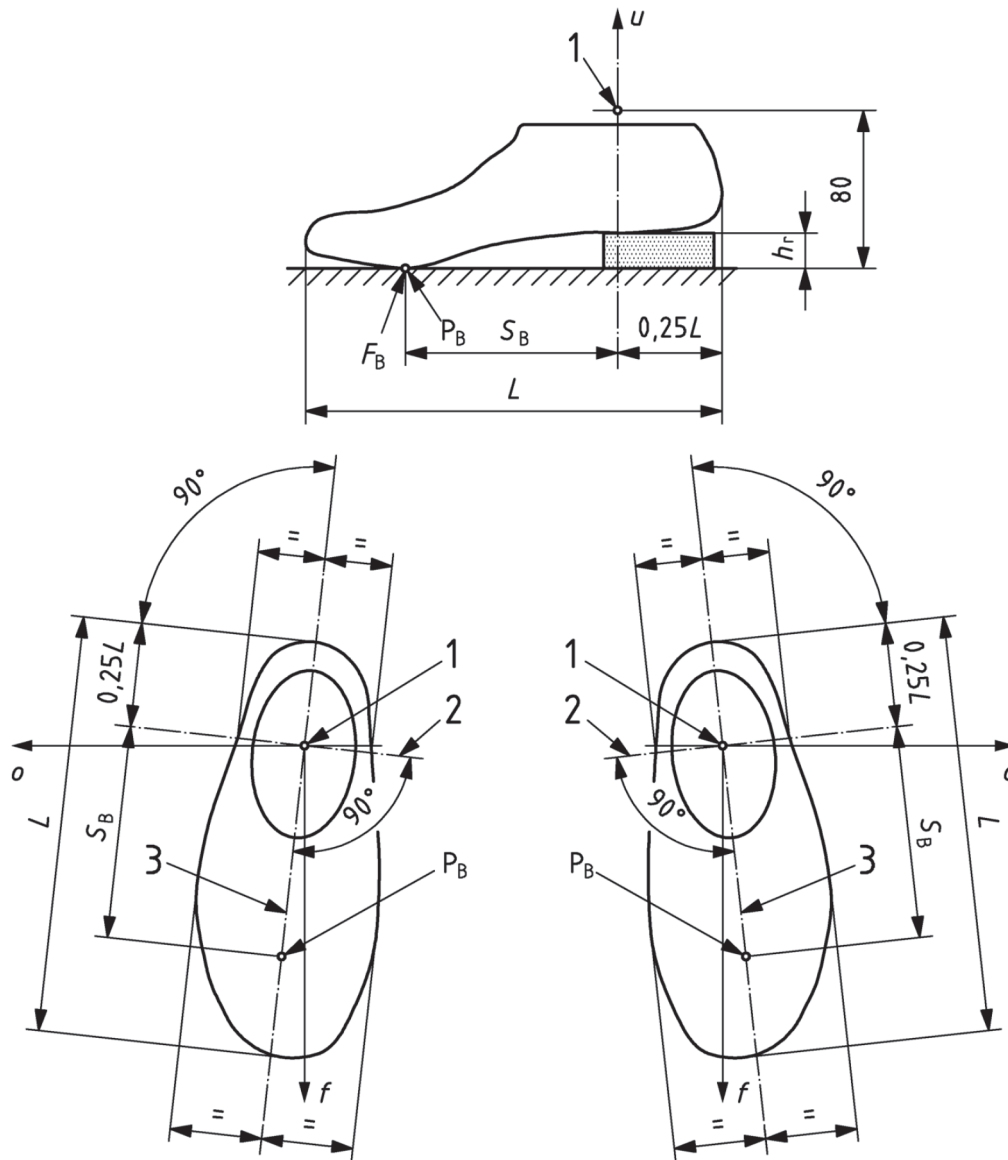
6.7.3.1 Locate the effective ankle-joint centre as described in 6.7.3.2 to 6.7.3.4. See also note in 6.2.2.

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](#)).

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



Key

- 1 effective ankle-joint centre
- 2 effective ankle-joint centreline
- 3 longitudinal axis of foot corresponding to [6.7.2](#)
- h_r heel height

- L foot length
 P_B bottom load application point on forefoot (test loading condition II)
 S_B combined bottom offset of bottom load application point P_B on forefoot from u -axis

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 is located

- a) in a vertical plane passing through the longitudinal axis of the foot;
- b) 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) at a quarter of the length of the foot from the most posterior part of the foot.

NOTE Connectors or ankle-joint units, connecting the ankle-foot unit to proximal elements, can be located in positions different to the effective ankle-joint centre.

6.7.4 Effective ankle-joint centreline

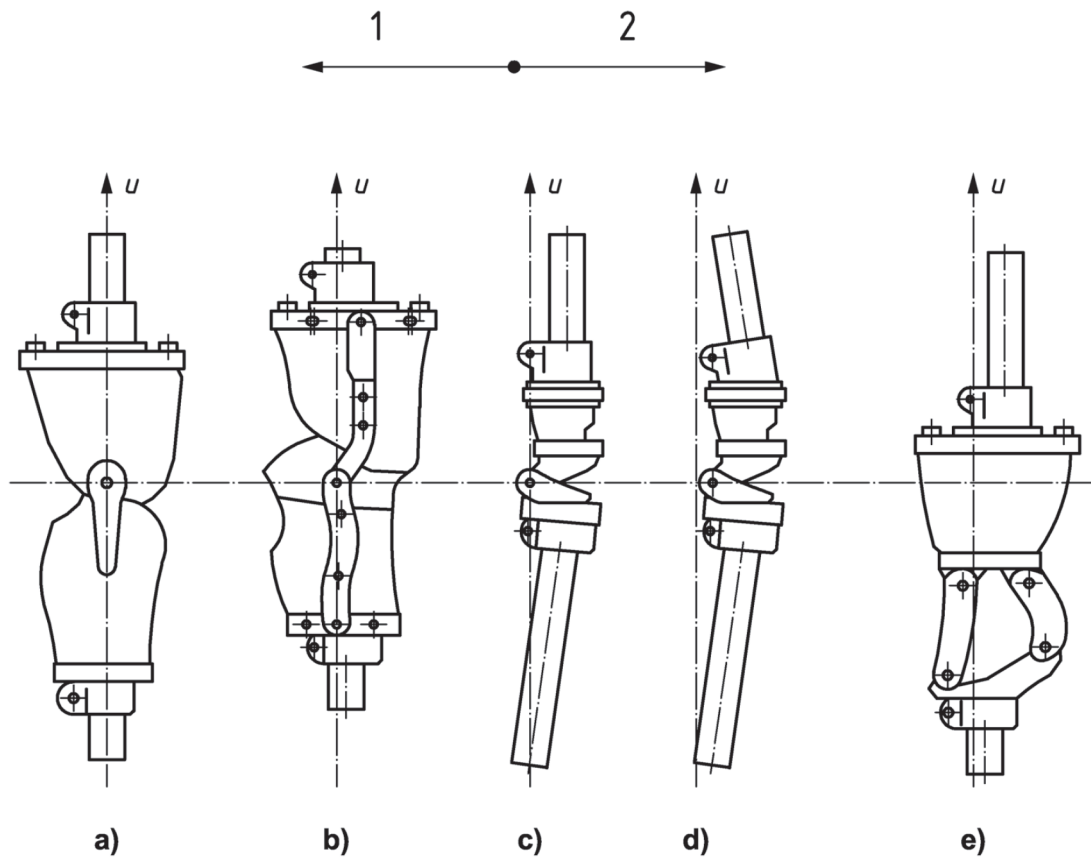
The effective ankle-joint centreline shall be the horizontal line passing through the effective ankle-joint centre (see 6.7.3) perpendicular to the longitudinal axis of the foot (see 6.7.2).

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)].



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](#).

Key

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

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 15 and specified in the relevant Tables 4 to 13. Further details are given in the relevant test procedures, specified in Clause 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 7, 8 and 9.

- 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 10](#).

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 11](#) and [12](#).

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 13](#).

7.1.3.4 Test loading condition of the optional separate tests on knee locks

Separate static and cyclic tests on knee locks are optional. The manufacturer/submitter specifies offsets and test loads in the submission document based on the intended use and the knees are tested accordingly.

7.2 Test loading levels and Test Ranges (R)

7.2.1 The load actions referred to in [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 [Table 4](#) and [Table 9](#)).

- 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](#) 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](#) are calculated by application of factors as specified in [Table 4](#); 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 The values of the dimensions and loads of test loading levels P3, P4, P5, P6, P7 and P8 are specified in separate tables in [Clause 8](#). Further test loading levels will be defined, if necessary.

7.2.4 Description of Test Ranges (R) for adults is given below.

The test parameter that is varied for the ranges is the force (see [Table 9](#) and [Table 12](#)) to emulate the biomechanical parameters and activities of Test Ranges R2, R3 and R4 defined in [Table 3](#).

Background Data about the average walking speed addressed in [Table 3](#) is given in [Annex F](#).

If a patient range assignment is uncertain, always use the next higher Test Range (R).

In absence of an accurate biomechanical assessment, Test Range R4 should be used.

Table 3 — Average walking speed and Description/Activities related to Test Ranges (R)

Test Range	Average Walking Speed ¹ m/s [km/h]	Description/Activities
R2	< 0,84 [3,0]	— Slow walking on level ground and low slope ramps; — Can require use of walking aids; — Limited ability to traverse obstacles and environmental barriers; — Examples: Moving around at home, limited walking in the community.
R3	< 1,11 [4,0]	— Moderate walking on level ground, moderate slope ramps, and stairs; — Ability to traverse most obstacles and environmental barriers; — Examples: Confident outdoor walking, moderate impact recreational activities (e.g. golfing, biking, hiking).
R4	≥ 1,11 [4,0]	— Fast walking on uneven terrain, ramps, and stairs; — Ability to traverse any obstacles and environmental barriers; — Examples: Temporarily carrying heavy objects, high impact recreational activities (e.g. jogging).²
¹ Average walking speed ranges tabled in Annex F about six-minute walk test (see Reference [5]).		
² Use in athletic performance and competitive sports is outside the conditions of Test Range 4 (R4).		

8 Values of test loads, dimensions and cycles

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

[Tables 4](#) to [13](#) describe and/or specify the values of

- test forces and twisting moments,
- dimensions such as segmental lengths, offsets and angles and
- load factor, prescribed factor to multiply tabulated test forces with, based on the Test Range (R)
- cycles (prescribed number of loading cycles).

Table 4 — Test loads and relevant references

Test force ^a or moment		Reference		
		Clause	Table	Test descriptor ^b
Proof test force on end attachments	$F_{pa} = 1,2 F_{su, upper level}$	13	5	A
Stabilizing test force	F_{stab}	13, 16, 17	5, 9, 15	A, 1, 2, 3, 9, 10, 11
Settling test force	$F_{set} = 0,8 F_{cr}$	13, 16, 17	5, 9, 15	A, 1, 2, 3, 9, 10, 11
Static proof test force	$F_{sp} = 1,75 F_{cr}$	16, 17	9, 15	1, 9
Static proof test force on heel	$F_{1sp} = 1,75 F_{1cr}$	17	12	5
Static proof test force on forefoot	$F_{2sp} = 1,75 F_{2cr}$	17	12	5
Static ultimate test force				
— lower level	$F_{su, lower level} = 1,5 F_{sp}$	16	9	2
— upper level	$F_{su, upper level} = 2,0 F_{sp}$	16	9	2
Static ultimate test force	F_{su}	17	13	8
Static ultimate test force	$F_{su} = 2,0 F_{sp}$	17	15	10
Static ultimate test force on heel				
— lower level	$F_{1su, lower level} = 1,5 F_{1sp}$	17	12	6
— upper level	$F_{1su, upper level} = 2,0 F_{1sp}$	17	12	6
Static ultimate test force on forefoot				
— lower level	$F_{2su, lower level} = 1,5 F_{2sp}$	17	12	6
— upper level	$F_{2su, upper level} = 2,0 F_{2sp}$	17	12	6
Minimum test force	F_{cmin}	13, 16, 17	9, 15	3, 11
Maximum test force	F_{cmax}	13, 16, 17	9, 15	3, 11
Range of pulsating test force	F_{cr}	13, 16, 17	9, 15	3, 11
Mean test force	$F_{cmean} = 0,5 (F_{cmin} + F_{cmax})$	13	9, 15	3, 11
Amplitude of pulsating test force	$F_{ca} = 0,5 F_{cr}$	13	9, 15	3, 11
Pulsating test force	$F_c(t)$	13, 16, 17	9, 15	3, 11
Final static test force	$F_{fin} = F_{sp}$	16, 17		3, 11
Minimum test force on heel/forefoot	F_{1cmin}, F_{2cmin}	13, 17	12	7
Maximum test force on heel/forefoot	F_{1cmax}, F_{2cmax}	13, 17	12	7
Range of pulsating test force on heel/forefoot	F_{1cr}, F_{2cr}	13, 17	12	7
Mean test force on heel/forefoot	F_{1cmean}, F_{2cmean}	13	12	7
Amplitude of pulsating test force on heel/forefoot	F_{1ca}, F_{2ca}	13	12	7
	$F_{1c}(t), F_{2c}(t)$	13, 17	12	7
Pulsating test force on heel/forefoot	F_{1fin}, F_{2fin}	17		7
Final static test force on heel/forefoot				
Stabilizing twisting moment	M_{u-stab}	17	10 10	4
Settling twisting moment	M_{u-set}	17	10	4
Maximum twisting moment	M_{u-max}	17		4

NOTE To simplify application of this document, 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

Table 5 — Test forces of the proof test of end attachments for all test loading levels P3, P4, P5, P6, P7 and P8 (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	P8	I	50	1 640	6 840
		II		1 560	6 300
	P7	I		1 416	6 360
		II		1 360	5 808
	P6	I		1 224	5 856
		II		1 120	5 310
	P5	I		1 024	5 376
		II		920	4 830
	P4	I		968	5 082
		II		800	4 200
	P3	I		752	3 948
		II		624	3 276

^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 document 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 document 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 6 — 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 all test loading levels P3, P4, P5, P6, P7 and P8 (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		
	A	B	C
u_T	—	—	—
u_K	$(u_T - u_K) = 150$	$(u_T - u_K) = 150$	$(u_T - u_A) = 570$
u_A	—	$(u_K - u_B) = 500$	—
u_B	$(u_A - u_B) = 80$	—	$(u_A - u_B) = 80$
Total length $(u_T - u_B)$ ^a	650	650	650
^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			

Table 7 — 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 Test loading levels P3, P4, P5, P6, P7 and P8	
		I	II
Top ^c	f_T	82	55
	o_T	– 79	– 40
Knee	f_K	52	72
	o_K	– 50	– 26
Ankle	f_A	– 32	120
	o_A	30	12
Bottom ^c	f_B	– 48	129
	o_B	45	19

^a See 6.8.1.

^b For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 6, the offsets f_T and o_T specified in this table need to be adapted, using the formulae in Figure 15].

^c Only for guidance in aligning test samples.

Table 8 — Values of combined offsets related to the values of offsets listed in Table 7 (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 All loading levels P3, P4, P5, P6, P7 and P8	
		I	II
Top	S_T	114	68
Knee	S_K	72	77
Ankle	S_A	44	120
Bottom	S_B	66	130

^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 7.

^b For individual values of total length ($u_T - u_B$) deviating from the value specified in Table 6, the combined offset S_T specified in this table needs to be adapted, using the formulae in the heading

Table 9 — Test forces of all principal tests and prescribed number of cycles of the cyclic test, for all test loading levels P3, P4, P5, P6, P7 and P8 (see 16.2 and 16.3)

Test procedure and test load			Unit	Test loading level (Px) and test loading condition (I; II)											
				P3		P4		P5		P6		P7		P8	
				I	II	I	II	I	II	I	II	I	II	I	II
Static and cyclic test procedures	Stabilizing test force	F_{stab}	N	50											
	Settling test force	F_{set}	N	752	624	968	800	1 024	920	1 224	1 120	1 416	1 360	1 640	1 560
Static test procedure	Proof test force	F_{sp}	N	1 645	1 365	2 118	1 750	2 240	2 013	2 490	2 263	2 900	2 650	3 200	2 950
	Ultimate static test force	$F_{su, lower level}$	N	2 468	2 048	3 176	2 625	3 360	3 019	3 760	3 419	4 100	3 775	4 450	4 150
		$F_{su, upper level}$	N	3 290	2 730	4 235	3 500	4 480	4 025	4 880	4 425	5 300	4 840	5 700	5 250
Cyclic test procedure	Minimum test force	F_{cmin}	N	50											
	Cyclic range	F_{cr}	N	940	780	1 210	1 000	1 280	1 150	1 530	1 400	1 770	1 700	2 050	1 950
	Maximum test force	F_{cmax} $F_{cmax} = F_{cmin} + F_{cr}$	N	990	830	1 260	1 050	1 330	1 200	1 580	1 450	1 820	1 750	2 100	2 000
	Mean test force	F_{cmean} $F_{cmean} = 0,5 (F_{cmin} + F_{cmax})$	N	520	440	655	550	690	625	815	750	935	900	1 075	1 025
	Cyclic amplitude	F_{ca} $F_{ca} = 0,5 F_{cr}$	N	470	390	605	500	640	575	765	700	885	850	1 025	975
	Final static force	F_{fin} $F_{fin} = F_{sp}$	N	1 645	1 365	2 118	1 750	2 240	2 013	2 490	2 263	2 900	2 650	3 200	2 950
	Force related to R_x	R2	1	1											
		R3		1											
		R4		1,15											
	Prescribed number of cycles	R2	1	3×10^6											
		R3													
		R4													

Table 10 — Twisting moments of the separate static test in torsion for all test loading levels P3, P4, P5, P6, P7 and P8 (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}
P3, P4, P5, P6, P7 and P8	3	1	50

Table 11 — Angles of directions of loading of all separate tests on ankle-foot devices and foot units, for all test loading levels P3, P4, P5, P6, P7 and P8 (see 17.2 and Figure 7)

Angles	Degrees
α	15
β	20
γ	7

Table 12 — Test forces of all separate tests on ankle-foot devices and foot units and prescribed number of cycles of the cyclic test, for all test loading levels P3, P4, P5, P6, P7 and P8 (see 17.2)

Test procedure and test load			Unit	Test loading level (P_x) and test loading condition (F_{1x} , F_{2x})					
				P3	P4	P5	P6	P7	P8
				Heel, fore-foot loading, F_{1x}, F_{2x}	Heel, fore-foot loading, F_{1x}, F_{2x}	Heel, fore-foot loading, F_{1x}, F_{2x}	Heel, fore-foot loading, F_{1x}, F_{2x}	Heel, fore-foot loading, F_{1x}, F_{2x}	Heel, fore-foot loading, F_{1x}, F_{2x}
Static test procedure	Proof test force	F_{1sp}, F_{2sp}	N	1 645	2 118	2 240	2 490	2 900	3 200
	Ultimate static test force	$F_{1su}, \text{lower level}, F_{2su}, \text{lower level}$	N	2 468	3 176	3 360	3 760	4 100	4 450
		$F_{1su}, \text{upper level}, F_{2su}, \text{upper level}$	N	3 290	4 235	4 480	4 880	5 300	5 700
Cyclic test procedure	Minimum test force	F_{1cmin}, F_{2cmin}	N	50					
	Cyclic range	F_{1cr}, F_{2cr}	N	940	1 210	1 280	1 530	1 770	2 050
	Maximum test force	F_{1cmax}, F_{2cmax} $F_{xcmax} = F_{xcmin} + F_{xcr}$	N	990	1 260	1 330	1 580	1 820	2 100
	Mean test force	F_{1cmean}, F_{2cmean} $F_{xcmean} = 0,5 (F_{xcmin} + F_{xcmax})$	N	520	655	690	815	935	1 075
	Cyclic amplitude	F_{1ca}, F_{2ca} $F_{xca} = 0,5 F_{xcr}$	N	470	605	640	765	885	1 025
	Final static force	F_{1fin}, F_{2fin} $F_{xfin} = F_{xsp}$	N	1 645	2 118	2 240	2 490	2 900	3 200
	Force related to R_x	R2	1	1					
		R3		1					
		R4		1,15					
	Prescribed number of cycles	R2	1	2×10^6					
		R3							
		R4							

NOTE: Toe moments at ankle height ($u=80$ mm) generated in ISO 22675:2024 for Test Range R3 are up to 4 % higher than toe moments generated according to this document in the same Test Range (depend on characteristic of sample under load). This higher moment can be reached by raising the test force by up to 4% in standard ISO 10328 foot test setup for only this u-level. Structures above 80 mm experience lower moments compared to ISO 22675:2024 R3 due to the mechanical setup. Therefore for feet higher than 80 mm, the connecting adapters need to be tested in separate principal structural tests (see 7.1.2).

Table 13 — Loading parameters of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts for all test loading levels P3, P4, P5, P6, P7 and P8 (see 17.3 and Figure 8)

Test loading level	Length, L_e mm	Ultimate static test force, F_{su} N
P3, P4, P5, P6, P7 and P8	400	1 750

9 Compliance

9.1 General

In order to claim compliance with this document for a prosthetic device/structure submitted for test, a prescribed number of test samples of this structure from the allowed batch, specified in [Table 15](#), 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 and the Test Range (R) at which tests were conducted.

Compliance of a prosthetic device/structure submitted for test with the performance requirements of a specific test of this document 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](#)).

Compliance demonstrated for devices subjected to a higher Test Range (R), also covers lower Test Ranges (R) at identical P-level.

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 document

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 document, are indicated in [Table 14](#).

9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this document

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 document 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 document, 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 document, 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 15](#)) 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 document 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 document 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 document 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 document

The minimum number of tests required for each type of test in the prescribed loading conditions in order to claim compliance with this document is shown in [Table 15](#).

The tests shall be conducted on test samples from the batch specified in [Table 15](#) 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 15](#) 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](#), [17.2.4.1.2](#), [17.2.4.1.2](#)).

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 document, may be subjected to other tests of this document, 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 15](#)).

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 optional separate static tests for knee locks ([17.4](#)) – (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 document 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 document cannot be claimed if the test sample has previously been subjected to any of the static ultimate strength tests of this document.

9.6 Testing at particular test loading levels not specified in this document

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

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

However, compliance with this document may be claimed for the next lower or a lower regular test loading level of this document, from which that particular test loading level has been derived.

Reference to this document can 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 document

or in a more specific manner

b) by applying the tests of this document at test loads set $x\%$ above test loading level P_y .

Table 14 — Tests required to claim compliance with this document 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
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis with foot unit	× (see 9.3)	×	×	×
Complete structure of transfemoral/knee-disarticulation prosthesis or distal part of hip-disarticulation prosthesis without foot unit	×	×		×
Complete structure of transtibial prosthesis with foot unit	×	×	×	
Complete structure of transtibial prosthesis without foot unit	×	×		
Partial structure including knee unit and ankle-foot device or foot unit	×	×	×	×
Partial structure including knee unit but not ankle-foot device or foot unit	×	×		×
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 document, 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 can be determined by other parts of the prosthesis which come into contact first.)				

Table 15 — Number of tests and test samples required to claim compliance with this document

Type of test	Test loading condition and manner of application	Mini- mum ^a num- ber of tests required	Batch ^b of test samples allowed for each type of test		
			Regular test samples	Possible substitute 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	2 2	1 1	16.2.1.1.12
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	2 2	1 1	16.2.2.1.9
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	2 2	1 1	16.3.2.22
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					
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 and Direction of loading at angle β (7.1.3.2)	2 2	2 2	1 1	17.2.4.1.15 17.2.4.1.15 and/or 17.2.4.1.16
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	—	—
^a The term minimum indicates that repetition of tests on permitted substitute test samples can be necessary to satisfy the compliance conditions. ^b For the definition of batch 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 can 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 8 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:

- a) select a size that gives the correct combined bottom offset, S_B ;
- b) if a correct size foot is not available, use the next larger size;
- c) 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 11 and 12).

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 can 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 document.

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](#).



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

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 document.

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

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 optional 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 6](#) 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.