



BSI Standards Publication

Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods

National foreword

This British Standard is the UK implementation of EN ISO 22675:2025. It is identical to ISO 22675:2024. It supersedes BS EN ISO 22675:2016, which is withdrawn.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 committee manager.

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Amendments/corrigenda issued since publication

Date	Text affected

English Version

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Prothèses - Essais d'articulations cheville-pied et
unités de pied - Exigences et méthodes d'essai (ISO
22675:2024)

Prothetik - Prüfung von Knöchel-Fuß-Pasteilen und
Fußeinheiten - Anforderungen und Prüfverfahren (ISO
22675:2024)

This European Standard was approved by CEN on 19 November 2024.

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European foreword

This document (EN ISO 22675:2025) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products and accessibility" 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of an identical text or by endorsement, at the latest by November 2025, and conflicting national standards shall be withdrawn at the latest by November 2025.

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

This document supersedes EN ISO 22675:2016.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 22675:2024 has been approved by CEN as EN ISO 22675:2025 without any modification.

Annex ZA (informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, 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 General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

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 Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance 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 Regulation (EU) 2017/745 [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks/Notes
14.1	5, 9, 19 and 20	Covered with respect to mechanical strength of the ankle-foot device or foot unit in combination with the remainder of a prosthetic structure. Risks arising from misconnections are not covered. Covered with respect to any restrictions on use which shall be indicated on the identifier or in the instructions for use.
20.1	5, 7, 8, 9, 10, 15, 16 and 17	Only covered for mechanical strength.
23.1	19 and 20.3	General Safety and Performance Requirement 23.1 is not fully covered here; only the aspects of classification are addressed.
23.2 b)	19 and 20	Only covered for classification of the use of the device.
23.2 m)	7, 19 and 20.1	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.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Column 1 Reference in Clause 2	Column 2 International Standard Edition	Column 3 Title	Column 4 Corresponding European Standard Edition
ISO 7000	ISO 7000:2019	Graphical symbols for use on equipment — Registered symbols	None For applicable standard edition see Column 2
ISO 8549-1	ISO 8549-1:2020	Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses	None For applicable standard edition see Column 2
ISO 10328:2016	ISO 10328:2016	Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods	EN ISO 10328:2016
ISO 22523:2006	ISO 22523:2006	External limb prostheses and external orthoses — Requirements and test methods	EN ISO 22523:2006
IEC 60417	IEC 60417:2002 DB	Graphical symbols for use on equipment	None For applicable standard edition see Column 2

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

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.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document 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 (a) patent(s). 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 (a) patent(s) 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.

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 22675:2016), which has been technically revised.

The main changes are as follows:

- test Ranges (R) have been introduced;
- test loading levels P7 and P8 have been introduced in [Table 5](#), [8](#), [9](#), [10](#), [11](#) and [A.1](#) and the clauses pointing at these tables have been updated;
- Former [Annex C](#) has been deleted and integrated in main text;
- [Subclause 15.2](#) has been updated;
- [Subclause 16.5](#) has been added.

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

This document offers alternatives to the structural tests on ankle-foot devices and foot units specified in ISO 10328:2016, 17.2, which still suffer from several “weaknesses”, such as:

- a) the inconsistency of the lines of application of the heel and forefoot test forces with those of the test forces of test loading conditions I and II for the principal structural tests specified in 16.2 (static tests) and 16.3 (cyclic test) of ISO 10328:2016;
- b) the unrealistic course and magnitude of loading in the phase between the instants of maximum heel and forefoot loading during the cyclic test;
- c) the effect of periodical “stepping in a hollow” during the cyclic test, resulting from simultaneous heel and forefoot loading at different angles.

In this relation, it is important to note that the complexity of the test equipment required for the testing of ankle-foot devices and foot units specified in this document is low, comparable to that of the test equipment required for the corresponding separate structural tests specified in ISO 10328:2016. Apparently, basic components of both types of test equipment are similar and can be re-used in a modified design.

Finally, the potential of the general concept applied to the test procedures specified in this document allows other applications directed to the assessment of specific performance characteristics of ankle-foot devices and foot units that can be of relevance in the future.

NOTE Further guidance on the specification of the test loading conditions and test loading levels and on the design of appropriate test equipment is given in ISO/TR 22676.

Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods

WARNING — This document is not suitable to serve as a guide for the selection of a specific ankle-foot device or foot unit in the prescription of an individual lower limb prosthesis! Any disregard of this warning can result in a safety risk for amputees.

1 Scope

This document primarily specifies a cyclic test procedure for ankle-foot devices and foot units of external lower limb prostheses, these differ in the potential to realistically simulate those loading conditions of the complete stance phase of walking from heel strike to toe-off which is relevant to the verification of performance requirements such as strength, durability and service life.

This potential is of particular importance for the assessment of the performance of a variety of recent designs of ankle-foot devices and foot units with specific characteristics that will only develop under realistic conditions of loading.

In addition, this document specifies a static test procedure for prosthetic ankle-foot devices and foot units, consisting of a static proof test and a static ultimate strength test, distinguished, besides other features (see NOTE), by the potential to generate heel and forefoot forces at lines of action conforming to those occurring at the instants of maximum heel and forefoot loading during the cyclic test.

These loading conditions are characterized by a loading profile determined by the resultant vector of the vertical and horizontal (A-P) ground reaction forces and by a locomotion profile determined by the tibia angle.

The test loading conditions specified in this document are characterized by standardized formats of these loading and locomotion profiles, applied by the cyclic and static test procedures to each sample of ankle-foot device or foot unit submitted for test.

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 ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

This document is suitable for the assessment and testing of prosthetic ankle-foot devices and foot units with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE). 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 10328:2016, need not be retested to this document.

NOTE The lines of action of the heel and forefoot forces generated by the static test procedure for Test Range 4 (R4) specified in this document approach those determining the sagittal plane loading of the test loading conditions I and II for the principal structural tests referring to ISO 10328:2016, without changing the values of the angles of the heel and forefoot platform(s) for the structural tests on ankle-foot devices and foot units specified in ISO 10328:2016.

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 10328:2016, *Prosthetics — Structural testing of lower-limb prostheses — 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 ankle-foot device or foot unit 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 ankle-foot device or foot unit but which could render it thereafter unusable

3.3

fatigue strength

cyclic load that can be sustained by the ankle-foot device or foot unit for a given number of cycles

3.4

batch

set of test samples of an ankle-foot device or foot unit 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

Note 1 to entry: Test equipment, build to test to previous versions of this document (using compression force with a positive sign) do not need to be reprogrammed.

3.7

accuracy of equipment

accuracy to which the test equipment and any jig and measuring device measures linear and angular dimensions, test forces and the frequency of cyclic tests

3.8

accuracy of procedure

tolerances with which linear and angular dimensions are set and finally adjusted, test forces and tilting angles are applied and the frequency of cyclic tests is controlled

4 Symbols

F, F_1, F_2	Test forces
F_{set}	Settling test force
F_{stab}	Stabilizing test force
F_{pa}	Proof test force of end attachments
$F_{1\text{sp}}, F_{2\text{sp}}$	Static proof test force on heel/forefoot
$F_{1\text{su}}, F_{2\text{su}}$	Static ultimate test force on heel/forefoot
$F_c(t); F_c(\beta)$	Pulsating test force
$F_{1\text{cmax}}, F_{2\text{cmax}}$	1 st and 2 nd maximum value of pulsating test force
F_{cmin}	Intermediate minimum value of pulsating test force
$F_{1\text{fin}}, F_{2\text{fin}}$	Final static test force on heel/forefoot

5 Strength and related performance requirements and conditions of use

5.1 A prosthetic ankle-foot device or foot unit 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 their written instructions on its intended use in accordance with ISO 22523:2006, 4.4.1. Based on the written instructions, the manufacturer assigns a Test Range (R) that is appropriate to test the strength 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 means of determining different categories of strength. These are listed in [Table 1](#), 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 ankle-foot device or foot unit, the following safety concept shall apply:

The device shall

- conform with the requirements in [9.1](#) and [9.2](#) and for a specific test loading level, with the requirements in [7.2](#),
- be used in accordance with the body mass limit specified by the manufacturer in consideration of the intended use of that device, and

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 their written instructions on the intended use of a specific ankle-foot device or foot unit, taking account of all other factors affecting the loads expected to be exerted on that ankle-foot device or foot unit by amputees (see [Clause A.1](#)).

- be used solely for the intended use as described in the IFU.

The conditions in a), b) and c), are regarded in both the classification and designation of ankle-foot devices and foot units according to [Clause 19](#) and their indicators according to [Clause 20](#).

Table 1 — 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 the proof test forces F_{1sp} and F_{2sp} at the prescribed values for the prescribed time (see 16.2.2).	Static proof test (see 16.2.1), successively applying heel and forefoot loading.
Ultimate strength	Structure shall sustain static loading by the ultimate test forces F_{1su} and F_{2su} at the prescribed values (see 16.3.2).	Static ultimate strength test (see 16.3.1), separately applying heel and forefoot loading.
Fatigue strength	Structure shall sustain successively (see 16.4.2) 1) cyclic loading by the pulsating test force $F_c(t)$ or $F_c(\beta)$ at the prescribed profile for the prescribed number of cycles and 2) final static loading by the final test forces F_{1fin} and F_{2fin} at the prescribed values for the prescribed time.	Cyclic test procedure (see 16.4.1), repeatedly applying a loading profile simulating the stance phase of walking, followed by final static heel and fore-foot loading.

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

6 Coordinate system and test configurations

6.1 General

The test configurations of this document are defined in a manner similar to that applied in ISO 10328:2016.

Each test configuration shall be defined in a two-dimensional, rectangular coordinate system (see Figure 1).

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 Origin and axes of the coordinate system

The origin and the axes of the coordinate system are specified in a) to d) in relation to a prosthesis which is standing on the ground in an upright position. In Figure 1 the ground is represented by the bottom plane B.

NOTE 1 ISO 9787 defines coordinate systems for robots. ISO 8855 defines the same coordinate system for vehicles in a right-hand system: Upward (u), thumb: z; Forward (f), pointer finger: x; Outward (o) (to the left), middle finger: y.

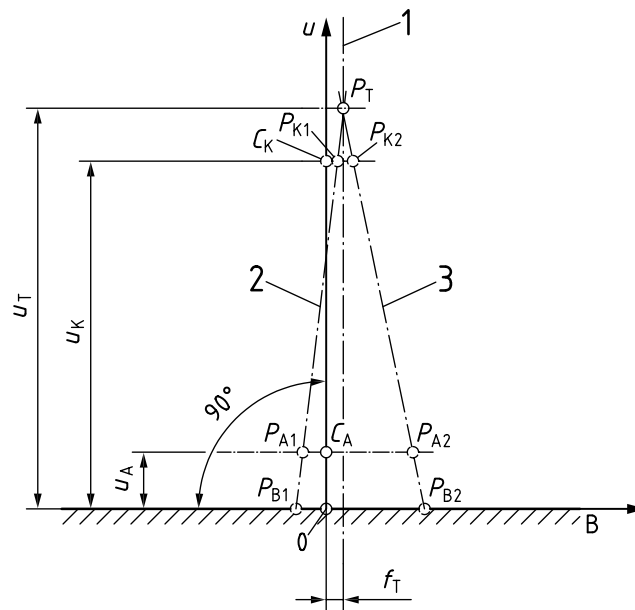
If a test sample is not in the vertical position, the axes of the coordinate system shall be rotated to correspond.

- a) The origin 0 of the coordinate system is located in the bottom plane B.
- b) The u -axis extends from the origin 0 perpendicular to the bottom plane B and passes through the effective ankle-joint centre C_A , specified in 6.7.3 (see Figure 1). Its positive direction is upwards (in the proximal direction).

NOTE 2 The location of the effective ankle-joint centre C_A (see Figure 1) is defined in 6.7.3.4. Connectors or ankle-joint units, connecting the ankle-foot unit to proximal elements, can be located in positions different to C_A .

NOTE 3 The u -axis also passes through the effective knee-joint centre C_K (see Figure 1). This can be relevant to the setting-up of test samples of specific designs of ankle-foot devices or foot units which extend towards the knee unit of a lower limb prosthesis and which, therefore, also require the knowledge of the position of the effective knee joint centre.

- c) The f -axis extends from the origin 0 perpendicular to the u -axis (see Figure 1). Its positive direction is forward towards the toe (in the anterior direction).
- d) The o -axis extends from the origin 0 perpendicular to both, the u -axis and to the f -axis (see Figure 1). Its positive direction points medial for right sided foot.



Key

B	bottom plane (see 6.2)
0	origin of coordinate system [see 6.2 a)]
u	(upward) axis of coordinate system [see 6.2 b)]
f	(forward) axis of coordinate system [see 6.2 c)]
C_A	effective ankle-joint centre [see 6.2 b) and 6.7.3]
C_K	effective knee-joint centre [see NOTE of 6.2 b)]
P_T	top load application point (see 6.3)
P_{K1}, P_{K2}	knee load reference points (see 6.3)
P_{A1}, P_{A2}	ankle load reference points (see 6.3)
P_{B1}, P_{B2}	bottom load application points (see 6.3)
1	line of application of test force F (see 6.5)
2	line of action of resultant reference force F_{R1} (heel loading) (see 6.6)
3	line of action of resultant reference force F_{R2} (forefoot loading) (see 6.6)

Figure 1 — Coordinate system with reference parameters

6.3 Reference points

The reference points determine the position of the line of application of the test force F (see 6.5) and the lines of action of the resultant reference forces F_{R1} (heel loading) and F_{R2} (forefoot loading) (see 6.6 and Figure A.1) within the f - u -plane of the coordinate system (see 6.2 and Figure 1). The coordinates of the reference points are as follows:

- top load application point (see NOTE 1), $P_T (f_T, u_T)$;
- knee load reference point, $P_K (f_K, u_K)$;
- ankle load reference point (see NOTE 2), $P_A (f_A, u_A)$;
- bottom load application point, $P_B (f_B, 0)$.

The only reference point to be defined and specified for the application of the test principles outlined in 15.1 is the top load application point P_T , at which the test force F (see 6.4) is applied to the test sample (see Figure 1).

The reference points at knee, ankle and bottom level are required to specify the lines of action of the resultant reference forces F_{R1} and F_{R2} .

In the subsequent clauses of this document, the f -coordinates are also referred to as "offsets".

NOTE 1 If appropriate, the dependence of the position of the top load application point $P_T (f_T, u_T)$ on the foot length L is indicated by the additional suffix 'L' in the form $P_{T,L} (f_{T,L}, u_{T,L})$ (see [10.5](#), [16.1.1](#), [A.2.2.3](#), [A.2.4.1](#), [D.3.4.2](#), [Figures 4](#) and [5](#) and [Table 7](#)). If appropriate, general suffix 'L' can be replaced by specific values (see [Figures A.2](#) and [D.4](#)).

NOTE 2 If the ankle load reference point $P_A (f_A, u_A)$ describes the position of specific lines of action as illustrated in [Figure 1](#) for heel loading by resultant reference force F_{R1} and forefoot loading by resultant reference force F_{R2} , this can be indicated by the additional suffixes '1' for heel loading and '2' for forefoot loading in the form $P_{A1} (f_{A1}, u_{A1})$ or $P_{A2} (f_{A2}, u_{A2})$, if appropriate (see [A.2.2](#)). The additional suffixes '1' and '2' are also used to identify the f_B -offsets addressed in [13.2.2.2.1](#) and listed in [Table 4](#).

6.4 Test force F

The test force F is a single load applied to the top load application point P_T specified in [6.3](#) along its line of application specified in [6.5](#).

NOTE During testing, a force component, F_H , perpendicular to the line of application of the test force F develops as shown in [Figure A.1](#) on the test machine.

6.5 Line of application of test force F

The line of application of the test force F passes through the top load application point P_T parallel to the u -axis (see [Figures 1](#), [5](#) and [A.1](#)).

6.6 Lines of action of resultant reference forces F_{R1} and F_{R2}

The lines of action of the resultant reference forces F_{R1} and F_{R2} (see [Figure A.1](#)) pass through the reference points specified in [6.3](#), intersecting at the top load application point P_T [see also [15.1 d](#)]. They determine the directions of static and maximum cyclic heel and forefoot reference loading (see [A.2.2](#)).

NOTE For further background information, see also [A.2.4](#).

6.7 Longitudinal axis of the foot and effective ankle joint centre

6.7.1 General

In order to align the test sample within the coordinate system (see [6.1](#) and [6.2](#)), 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](#)).

If the location of the longitudinal axis of the foot or the effective ankle-joint centre 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 2](#).

6.7.3 Effective ankle-joint centre C_A

6.7.3.1 Locate the effective ankle-joint centre C_A 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 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 2).

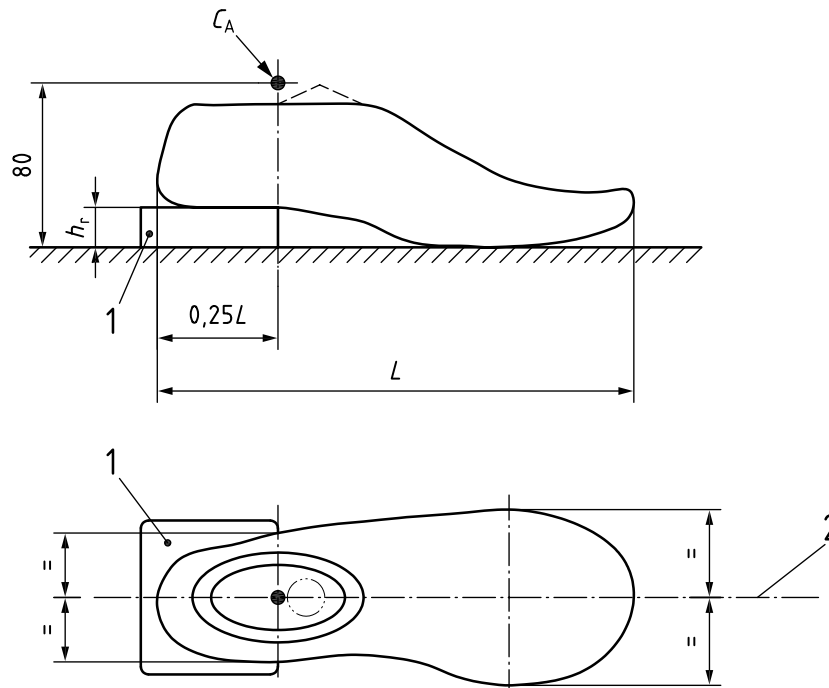
Unless otherwise specified by the manufacturer/submitter, the recommended heel height for the ankle-foot device or foot unit under test is taken as $h_r = 20$ mm (see also Figures 4 and 5).

6.7.3.4 The effective ankle-joint centre C_A lies

- a) in a vertical plane passing through the longitudinal axis of the foot;
- b) 80 mm above the bottom surface;
- c) a quarter of the length of the foot from the most posterior part of the foot.

See also 6.2 b), Note 2.

Dimensions in millimetres



Key

- 1 block of recommended heel height, h_r (see 6.7.3.3)
- 2 longitudinal axis of foot (see 6.7.2)
- C_A effective ankle-joint centre (see 6.7.3)
- L foot length (see 7.1)

Figure 2 — Determination of longitudinal axis of foot and effective ankle-joint centre C_A

7 Test loading conditions and test loading levels

7.1 Test loading conditions

The complexity of the load actions to which the ankle-foot device or foot unit of a lower-limb prosthesis is actually subjected during use by the amputee cannot be simulated by a single test procedure. Therefore, several types of cyclic and static tests are specified, each applying a single or two different test loading condition(s).

The single test loading condition of the cyclic test is characterized by a specific profile of pulsating test force, $F_c(t)$ or $F_c(\beta)$, applied to the top of the test sample while this is supported by a foot platform which performs angular movement following a specific profile of tilting angle, $\beta(t)$.

The two different test loading conditions of the static tests are characterized by a specific test force, F , applied to the top of the test sample while this is supported either on the heel or on the forefoot by a foot platform which is fixed at specific tilting angles, β_1 and β_2 .

Each test loading condition produces compound loadings typical of the stance phase of walking or other single events of loading occurring in the daily use of a lower limb prosthesis by the amputee.

Each test loading condition is applicable to test samples of ankle-foot devices and foot units of any size, due to the establishment of a relationship between the position of the top load application point P_T and the foot length L (see [Figures 2, 4](#) and [A.2](#)).

The test loading condition(s) of each type of test are addressed in [Table 12](#) together with their manner of application and specified in the relevant table of [Tables 3](#) to [11](#). Further information is given in [Clauses 15](#) and [16](#).

NOTE For further information see [Annex A](#).

7.2 Test loading levels and Test Ranges (R)

7.2.1 The load actions referred to in [7.1](#) vary with individual physical parameters, locomotion characteristics of the amputee and other factors. For these reasons different categories of prosthesis are needed and, consequently, different test loading levels are required, each being specified by individual values of dimensions, number of loading cycles 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 A](#).

The series Test Ranges (R) define locomotion characteristics together with the number of loading cycles as given in [7.2.4](#)

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 [9](#)).

- The values of the test forces F_{1cmax} and F_{2cmax} of the cyclic test according to [16.4.1](#) 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 A](#)).
- The corresponding values of the test forces F_{1sp} and F_{2sp} of the static proof test according to [16.2.1](#) and the test forces F_{1su} and F_{2su} of the static ultimate strength test according to [16.3.1](#) are calculated by application of factors as specified in [Table 3](#).
- 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 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 and are defined for the principal structural tests and the separate structural tests on ankle-foot devices and foot units in this document.

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

The test parameter that is varied for the ranges is the angular profile (see [Table 8](#)) to emulate the biomechanical parameters and activities of Test Ranges R2, R3 and R4 defined in [Table 2](#).

Background Data about the average walking speed addressed in [Table 2](#) is given in [Annex E](#).

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

Test Range	Average walking speed ^a 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).^b

^a Average walking speed ranges in [Table E.1](#) about six-minute walk test (see Reference [\[4\]](#)).

^b Use in athletic performance and competitive sports is outside the conditions of Test Range 4 (R4).

8 Values of test forces, dimensions and cycles

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

[Tables 3](#) to [11](#) describe and/or specify the values of

- test forces;
- test forces, related to Test Range (R);
- dimensions such as segmental lengths, foot lengths and coordinates (offsets);
- cycles (prescribed number of loading cycles).

Figure 3 illustrates thresholds for the loading profile of the cyclic test.

Annex D indicates how the adjustment of the tilting axis, TA, of the foot platform in dependence on the foot length, L , specified by the values listed in Table 7, can be avoided or limited by transposing the top load application point P_T (see D.3.4).

Table 3 — Test forces and relevant references

Test force ^a	Reference		
	Subclause	Table	Relevant test
Settling test force	13.2.2	Table 5	Proof test of end attachment
Stabilizing test force			
Proof test force on end attachments			
Static proof test force on heel	16.2.1	Table 9	Static proof test
Static proof test force on forefoot	16.3.1	Table 9	Static ultimate strength test
Static ultimate test force on heel			
— lower level			
— upper level			
Static ultimate test force on forefoot			
— lower level			
— upper level			
Pulsating test force	13.4.2, 16.4.1	Table 9, (Tables 10 and 11)	Cyclic test procedure
1st and 2nd maximum value of pulsating test force			
Intermediate minimum value of pulsating test force			
Final static test force on heel / forefoot			
^a The test forces F_{set} , F_{pa} , F_{sp} and F_{su} are determined using appropriate factors.			

Table 4 — Values of bottom offsets $f_{B1,L}$ (heel) and $f_{B2,L}$ (forefoot) for given values of foot length L , relevant to the design and/or adjustment of the rigid foot dummy required to simulate the effective lever arms of an ankle-foot device or foot unit in the proof test of end attachments

Parameter	Dimension	Value												
Foot length L	cm	20	21	22	23	24	25	26	27	28	29	30	31	32
$f_{B1,L}$ ^a	mm	$f_{B1,L} = f_{B1,26} \cdot (L/26)$												
		- 32	- 33	- 35	- 36	- 38	- 39	- 41	- 43	- 44	- 46	- 47	- 49	- 50
$f_{B2,L}$ ^a	mm	$f_{B2,L} = f_{B2,26} \cdot (L/26)$												
		105	110	115	120	126	131	136	141	146	152	157	162	167
See 13.2.2														
^a The values of $f_{B,26}$ are determined by the condition given in Formula (1): $(f_{B,26} - f_{T,26}) / u_{T,26} = (f_{A,26} - f_{T,26}) / (u_{T,26} - u_{A,26})$. For the values of $f_{A,26}$, see A.2.2.1 d); for the values of $u_{A,26}$ and $u_{T,26}$, see Tables 6 and 7 .														

Table 5 — Test forces of the proof test of end attachments

End attachments for				Stabilizing test force, $F_{stab}; (F_{Rstab})^b$ N	Settling test force, $F_{set}; (F_{Rset})^b$ N	Proof test force, $F_{pa}; (F_{Rpa})^b$ N
Test procedure	Test loading level	Test loading condition				
		Heel loading F_1 at β_1	Forefoot loading F_2 at β_2			
All tests ^a	P8	X		50	-1 630 (-1 640)	-6 800 (-6 840)
			X		-1 609 (-1 640)	-6 711 (-6 840)
	P7	X			-1 408 (-1 416)	-6 323 (-6 360)
			X		-1 389 (-1 416)	-6 240 (-6 360)
	P6	X			-1 217 (-1 224)	-5 822 (-5 856)
			X		-1 201 (-1 224)	-5 746 (-5 856)
	P5	X			-1 018 (-1 024)	-5 345 (-5 376)
			X		-1 005 (-1 024)	-5 275 (-5 376)
	P4	X			-939 (-944)	-4 927 (-4 956)
			X		-926 (-944)	-4 863 (-4 956)
	P3	X			-732 (-736)	-3 842 (-3 864)
			X		-722 (-736)	-3 791 (-3 864)

See [13.2.1](#)

X: Indicator linking test loading condition to test force.

^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 ankle-foot devices or foot units submitted for test, particular conditions apply (see the option described in [13.2.2.1](#)).

^b The relationship between the values of F and F_R (Resulting force, placed in parentheses) is determined by [Formula \(A.5\)](#), using the values of δ_1 and δ_2 specified in [A.2.3](#). The values of F_R are calculated from the relevant values listed in [Table A.1](#) (see [A.2.3](#)), using the factors specified in [Table 3](#). Which set of values applies depends on how the assembly of end attachments is placed in the test equipment (see [13.2.2.2.3](#)).

Table 6 — Total length of test samples and segmental lengths of end attachments

Dimensions in millimetres

<i>u</i> -level	Typical combinations of segmental lengths of end attachments ^a		
	A	B	C
$u_{T,L}$ ^b	—	—	—
	$u_{T,26} - u_K = 78$ ($u_{T,L} - u_K = \text{Total length} - 500$)		
u_K	—	$u_{T,26} - u_C = 328$ ($u_{T,L} - u_C = \text{Total length} - 250$)	—
			$u_{T,26} - u_A = 498$ [$u_{T,26} - u_A = 578 \cdot (L/26) - 80$]
$u_C = 250$ ^c	($u_K - u_A$) Any foot length = 420	—	—
		($u_C - u_A$) = 170	
u_A	—	—	—
	u_A , Any foot length = 80	u_A , Any foot length = 80	u_A , Any foot length = 80
Zero	—	—	—
Total length ^a	$u_{T,26} = 578$	$u_{T,26} = 578$	$u_{T,26} = 578$
$u_{T,L}$ ^b	$u_{T,L} = 578 \cdot (L/26)$; (L in cm)		

^a The total length of test samples can be achieved by different combinations of segmental lengths of end attachments. Examples of combinations of segment lengths, typical of the different types of end attachments, are listed in columns A, B and C, where

- column A specifies the segmental lengths of a test sample set-up using end attachments extending from the knee level to the top load application level,

- column B specifies the segmental lengths of a test sample set-up using end attachments extending from a connecting level at $u_C = 250$ mm [see c)] to the top load application level, and

- column C specifies the segmental lengths of a test sample set-up using end attachments extending from the ankle level to the top load application level. This specific set-up is illustrated in [Figure 4](#).

^b The value of $u_{T,L}$ is dependent on the foot length L , as indicated. The foot length L is shown in [Figures 2](#) and [4](#) and specified in [Table 7](#). The dimension $u_{T,L}$ is shown in [Figures 4](#) and [5](#) and specified in [Table 7](#).

^c The value of u_C specifies any connecting level between the knee and ankle level, to be determined in consideration of the individual design of ankle-foot device or foot unit under test. For the example used in this table, u_C has been given the value of 250 mm.

Table 7 — Coordinates of top load application point P_T and tilting axis TA of foot platform based on given values of foot length L , for all test loading levels

Subject	Test procedure		Foot length L ^{a, b} cm													
		20	21	22	23	24	25	26	27	28	29	30	31	32		
		Related values of f - and u -offsets of P_T ^c and TA ^d														
	Direction and location	Numerical value mm														
Position of top load application point, P_T ^c	All tests	$f_{T,L}$	$f_{T,L} = f_{T,26} \cdot (L/26)$													
			17	18	19	19	20	21	22	23	24	25	25	26	27	
		$u_{T,L}$	$u_{T,L} = u_{T,26} \cdot (L/26)$													
			445	467	489	511	534	556	578	600	622	645	667	689	711	
Position of tilting axis TA of foot platform ^d	All tests	$f_{TA,L}$	$f_{TA,L} = 0,365 \cdot L$													
			73	77	80	84	88	91	95	99	102	106	110	113	117	
		$u_{TA,L}$	$u_{TA,L} = 0,1 \cdot L$													
			20	21	22	23	24	25	26	27	28	29	30	31	32	
^a The foot length L is specified in cm, taking into account that in many countries the foot size determining the foot length is measured in cm.																
^b The selection of appropriate sizes of ankle-foot devices and foot units for test purposes is not limited by the range given in this table. The Formulae allow the calculation of f - and u -offsets of P_T and TA relating to any foot length L .																
^c See 6.3 and Figures 1, 4 and 5 . (For further information see 16.1.1 and A.2.2.3 .)																
^d See 13.4.2.3 and Figure 5 . (For further information see 16.1.1 , D.3.2 and D.3.3 .)																

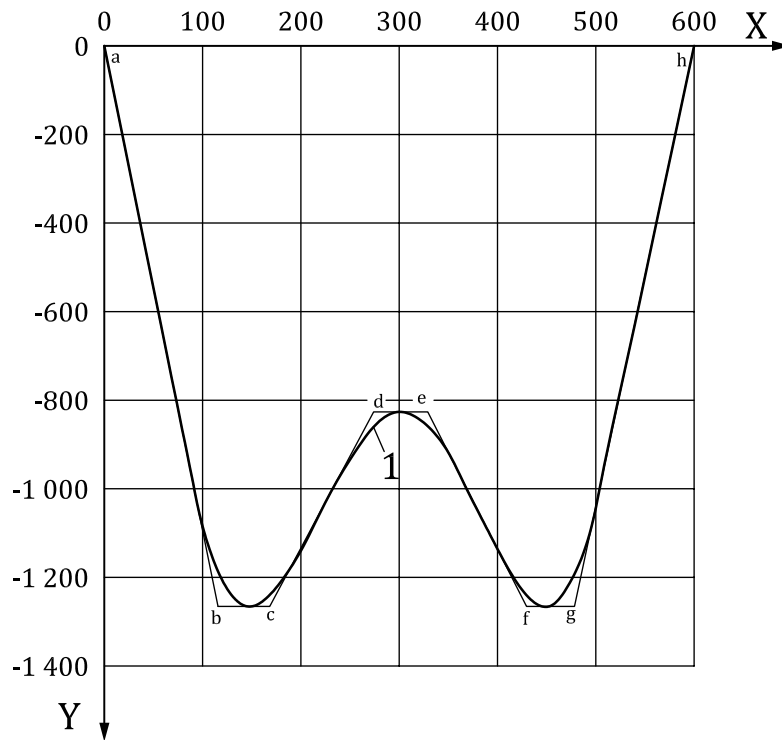
Table 8 — Angles of toe-out position of foot and specific tilting positions of foot platform, based on Test Ranges (R) for all test loading levels

Subject	Test procedure	Angles				
		Event	Direction ^a	Numerical value/degree		
Toe-out position of foot (see Figure 4)	All tests	—	γ	7		
Instantaneous tilting positions of foot platform (see 13.4.2.8)	Cyclic test	Intermediate minimum value, F_{cmin}		β_{Fcmin}	0	
		Tilting angle $\beta_{\text{(t)}}$ of foot platform	R2	$\beta_{\text{(0)}}$	-11,9	
				$\beta_{\text{(600)}}$	26,0	
			R3	$\beta_{\text{(0)}}$	-16,6	
				$\beta_{\text{(600)}}$	34,0	
			R4	$\beta_{\text{(0)}}$	-20,1	
				$\beta_{\text{(600)}}$	40,0	
Fixed tilting positions of foot platform (see 13.4.1.3) and Instantaneous tilting positions of foot platform (see 13.4.2.8)	Static proof test, static ultimate strength test and Cyclic test	Heel loading, F_1 and $F_{1\text{cmax}}$		R2	β_1	-10
		Forefoot loading, F_2 and $F_{2\text{cmax}}$			β_2	13
		Heel loading, F_1 and $F_{1\text{cmax}}$		R3	β_1	-14
		Forefoot loading, F_2 and $F_{2\text{cmax}}$			β_2	17
		Heel loading, F_1 and $F_{1\text{cmax}}$		R4	β_1	-17
		Forefoot loading, F_2 and $F_{2\text{cmax}}$			β_2	20
	^a The positive direction of the angles γ and β is shown in Figures 4 or 5 , respectively.					

Table 9 — Test forces for all tests and prescribed number of cycles for the cyclic test, for all test loading levels and for all Test Ranges (R)

Test procedure and test force		Unit	Test loading level (P_x) and test loading condition (F_{1x}, F_{2x})											
			P3		P4		P5		P6		P7		P8	
			Heel loading F_{1x}	Forefoot loading F_{2x}	Heel loading F_{1x}	Forefoot loading F_{2x}	Heel loading F_{1x}	Forefoot loading F_{2x}	Heel loading F_{1x}	Forefoot loading F_{2x}	Heel loading F_{1x}	Forefoot loading F_{2x}	Heel loading F_{1x}	Forefoot loading F_{2x}
Static test procedure	Static proof test force	F_{1sp} F_{2sp}	-1 601 —	— -1 580	-2 053 —	— -2 026	-2 227 —	-2 198 —	-2 476 —	-2 443 —	-2 883 —	— -2 845	-3 181 —	— -3 140
	Static ultimate test force	$F_{1su, lower level}$ $F_{2su, lower level}$	-2 401 —	— -2 369	-3 079 —	— -3 039	-3 340 —	— -3 297	-3 738 —	— -3 689	-4 076 —	— -4 023	-4 424 —	— -4 366
	Static ultimate test force	$F_{1su, upper level}$ $F_{2su, upper level}$	-3 201 —	— -3 159	-4 106 —	— -4 052	-4 454 —	— -4 396	-4 852 —	— -4 788	-5 269 —	— -5 200	-5 667 —	— -5 593
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax}	-915	—	-1 173	—	-1 273	—	-1 521	—	-1 760	—	-2 038	—
	Inter-mediate minimum value of pulsating test force	F_{cmin}	-611	—	-783	—	-850	—	-1 016	—	-1 175	—	-1 361	—
	2nd maximum value of pulsating test force	F_{2cmax}	—	-903	—	-1 158	—	-1 256	—	-1 501	—	-1 737	—	-2 011
	Final static test force	$F_{1fin} (= F_{1sp})$ $F_{2fin} (= F_{2sp})$	-1 601 —	— -1 580	-2 053 —	— -2 026	-2 227 —	— -2 198	-2 476 —	— -2 443	-2 883 —	— -2 845	-3 181 —	— -3 140
	Force related to Test Range (R)	R2 R3 R4	1											
	Prescribed number of cycles	R2	2 × 10 ⁶											
		R3	2 × 10 ⁶											
		R4	2 × 10 ⁶											

NOTE The specific values of the different test forces are based on reference values of the resultant reference forces described in A.2.3 and specified in Table A.1.



Key

X time in ms

Y force in N

1 test force F

The loading period of 600 ms corresponds to the average stance phase time of a typical walking cycle of 1 s duration. (The remaining time of 400 ms of the walking cycle corresponds to the swing phase).

The reference points a to h are specified in [Table 10](#).

Figure 3 — Illustration of reference points for the establishment of thresholds listed in [Table 10](#) for specification of the loading profile of the cyclic test

Table 10 — Thresholds according to [Figure 3](#) for specification of the application of the loading profile of the cyclic test

Reference point	Threshold														
	Instant (Time after heel contact)	Inter-val of time	Rate of loading/unloading (Value relevant to test loading level) kN/s						Test force $F_c(t)$ at reference point N						
			P3	P4	P5	P6	P7	P8	Sym-bol	Value relevant to test loading level					
										P3	P4	P5	P6	P7	P8
a	0								$F_c(t_a)$	0	0	0	0	0	0
		115	-8,0	-10,2	-11,1	-13,3	-15,4	-17,8							
b	115								F_{1cmax}	-915	-1 173	-1 273	-1 521	-1 760	-2 038
		51													
c	166								F_{1cmax}	-915	-1 173	-1 273	-1 521	-1 760	-2 038
		103	2,9	3,8	4,1	4,9	5,6	6,5							
d	269								F_{cmin}	-611	-783	-850	-1 016	-1 175	-1 361
		62													
e	331								F_{cmin}	-611	-783	-850	-1 016	-1 175	-1 361
		102	-2,9	-3,7	-4,0	-4,8	-5,6	-6,4							
f	433								F_{2cmax}	-903	-1 158	-1 256	-1 501	-1 737	-2 011
		51													
g	484								F_{2cmax}	-903	-1 158	-1 256	-1 501	-1 737	-2 011
		116	7,9	9,9	10,8	13,0	15,0	17,4							
h	600								$F_c(t_h)$	0	0	0	0	0	0
Force related to Test Range (R)								R2	1						
								R3	1						
								R4	1						

NOTE The loading period of 600 ms corresponds to the average stance phase time of a typical walking cycle of 1 s duration (the remaining time of 400 ms of the walking cycle corresponds to the swing phase). Simulating this stance phase time–swing phase time–relationship in a cyclic test, a loading period of 600 ms corresponds to a test frequency $f = 1$ Hz. For other test frequencies, preferably between 0,5 Hz and 3 Hz (see [16.4.1.6](#) and [16.4.1.7](#)), the time intervals between each instant after heel contact for which rates of loading/unloading or test force are specified in this table can easily be adapted by linear scaling.

Table 11 — Data specifying the values of test force $F_c(t)$ illustrated in Figure 6 in 30 ms-time increments for guidance on their application

Time (Instant after heel contact) ms	Pulsating test force $F_c(t)$ (Value relevant to test loading level)					
	P3 N	P4 N	P5 N	P6 N	P7 N	P8 N
0	0	0	0	0	0	0
30	-238	-306	-331	-396	-458	-530
60	-477	-612	-663	-793	-918	-1 062
90	-716	-919	-996	-1 190	-1 377	-1 595
120	-878	-1 126	-1 221	-1 460	-1 689	-1 956
150	-915	-1 173	-1 273	-1 521	-1 760	-2 038
180	-873	-1 120	-1 215	-1 451	-1 679	-1 944
210	-785	-1 007	-1 092	-1 305	-1 510	-1 748
240	-697	-893	-969	-1 159	-1 341	-1 552
270	-632	-811	-880	-1 051	-1 216	-1 408
300	-611	-783	-850	-1 016	-1 175	-1 361
330	-632	-810	-879	-1 051	-1 216	-1 408
360	-694	-891	-966	-1 154	-1 335	-1 546
390	-781	-1 003	-1 086	-1 298	-1 502	-1 740
420	-866	-1 110	-1 204	-1 440	-1 666	-1 929
450	-903	-1 158	-1 256	-1 501	-1 737	-2 011
480	-861	-1 105	-1 198	-1 431	-1 656	-1 918
510	-698	-895	-971	-1 160	-1 343	-1 555
540	-463	-593	-643	-770	-891	-1 031
570	-231	-296	-321	-384	-444	-515
600	0	0	0	0	0	0

9 Compliance

9.1 General

In order to claim compliance with this document for an ankle-foot device or foot unit submitted for test, a prescribed number of test samples of this structure from the allowed batch, specified in Table 12, shall satisfy the relevant requirements of Clauses 9, 10 and 16 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 an ankle-foot device or foot unit submitted for test with the performance requirements of a specific test of this document shall have a certificate from 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 ankle-foot device or foot unit which have been subjected to this test (see 9.3).

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 can also claim compliance for other prosthetic assemblies and/or alignments in which the ankle-foot device or foot unit submitted for test can be used, provided it can be proven 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 ankle-foot device or foot unit submitted for test.

9.2 Particular arrangements and requirements concerning the part required to connect an ankle-foot device or foot unit to the remainder of a prosthetic structure

9.2.1 Arrangements for testing

Batches of the part required to connect an ankle-foot device or foot unit to the remainder of a prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base, shall be tested in either of the ways described in a) and b), depending on its combination with ankle-foot devices or foot units intended to be allowed by the manufacturer/submitter.

- a) If the type of connecting part is intended to be allowed for use in combination with one or several specified type(s) of ankle-foot device or foot unit, then batches of samples of assemblies of this part and each specified type of ankle-foot device or foot unit shall be subjected to the tests specified in this document.
- b) If the type of connecting part is intended to be allowed for use in combination with any type of ankle-foot device or foot unit, then batches of samples of this part shall be subjected to the principal structural tests specified in ISO 10328:2016 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.

9.2.2 Requirements for claiming compliance

- a) In the case of [9.2.1 a\)](#), the manufacturer/submitter can claim compliance with this document for each specified assembly of connecting part and ankle-foot device or foot unit passing the tests of this document, as stated in the certificate issued by the test laboratory/facility (see 2nd paragraph of [9.1](#)).
- b) In the case of [9.2.1 b\)](#), the manufacturer/submitter can claim compliance with ISO 10328:2016 for the “universal” connecting part passing the principal structural tests of that document, as stated in the certificate issued by the test laboratory/facility (see 2nd paragraph of [9.1](#)).

NOTE Based on this claim of compliance, the manufacturer/submitter can allow the use of the “universal” connecting part in combination with any ankle-foot device or foot unit. In order to claim compliance for such assemblies, it is, however, necessary that the ankle-foot devices or foot units involved pass the tests of this document (see NOTE of [9.1](#)).

9.3 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 12](#).

The tests shall be conducted on test samples from the batch specified in [Table 12](#) for each type of test.

The minimum number indicates, how many test samples of an ankle-foot device or foot unit submitted for test shall complete the tests without failing.

If appropriate, the tests shall be conducted in the worst-case alignment position of the test samples (see [10.6](#)).

NOTE The total number of test samples actually needed for the conduct of all tests required can differ from the total calculated by addition of the number of test samples specified in [Table 12](#) for each type of test, since the number of substitutes needed can vary, and since test samples that have completed a specific test without failing may be used for another test (see [9.4](#), [16.2.1](#) and [16.3.1](#)).

9.4 Multiple use of test samples

9.4.1 General

Test samples, which have demonstrated compliance with the requirements of any of the tests specified in this document, may be subjected to other tests of this document, except as stated in [9.4.2](#).