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Date: 23 December 2021

Origin: European

Latest date for receipt of comments: 15 February 2022

Project No. 2019/03195

Responsible committee: CH/168 Prosthetics and orthotics

Interested committees:

Title: Draft BS EN ISO 22675 Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/Figure/ Table/Note	Type of comment	Commend (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 22675

ISO/TC 168

Secretariat: DIN

Voting begins on:
2021-12-23

Voting terminates on:
2022-03-17

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

Prothèses — Essais d'articulations cheville-pied et unités de pied — Exigences et méthodes d'essai

ICS: 11.040.40

This document is circulated as received from the committee secretariat.

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Published in Switzerland

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Foreword

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

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

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

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 22675:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

- Test loading levels P7 and P8 have been introduced in [Table 11](#), [Table A.1](#), Table C.1, Table C.2 and the clauses pointing at these tables have been updated or removed.
- [Table 10](#) "Test forces for all tests and prescribed number of cycles for the cyclic test, for all test loading levels and for all Test Ranges" has been revised.
- The content of [Annex C](#) has changed from informative to normative by moving it from Annex into the standard.
- This edition specifies three Test Ranges by specifying locomotion profiles in combination with the number of test cycles for the cyclic test in relation to the intended use. Furthermore it clarifies the position of the Ankle joint related to the connecting device of ankle foot devices and it emphasizes the fact, that the top load application point Pt shall not bear moments exceeding the accuracy defined in this standard.
- This edition describes, how to consider testing ankle-foot-devices and foot units used in less severe loading conditions than the average most active users do. Therefore this standard not only distinguishes the test level (p-level) by the applied force (profile), but also the Test Range (R) by different tilting or static plate angles.
- This edition takes into consideration, that technical development for example in the area of robotics increase the availability for sensors, signal processors and control units, which can be used for the defined test of this standard too. Therefore the coordinate systems for geometries and forces of this Standard are adapted to the ISO definitions for robotics.

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 17.2 of ISO 10328:2016, 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, it has to be noted that 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 may 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 a separate document, published as a Technical Report (see Bibliography).

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

1 Scope

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

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.

This document primarily specifies a cyclic test procedure for ankle-foot devices and foot units of external lower limb prostheses, distinguished by the potential to realistically simulate those loading conditions of the complete stance phase of walking from heel strike to toe-off that are 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 2) 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.

The loading conditions addressed in the third paragraph 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, to be 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 by specifying locomotion profiles for the cyclic test in relation to the intended use. According to the concept of the tests of this International Standard, each sample of ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

NOTE 1 The lines of action of the heel and forefoot forces generated by the static test procedure for Test Range 4 (R4) specified in this International Standard 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, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 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*

3 Terms and definitions

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

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 compliance with one or more requirements of this document

3.5 shock absorption capacity

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

3.6 force

force applied to a sample under test. Following technical development, this version uses forces in the direction of ISO definitions in other fields of applications (like robotics). Test equipment, build to test to previous versions of this standard (using compression force with a positive sign) do not need to be reprogrammed.

4 Designations and symbols of test forces

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

Table 1 — Designations and symbols of test forces

Designation	Symbol
Test forces	F, F_1, F_2
Settling test force	F_{set}
Stabilizing test force	F_{stab}
Proof test force of end attachments	F_{pa}
Static proof test force on heel/forefoot	$F_{1\text{sp}}, F_{2\text{sp}}$
NOTE Further details of the test forces listed are given in Table 4 .	

Table 1 (continued)

Designation	Symbol
Static ultimate test force on heel/forefoot	F_{1su}, F_{2su}
Pulsating test force	$F_c(t); F_c(\beta)$
1st and 2nd maximum value of pulsating test force	F_{1cmax}, F_{2cmax}
Intermediate minimum value of pulsating test force	F_{cmin}
Final static test force on heel/forefoot	F_{1fin}, F_{2fin}
NOTE Further details of the test forces listed are given in Table 4 .	

5 Strength and related performance requirements and conditions of use

5.1 According to 4.4.1 of ISO 22523:2006, 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 his written instructions on its intended use”. Based on the written instructions, the manufacturer assigns a Test Range (Rx) which 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 conformity of ankle-foot devices and foot units with the above requirement (see also Scope), this document provides means of determining different categories of strength. These are defined in [3.1](#) to [3.3](#) and listed in [Table 2](#), together with the related performance requirements and the test methods for their verification.

5.2 In order to satisfy the general requirement in [5.1](#) for a specific ankle-foot device or foot unit, the following safety concept shall apply:

The device shall

- a) comply with the requirements of this document (see [9.1](#) and [9.2](#)) for a specific test loading level (see [7.2](#))

and

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

and

- c) 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](#).

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 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](#)).

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 (see 3.1)	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 (16.2.1), successively applying heel and forefoot loading.
Ultimate strength (see 3.2)	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 (16.3.1), separately applying heel and forefoot loading.
Fatigue strength (see 3.3)	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 (16.4.1), repeatedly applying a loading profile simulating the stance phase of walking, followed by final static heel and forefoot 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 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.

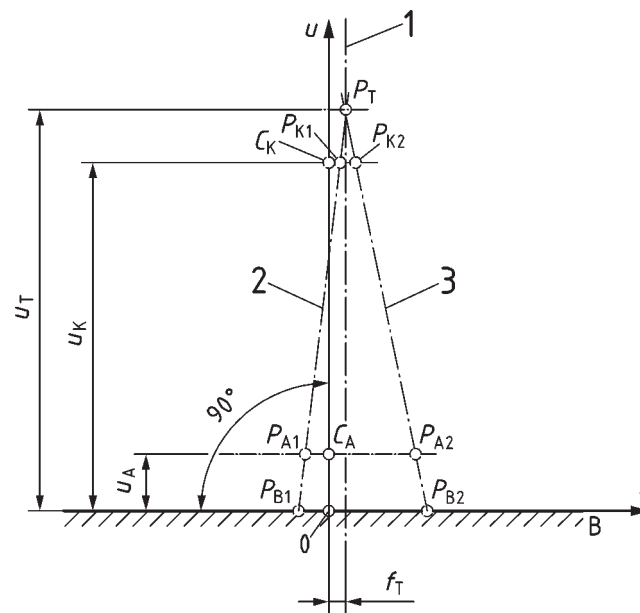
If a test sample is not in the vertical position, the axes of the coordinate system shall be rotated to correspond.

- The origin 0 of the coordinate system is located in the bottom plane 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 1 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 2 The u -axis also passes through the effective knee-joint centre C_K (see Figure 1). This may 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, may 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)]
O	(outward) axis of coordinate system [see 6.2 d)]
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} .

IMPORTANT — 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](#), [E.3.4.2](#), [Figures 4](#) and [5](#) and [Table 8](#)). If appropriate, general suffix 'L' may be replaced by specific values (see [Figures A.2](#) and [E.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 may 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.

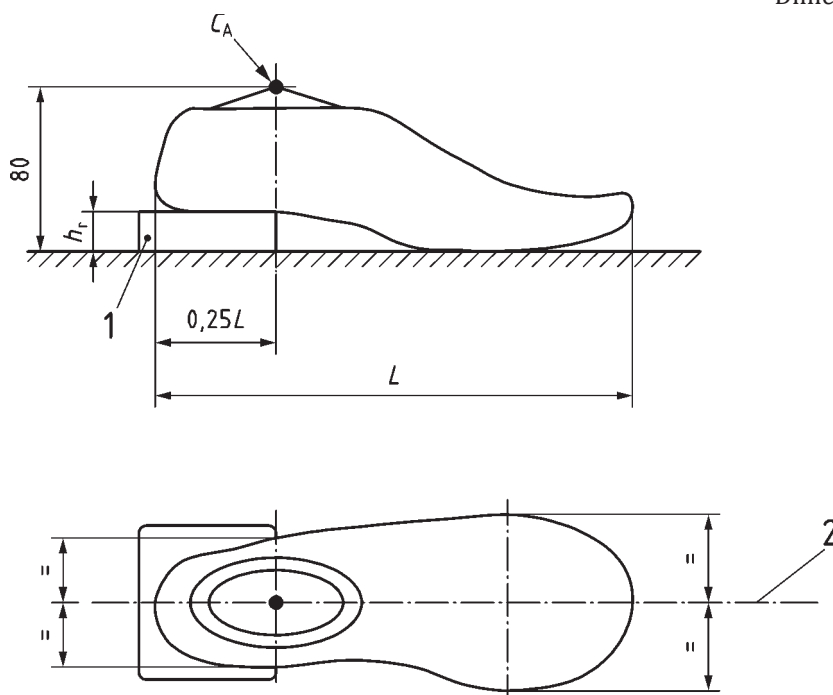
6.7.3.2 Locate the longitudinal axis of the foot as described in [6.7.2](#) or in accordance with any specific instruction from the manufacturer/submitter.

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](#)).

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 1.



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)

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

Figure 2 — Determination of longitudinal axis of foot (see 6.7.2) and effective ankle-joint centre C_A (see 6.7.3)

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 13](#) together with their manner of application and specified in the relevant [Tables 4](#) to [12](#) of [Clause 8](#). Further information is given in [Clauses 15](#) and [16](#).

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

7.2 Test loading levels and Test Ranges

7.2.1 The load actions referred to in the first paragraph of [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 R Test Ranges 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 4](#) and [10](#)).

- 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 4](#).
- 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 Standard.

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 9](#)) to emulate the biomechanical parameters and activities of Test Ranges R2, R3 and R4 defined in [Table 3](#).

IMPORTANT — If a patient range assignment is uncertain, always use the next higher Test Range.

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. • May 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 based on 95th percentile control limits from Sions, J.[3]		
² 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 4](#) to [12](#) describe and/or specify the values of

- test forces;
- test forces, related to Test Range;
- 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.

IMPORTANT — [Annex E](#) 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 8](#), can be avoided or limited by transposing the top load application point P_T (see [E.3.4](#)).

Table 4 — Test forces and relevant references

Test force ^a		Reference		
		Subclause	Table	Relevant test
Settling test force	$F_{\text{set}} = 0,8 F_{1\text{cmax}}$	13.2.2	5	Proof test of end attachment
Stabilizing test force	F_{stab}			
Proof test force on end attachments	$F_{\text{pa}} = 1,2 F_{\text{su, upper level}}$			
Static proof test force on heel	$F_{1\text{sp}} = 1,75 F_{1\text{cmax}}$	16.2.1	9	Static proof test
Static proof test force on forefoot	$F_{2\text{sp}} = 1,75 F_{2\text{cmax}}$			
Static ultimate test force on heel		16.3.1	9	Static ultimate strength test
— lower level	$F_{1\text{su, lower level}} = 1,5 F_{1\text{sp}}$			
— upper level	$F_{1\text{su, upper level}} = 2,0 F_{1\text{sp}}$			
Static ultimate test force on forefoot				
— lower level	$F_{2\text{su, lower level}} = 1,5 F_{2\text{sp}}$			
— upper level	$F_{2\text{su, upper level}} = 2,0 F_{2\text{sp}}$			
Pulsating test force	$F_c(t); F_c(\gamma)$	13.4.2 , 16.4.1	9, (10, 11)	Cyclic test procedure
1st and 2nd maximum value of pulsating test force	$F_{1\text{cmax}}, F_{2\text{cmax}}$			
Intermediate minimum value of pulsating test force	F_{cmin}			
Final static test force on heel / forefoot	$F_{1\text{fin}}, F_{2\text{fin}}$			
^a The test forces $F_{\text{set}}, F_{\text{pa}}, F_{\text{sp}}$ and F_{su} are determined using appropriate factors.				

Table 5 — 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 (see 13.2.2)

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	

^a The values of $f_{B, 26}$ are determined by the condition $(f_{B, 26} - f_{T, 26}) / u_{T, 26} = (f_{A, 26} - f_{T, 26}) / (u_{T, 26} - u_{A, 26})$.
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 6 — Test forces of the proof test of end attachments (see 13.2.1)

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	•		50	-1 630 (-1 640)	-6 800 (-6 840)
			•		-1 609 (-1 640)	-6 711 (-6 840)
	P7	•			-1 408 (-1 416)	-6 323 (-6 360)
			•		-1 389 (-1 416)	-6 240 (-6 360)
	P6	•			-1 217 (-1 224)	-5 822 (-5 856)
			•		-1 201 (-1 224)	-5 746 (-5 856)
	P5	•			-1 018; (-1024)	-5 345; (-5 376)
			•		-1 005; (-1024)	-5 275; (-5 376)
	P4	•			-939; (-944)	-4 927; (-4 956)
			•		-926; (-944)	-4 863; (-4 956)
	P3	•			-732; (-736)	-3 842; (-3 864)
			•		-722; (-736)	-3 791; (-3 864)

^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 International Standard 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_x and F_{Rx} (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_{Rx} are calculated from the relevant values listed in Table A.1 (see A.2.3), using the factors specified in Table 4. 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 7 — 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
<i>u</i> _{T, L} ^b	— $u_{T, 26} - u_K = 78$ ($u_{T, L} - u_K = \text{Total length} - 500$)	—	—
<i>u</i> _K	—	$u_{T, 26} - u_C = 328$ ($u_{T, L} - u_C = \text{Total length} - 250$)	—
<i>u</i> _C = 250 ^c	($u_K - u_A$) Any foot length = 420	—	$u_{T, 26} - u_A = 498$ [$u_{T, L} - u_A = 578 \cdot (L/26) - 80$]
<i>u</i> _A	—	($u_C - u_A$) = 170	—
Zero	u_A , Any foot length = 80	u_A , Any foot length = 80	u_A , Any foot length = 80
Total length ^a <i>u</i> _{T, L} ^b	$u_{T, 26} = 578$	$u_{T, 26} = 578$ $u_{T, L} = 578 \cdot (L/26)$; (<i>L</i> in cm)	$u_{T, 26} = 578$

^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 8](#). The dimension *u*_{T, L} is shown in [Figures 4](#) and [5](#) and specified in [Table 8](#).

^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 8 — 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, E.3.2 and E.3.3.)

Table 9 — Angles of toe-out position of foot and specific tilting positions of foot platform, based on Test Ranges (R) for all test loading levels

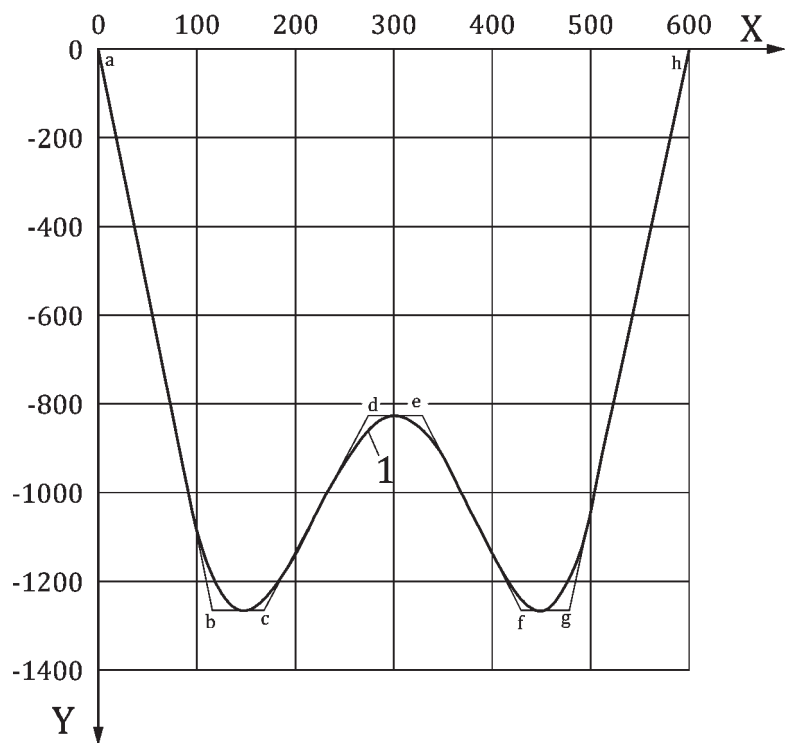
Subject	Test procedure	Angles		
		Event	Direction ^a	Numerical value/degree
Toe-out position of foot (see Figure 4)	All tests	—	γ	7
Instantaneous tilting positions of foot platform (see 13.4.2.8)	Cyclic test	Intermediate minimum value, F_{cmin}	$\beta_{F_{cmin}}$	0
		Tilting angle $\gamma_{(t)}$ of foot platform	$\beta_{(0)}$	-11,8
			$\beta_{(600)}$	26,0
			$\beta_{(0)}$	-16,5
			$\beta_{(600)}$	34,0
			$\beta_{(0)}$	-20,0
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_{1cmax}	β_1	-10
		Forefoot loading, F_2 and F_{2cmax}	β_2	13
		Heel loading, F_1 and F_{1cmax}	β_1	-14
		Forefoot loading, F_2 and F_{2cmax}	β_2	17
		Heel loading, F_1 and F_{1cmax}	β_1	-17
		Forefoot loading, F_2 and F_{2cmax}	β_2	20

^a The positive direction of the angles γ and β is shown in Figures 4 or 5, respectively.

Table 10 — Test forces for all tests and prescribed number of cycles for the cyclic test, for all test loading levels (see 16.2, 16.3 and 16.4) and for all Test Ranges

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}	N	-1601 -1580	-2053 -2026	-2227 -2198	-2476 -2443	-2883 -2845	-3181 -3140	—	—	—	—	—
	Static ultimate test force	$F_{1su, lower level}$ $F_{2su, lower level}$	N	-2401 -2369	-3079 -3039	-3340 -3297	-3738 -3689	-4076 -4023	-4424 -4366	—	—	—	—	—
	1st maximum value of pulsating test force	$F_{1su, upper level}$ $F_{2su, upper level}$	N	-3201 -3159	-4106 -4052	-4454 -4396	-4852 -4788	-5269 -5200	-5667 -5593	—	—	—	—	—
	Inter-mediate minimum value of pulsating test force	F_{1cmax}	N	-915	-1173	-1273	-1521	-1760	-2038	—	—	—	—	—
Cyclic test procedure	2nd maximum value of pulsating test force	F_{cmin}	N	-611	-783	-850	-1016	-1175	-1361	—	—	—	—	—
	Final static test force	$F_{1fin} (= F_{1sp})$ $F_{2fin} (= F_{2sp})$	N	-1601 -1580	-2053 -2026	-2227 -2198	-2476 -2443	-2883 -2845	-3181 -3140	—	—	—	—	—
	Force related to Rx	R2	1	1	1	1	1	1	1	1	1	1	1	1
	Force related to Rx	R3	1	1	1	1	1	1	1	1	1	1	1	1
	Force related to Rx	R4	1	1	1	1	1	1	1	1	1	1	1	1
	Prescribed number of cycles	R2	1	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶
	Prescribed number of cycles	R3	1	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶
	Prescribed number of cycles	R4	1	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	2 × 10 ⁶	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 milliseconds
- Y force in newtons
- 1 test force F

NOTE 1 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.)

NOTE 2 The reference points a to h are specified in [Table 11](#).

Figure 3 — Illustration of reference points for the establishment of thresholds listed in [Table 11](#) for specification of the loading profile of the cyclic test

Table 11 — 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 offtime	Rate of loading/unloading (Value relevant to test loading level)						Test force $F_c(t)$ at reference point						
			kN/s						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	-1173	-1273	-1521	-1760	-2038
		51													
C	166								F_{1cmax}	-915	-1173	-1273	-1521	-1760	-2038
		103	2,9	3,8	4,1	4,9	5,6	6,5							
D	269								F_{cmin}	-611	-783	-850	-1016	-1175	-1361
		62													
E	331								F_{cmin}	-611	-783	-850	-1016	-1175	-1361
		102	-2,9	-3,7	-4,0	-4,8	-5,6	-6,4							
F	433								F_{2cmax}	-903	-1158	-1256	-1501	-1737	-2011
		51													
G	484								F_{2cmax}	-903	-1158	-1256	-1501	-1737	-2011
		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 Rx								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 12 — 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	-1062
90	-716	-919	-996	-1190	-1377	-1595
120	-878	-1 126	-1 221	-1460	-1689	-1956
150	-915	-1 173	-1 273	-1 521	-1 760	-2 038
180	-873	-1 120	-1 215	-1451	-1679	-1944
210	-785	-1 007	-1 092	-1305	-1510	-1748
240	-697	-893	-969	-1159	-1341	-1552
270	-632	-811	-880	-1051	-1216	-1408
300	-611	-783	-850	-1 016	-1 175	-1 361
330	-632	-810	-879	-1051	-1216	-1408
360	-694	-891	-966	-1154	-1335	-1546
390	-781	-1 003	-1 086	-1298	-1502	-1740
420	-866	-1 110	-1 204	-1440	-1666	-1929
450	-903	-1 158	-1 256	-1 501	-1 737	-2 011
480	-861	-1 105	-1 198	-1431	-1656	-1918
510	-698	-895	-971	-1160	-1343	-1555
540	-463	-593	-643	-770	-891	-1031
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 13, 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 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 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 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, also covers lower Test Ranges at identical P-level.

NOTE The manufacturer/submitter may claim compliance also 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 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 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 Standard.
- 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 Standard, as certified 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 Standard, as certified 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 13](#).

The tests shall be conducted on test samples from the batch specified in [Table 13](#) 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 may differ from the total calculated by addition of the number of test samples specified in [Table 13](#) for each type of test, 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 [9.4](#), [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](#).

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 13](#)).

NOTE The multiple use of test samples is specifically addressed in the static proof test ([16.2.1](#)) and the static ultimate strength test ([16.3.1](#)).

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 ankle-foot device or foot unit submitted for test be conducted in a particular order, with the exception of the restriction specified in [9.4.2](#).

9.4.2 Restriction

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

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

For different reasons the intended use of a particular design of ankle-foot device or foot unit may require the tests of this Standard 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 can be claimed for the next lower regular test loading level of this document, from which that particular test loading level has been derived.

Reference to this document may also be given by stating that the prescribed batch (or batches) of test samples of ankle-foot device or foot unit 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 13 — Number of tests and test samples required to claim compliance with this document

Type of test	Test loading condition and manner of application	Minimum ^a number of tests required	Batch ^b of test samples allowed for each type of test		
			Regular test samples	Possible substitute test samples	
				No. ^c	Reference
Static proof test (see 16.2.1)	Direction of heel loading and direction of forefoot loading, successively applied to each test sample	2	2	1	16.2.1.11
^a The term <i>minimum</i> indicates that the repetition of tests on allowed substitute test samples may be necessary to satisfy the compliance conditions. ^b For the definition of <i>batch</i> see 3.4 . ^c The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed under "Reference" applies.					

Table 13 (continued)

Type of test	Test loading condition and manner of application	Minimum ^a number of tests required	Batch ^b of test samples allowed for each type of test		
			Regular test samples	Possible substitute test samples	
				No. ^c	Reference
Static ultimate strength test (see 16.3.1)	Direction of heel loading	2	2	1	16.3.1.15 and 16.3.1.17 (option)
	Direction of forefoot loading	2	2	1	16.3.1.15 and/or 16.3.1.16, and 16.3.1.17 (option)
Cyclic test (see 16.4.1)	Continuous loading from heel contact to toe-off, repeatedly applied to each test sample, followed by final static tests on heel and forefoot	2	2	—	—

^a The term *minimum* indicates that the repetition of tests on allowed substitute test samples may 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 under “Reference” applies.

10 Test samples

10.1 Selection of test samples

10.1.1 General

The test samples of ankle-foot devices and foot units 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 ankle-foot devices and foot units may also be submitted for specific tests by any interested party.

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

For the purposes of this document, 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 test loading conditions of the static and cyclic tests specified in Clause 8.

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

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

An appropriate measure for the worst-case loading is the direction and magnitude of the ankle (A-P) bending moment, 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 sample

10.2.1 Complete structure

Test samples representing a complete structure consist of the ankle-foot device or foot unit and the part required to connect it to the remainder of the prosthetic structure.

If the type of connecting part used in a complete structure submitted for test according to this document has already been subjected, as a universal connecting part, to the principal structural tests of ISO 10328:2016 and complies with the requirements of that Standard [see [9.2.1 b\)](#) and [9.2.2 b\)](#)], this does not affect the conduct or the results of the tests of this document, unless the connecting part fails.

10.2.2 Partial structure

Test samples representing a partial structure consist of an ankle-foot device or foot unit as a single component, intended by the manufacturer/submitter to be connected to the remainder of the prosthetic structure by any appropriate type of universal connecting part.

The manufacturer/submitter shall specify in the test submission document or agree with the test laboratory/facility, which type of connecting part shall be used in the set-up of test samples of this type and shall supply the necessary number of parts.

Types of universal connecting parts used shall comply with the requirements of ISO 10328:2016.

10.3 Preparation of test samples

10.3.1 The samples shall include all parts normally fitted. This also applies to foot covers.

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

10.3.3 All test sample types according to [10.2](#) shall be given a fixed total length, using end attachments, as required [see [13.2](#) and NOTE].

The fixed total length shall be determined by the dimension u_T specified in [Table 8](#) and shall be achieved by selecting one of the combinations specified in [Table 7](#) for different types of test sample (see [10.2](#)) or any other relevant combination. The combination of segment lengths selected shall be recorded.

NOTE [Figure 4](#) illustrates a specific test sample set-up corresponding to the combination specified in column C of [Table 8](#) and also marks the reasonable area for the arrangement of alternative end attachments in consideration of the current spectrum of foot designs.

10.3.4 The ankle-foot device or foot unit, selected in accordance with [10.1.2](#), shall be submitted assembled by the manufacturer/submitter at least 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.

The manufacturer/submitter may also attach end attachments, as required (see [11.4](#)).

10.4 Identification of test samples

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

10.5 Alignment of test samples

The alignment of the test sample of an ankle-foot device or foot unit within the coordinate system shall be set in accordance with [6.1](#) to [6.3](#), [6.7.2](#), [6.7.3](#), [10.6](#), [14.3 a\)](#) and [d\)](#), [Tables 7, 8 and 9](#) and [Document](#)

as specified in the test submission document (see [Clause 12](#)). In particular, the following requirements shall be satisfied:

- a) the ankle-foot device or foot unit shall be placed on the bottom plane B representing the ground (see [6.2](#)), with its heel placed on a block of the recommended heel height h_r ;
- b) the longitudinal axis of the foot (see [6.7.2](#)) shall be turned by $\gamma = 7^\circ$ as shown in [Figure 4](#) and specified in [Table 9](#) to give a toe-out position of the ankle-foot device or foot unit;
- c) the u -axis of the coordinate system, extending upwards perpendicular to the bottom plane (see [6.2](#)), shall pass through the effective ankle-joint centre C_A (see [6.7.3](#));
- d) the top load application point P_T shall be set at the values of $f_{T,L}$ and $u_{T,L}$ relevant to the length L of the foot of the test sample (see [Table 8](#)), using end attachments, as required (see [13.2](#)).

10.6 Worst-case alignment position of test samples

10.6.1 The worst-case alignment position shall be exclusively related to the A-P position of the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample.

The tests of this document shall be conducted in the worst-case alignment position

- if the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample is a prosthetic component normally used for its connection to a prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base (see [9.2](#))

and

- if this part is adjustable in the A-P direction relative to the effective ankle-joint centre C_A (see [6.7.3](#)).

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

10.6.3 Where the structurally worst position cannot be defined as required in [10.6.2](#), then the prosthetic connecting part shall be moved 90 % of the distance from neutral alignment to extreme posterior alignment, i.e. its adjustment shall be directed towards the heel so as to increase its distance from the line of action of the resultant reference force F_{R2} determining static and maximum cyclic forefoot reference loading (see [Figures 1](#) and [A.1](#)).