International Standard

ISO 22675

Third edition
2024-12

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

Reference number
ISO 22675:2024(en)

Contents

Page

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.

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*, 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_{1sp}, F_{2sp}	Static proof test force on heel/forefoot
F_{1su}, F_{2su}	Static ultimate test force on heel/forefoot
$F_c(t)$; $F_c(\beta)$	Pulsating test force
F_{1cmax}, F_{2cmax}	1st and 2nd maximum value of pulsating test force
F_{cmin}	Intermediate minimum value of pulsating test force
F_{1fin}, F_{2fin}	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

a) conform with the requirements in 9.1 and 9.2 and for a specific test loading level, with the requirements in 7.2,

b) 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).

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.

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.

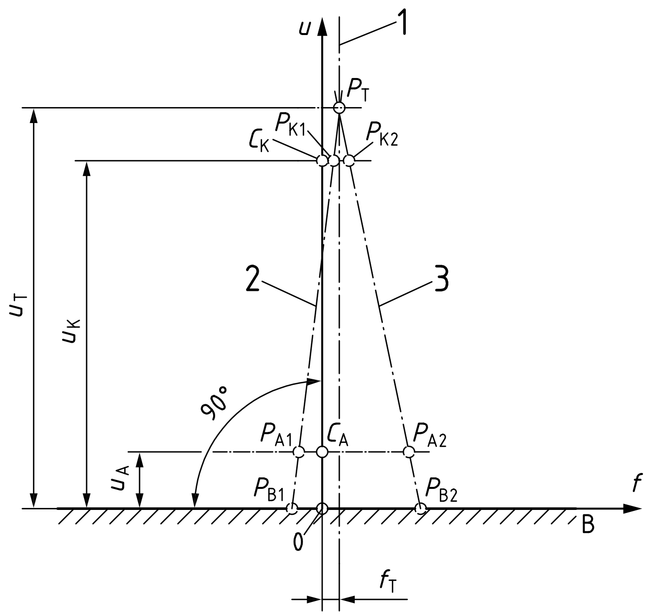
b) The *u*-axis extends from the origin 0 perpendicular to the bottom plane B and passes through the effective ankle-joint centre C_A, specified in 6.7.3 (see Figure 1). Its positive direction is upwards (in the proximal direction).

   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

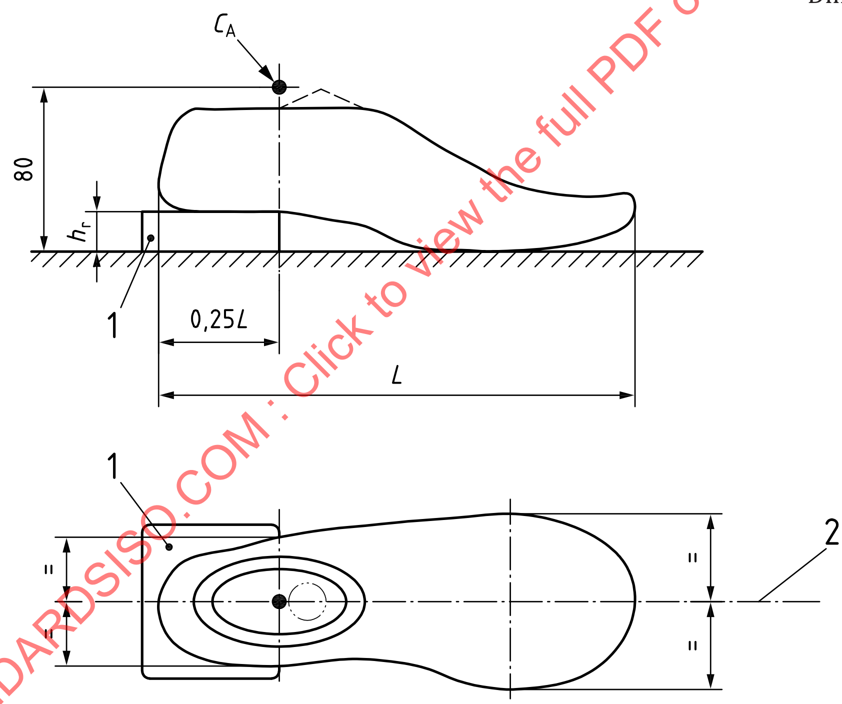
a) in a vertical plane passing through the longitudinal axis of the foot;

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, β (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	Reference: Table	Reference: Relevant test
Settling test force Stabilizing test force Proof test force on end attachments	$F_{set} = 0{,}8\ F_{1cmax}$ F_{stab} $F_{pa} = 1{,}2\ F_{su,\ upper\ level}$	13.2.2	Table 5	Proof test of end attachment
Static proof test force on heel Static proof test force on forefoot	$F_{1sp} = 1{,}75\ F_{1cmax}$ $F_{2sp} = 1{,}75\ F_{2cmax}$	16.2.1	Table 9	Static proof test
Static ultimate test force on heel — lower level — upper level Static ultimate test force on forefoot — lower level — upper level	$F_{1su,\ lower\ level} = 1{,}5\ F_{1sp}$ $F_{1su,\ upper\ level} = 2{,}0\ F_{1sp}$ $F_{2su,\ lower\ level} = 1{,}5\ F_{2sp}$ $F_{2su,\ upper\ level} = 2{,}0\ F_{2sp}$	16.3.1	Table 9	Static ultimate strength test
Pulsating test force 1st and 2nd maximum value of pulsating test force Intermediate minimum value of pulsating test force Final static test force on heel / forefoot	$F_c(t)$; $F_c(\beta)$ F_{1cmax}, F_{2cmax} F_{cmin} F_{1fin}, F_{2fin}	13.4.2, 16.4.1	Table 9, (Tables 10 and 11)	Cyclic test procedure

[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

u-level	Typical combinations of segmental lengths of end attachments[a] A	B	C
$u_{T,L}$[b]	—	—	—
	$u_{T,26} - u_K = 78$ ($u_{T,L} - u_K$ = Total length − 500)		
u_K	—	$u_{T,26} - u_C = 328$ ($u_{T,L} - u_C$ = Total length − 250)	—
			$u_{T,26} - u_A = 498$ [$u_{T,26} - u_A = 578 \cdot (L/26) - 80$]
$u_C = 250$[c]	$(u_K - u_A)_{\text{Any foot length}} = 420$	—	—
		$(u_C - u_A) = 170$	
u_A	—	—	—
	$u_{A,\text{Any foot length}} = 80$	*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	Direction and location	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]												
			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

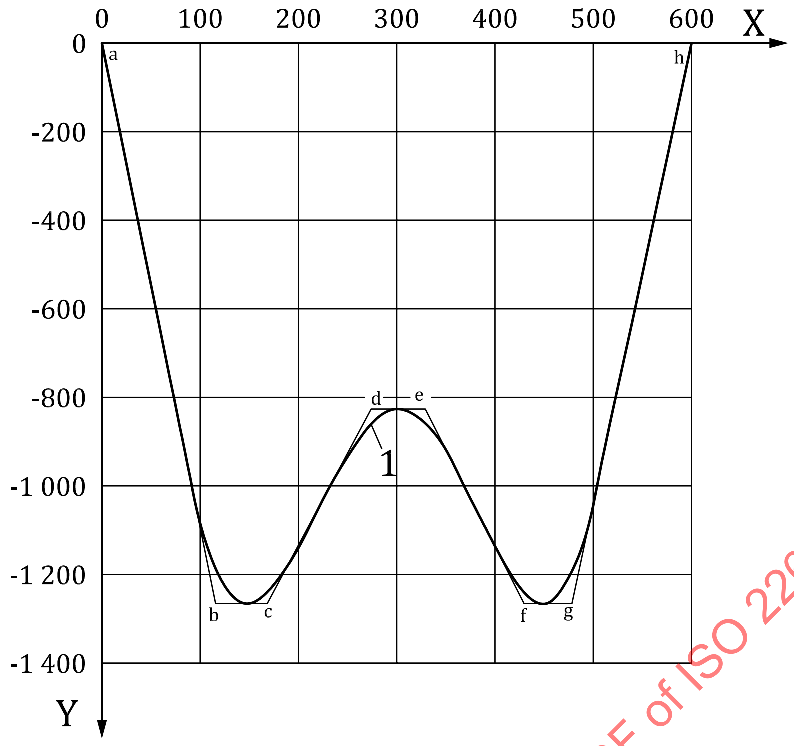
Subject	Test procedure	Angles			
		Event		Direction[a]	Numerical value/degree
Toe-out position of foot (see Figure 4)	All tests	—		γ	7
Instantaneous tilting positions of foot platform (see 13.4.2.8)	Cyclic test	Intermediate minimum value, F_{cmin}		β_{Fcmin}	0
		Tilting angle $\beta_{(t)}$ of foot platform	R2	$\beta_{(0)}$	-11,9
				$\beta_{(600)}$	26,0
			R3	$\beta_{(0)}$	-16,6
				$\beta_{(600)}$	34,0
			R4	$\beta_{(0)}$	-20,1
				$\beta_{(600)}$	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_{1cmax}	R2	β_1	-10
		Forefoot loading, F_2 and F_{2cmax}		β_2	13
		Heel loading, F_1 and F_{1cmax}	R3	β_1	-14
		Forefoot loading, F_2 and F_{2cmax}		β_2	17
		Heel loading, F_1 and F_{1cmax}	R4	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 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}	N	-1 601 —	— -1 580	-2 053 —	— -2 026	-2 227 —	— -2 198	-2 476 —	— -2 443	- 2883 —	— -2 845	-3 181 —	— -3 140
	Static ultimate test force	$F_{1su, lower level}$ $F_{2su, lower level}$	N	-2 401 —	— -2 369	-3 079 —	— -3 039	-3 340 —	— -3 297	-3 738 —	— -3 689	-4 076 —	— -4 023	-4 424 —	— -4 366
		$F_{1su, upper level}$ $F_{2su, upper level}$	N	-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}	N	-915	—	-1 173	—	-1 273	—	-1 521	—	-1 760	—	-2 038	—
	Inter-mediate minimum value of pulsating test force	F_{cmin}	N	-611		-783		-850		-1 016		-1 175			-1 361
	2nd maximum value of pulsating test force	F_{2cmax}	N	—	-903	—	-1 158	—	-1 256	—	-1 501	—	-1 737	—	-2 011
	Final static test force	F_{1fin} (= F_{1sp}) F_{2fin} (= F_{2sp})	N	-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	1	1											
		R3		1											
		R4		1											
	Prescribed number of cycles	R2	1	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)	Interval 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	Symbol	Value relevant to test loading level				
	ms	ms								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.

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 12).

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 can require the tests of this document to be applied at a particular test loading level not specified in this document, derived from the next lower regular test loading level of this document by increasing its test loads by x %.

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

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

Reference to this document can also be given by stating that the prescribed batch (or batches) of test samples of 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 12 — 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
Static ultimate strength test (see 16.3.1)	Direction of heel loading and Direction of forefoot loading	2 2	2 2	1 1	16.3.1.15, 16.3.1.15 and/or 16.3.1.16
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 can be necessary to satisfy the compliance conditions.

[b] For the definition of batch see 3.4.

[c] The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed 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 can also be submitted for specific tests by any interested party.

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

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 can be based on design features, on findings of risk management and/or on the results of appropriate preliminary tests conducted on feet of different size.

An appropriate measure for the worst-case loading is the direction and magnitude of the ankle (A-P) bending moment, 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 its requirements [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 conform 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 7 and shall be achieved by selecting one of the combinations specified in Table 6 for different types of test sample (see 10.2) or any other relevant combination. The combination of segment lengths selected shall be recorded.

NOTE Figure 4 illustrates a specific test sample set-up corresponding to the combination specified in Table 6, column C, 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 can 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 6, 7 and 8 and Figure 4 or 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 γ = 7° as shown in Figure 4 and specified in Table 8 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 7), 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

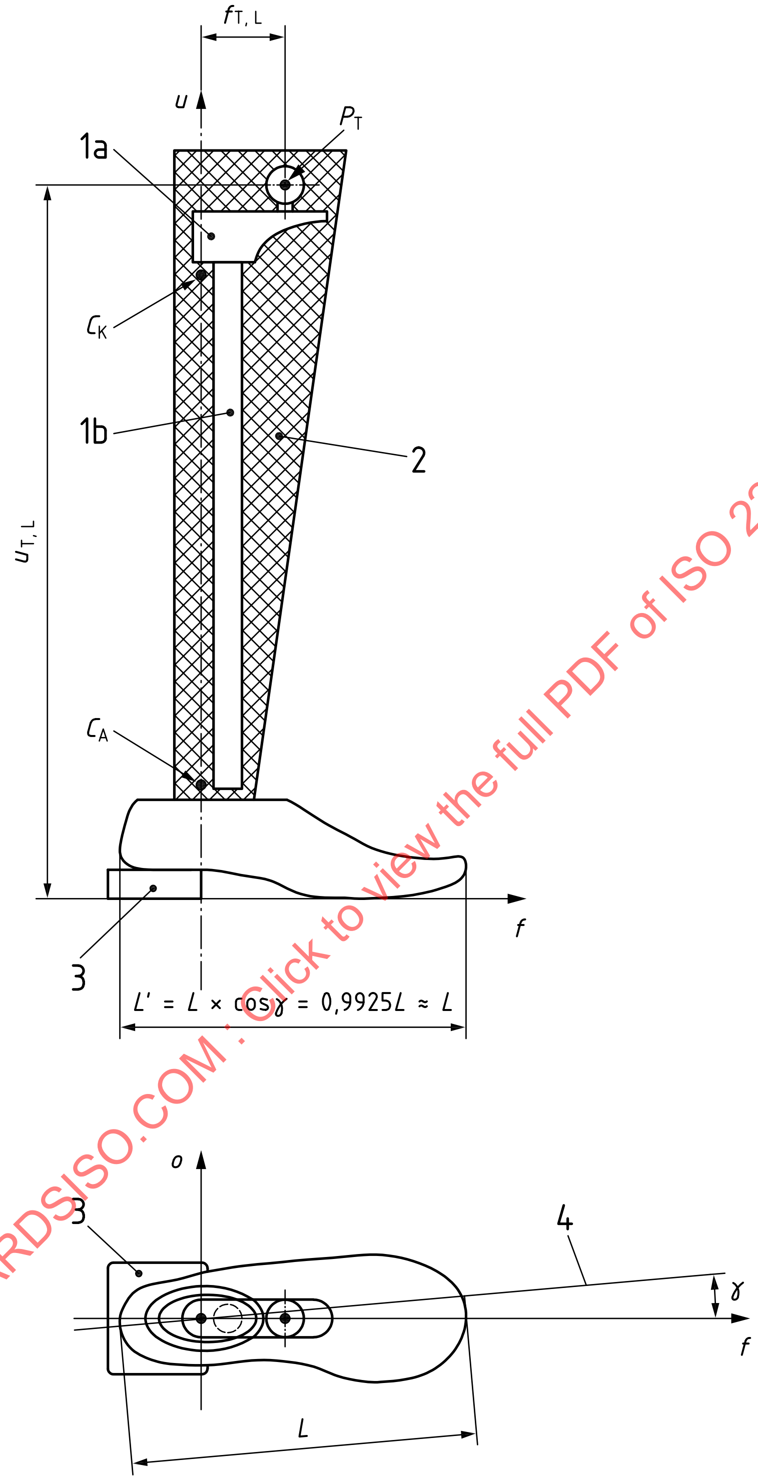
— if the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample is a prosthetic component normally used for its connection to a prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base (see 9.2)

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).



Key

f, u, o axes of coordinate system

1 specific arrangement of end attachment consisting of extension piece “1b” and top load application lever “1a”, providing specific position of top load application point P_T on test sample [see 10.5 d)]

2 reasonable area for the arrangement of alternative end attachments in consideration of the current spectrum of foot designs [see NOTE of 10.3.3 and NOTE 1 of 6.2.b)]

3 block of recommended heel height h_r (see 6.7.3.3 and also Figure 2)

4 longitudinal axis of foot (see 6.7.2)

γ outward rotation angle of the foot

P_T top load application point, allowing rotation of the test sample about each of the 3 spatial axes (see 13.4.1.1, 13.4.2.1 and also Figure 5)

C_K effective knee-joint centre [see NOTE of 6.2 b)]

C_A effective ankle-joint centre (see 6.7.3)

L foot length [see 10.5 d)]

L' projection of foot length L on f-u-plane

NOTE The specific set-up illustrated in Figure 4 corresponds to the combination specified in column C of Table 6.

Figure 4 — Illustration of specific set-up of left-sided test sample with top load application point P_T

11 Responsibility for test preparation

11.1 The manufacturer/submitter shall be responsible for the selection and assembly of the components to be tested.

11.2 The manufacturer/submitter shall be responsible for the provision with the test sample of specified parts to be replaced when the number of cycles of the cyclic test has reached a value at which such replacement is indicated [see 16.4.1.2 a)/16.4.1.9].

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

11.4 The manufacturer/submitter or the test laboratory/facility shall be responsible for the attachment of the end attachments required (see 13.2). Whoever assembles them shall be responsible for their static alignment in accordance with 10.5.

11.5 The manufacturer/submitter or the test laboratory/facility shall be responsible for the provision of a specific heel block (specific heel blocks) to be mounted on the foot platform(s) of the test equipment in accordance with 13.4.1.6 and 13.4.2.5.

Whoever provides them shall be supported by the other in the following manner:

— If the manufacturer/submitter provides the heel block(s), the test laboratory/facility shall contribute the particular dimensions (and other relevant details) related to its (their) mounting and correct positioning on the foot platform(s) of the test equipment.

— If the test laboratory/facility provides the heel block(s), the manufacturer/submitter shall contribute the particular dimensions (and other relevant details) related to its (their) shape, specified in accordance with 13.4.1.6 and 13.4.2.5. This information shall be included in the test submission document [see 12.3.2 f)].

If appropriate, the manufacturer/submitter shall specify in the test submission document the position of the heel block relative to the position of the ankle-foot device or foot unit in the test set-ups in accordance with 13.4.1.6 c) 2) and 13.4.2.5 [see 12.3.2 e)].

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

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

11.7 The test laboratory/facility shall be responsible for adjustment of the alignment to give the correct dimensions during test in accordance with 10.5 (see also 16.2.1.2, 16.3.1.2, 16.3.1.8 and 16.4.1.3).

11.8 The test laboratory/facility shall be responsible for the verification that the design of the heel block(s) is in accordance with the requirements of 13.4.1.6, 13.4.2.5 and the test submission document [12.3.2 e) and 12.3.2 f)].

If the design of the heel block(s) is not correct, the test laboratory/facility shall consult with the manufacturer/submitter to decide who alters it (them) to the specified design.

11.9 The test laboratory/facility shall be responsible for the mounting and correct positioning of the heel block(s) on the foot platform(s) of the test equipment in accordance with 13.4.1.6, 13.4.2.5 and the test submission document [12.3.2 e) and 12.3.2 f)].

12 Test submission document

12.1 General requirements

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

12.1.2 The manufacturer/submitter shall, if appropriate, state in the test submission document which of the information to be recorded in the test log in accordance with this document shall be included in the test report in addition to the information required to be included according to Clause 18.

12.1.3 The manufacturer/submitter shall clearly indicate a name and address for communication purposes. If appropriate, the identity of the original equipment manufacturer shall be provided.

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

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

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

12.2 Information required for test samples

The following information, attributable to a fully traceable identification for each test sample, shall be included in the test submission document:

a) manufacturer's name and model identification and/or number or other means of identification;

b) any certification from the manufacturer which states that the test sample has been taken from normal production and which gives details of the method of selection, in accordance with 10.1.1;

c) type of ankle-foot device or foot unit, in accordance with 10.2.1 or 10.2.2;

d) statement with justification that the size of foot selected provides the worst-case loading, in accordance with 10.1.2;

e) if not straightforward, identification of the longitudinal axis of the foot (6.7.2) and the position of the effective ankle-joint centre C_A (6.7.3), in accordance with 10.5;

f) information related to particular arrangements concerning the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample, in accordance with 9.2.1;

g) identification of the worst-case alignment position in accordance with 10.6;

h) any special assembly instructions for the test sample and/or attachments, in accordance with 10.3;

i) type of end attachments and their static alignment, in accordance with 10.3, 10.5 (and 11.4).

12.3 Information required for tests

12.3.1 General

The information addressed in 12.3.2 to 12.3.5 for each test sample shall be included in the test submission document.

12.3.2 For all tests

a) the particular test requested (Clauses 9 and 16) and the test loading condition(s), test loading levels [Clauses 7 and 8] and Test Ranges (R);

b) particular values of dimensions and forces for the conducting of the test (Clause 8);

c) the worst-case alignment of the test sample (10.6);

d) information related to particular arrangements concerning the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample (9.2.1);

e) the position of the heel block relative to the position of the ankle-foot device or foot unit submitted for test in the test set-ups (11.5);

f) the dimensions (and other relevant details) of the design of the heel block that are related to the shape of the foot sole of the ankle-foot device or foot unit submitted for test [only if the test laboratory/facility provides the heel block(s) (11.5)].

12.3.3 For the static proof test and the static ultimate strength test

The request to proceed with the test procedure in the second direction of loading on the occurrence of failure in the test procedure in the first direction of loading in accordance with 16.2.1.5 and 16.3.1.6.

12.3.4 For the static ultimate strength test

a) if appropriate, request the continuation of the test until failure actually occurs in accordance with 16.3.1.5 and 16.3.1.11 and recording of the value of the failure load and any further instructions concerning the documentation of test results;

b) the application of an increased rate of loading according to 16.3.1.5, 16.3.1.11 and Annex B.

12.3.5 For the cyclic test

a) the test frequency called for in accordance with 16.4.1.7 and 16.4.1.8;

b) replacement intervals of service items in accordance with 16.4.1.2 a) and 16.4.1.9;

c) if appropriate, request for visual examination with specification of magnification in accordance with 16.4.1.2 c) and 16.4.1.14. This request shall include instructions concerning the documentation of test results.

13 Equipment

13.1 General

The different types of test listed in Table 12 and specified in Clause 16 require different types of test equipment specified in 13.4.

Each piece of test equipment shall provide sufficient freedom of movement for the test sample to permit and not restrict its deformation under load within the specified range.

Other pieces of equipment are end attachments (see 13.2) required for specific set-ups of test samples, a special jig that may be used on an optional basis to facilitate the setting-up of test samples (see 13.3) and any devices used to measure loads and dimensions (not specifically addressed).

13.2 End attachments

13.2.1 General

For the application of the test loading conditions specified in this document, the test sample set-up requires the use of end attachments, consisting of non-prosthetic extension pieces and any appropriate top load application adaptor or lever, as required.

The end attachments shall not enhance or reduce the specified test loads in the structure under test.

The end attachments shall satisfy the requirements of the proof test of end attachments specified in 13.2.2.

13.2.2 Proof test of end attachments

13.2.2.1 General

The test shall be carried out on end attachments required for the application of the test loading conditions and Test Ranges (R) specified in this document. End attachments which satisfy the stiffness requirements of this test for proof test forces F_{pa} = 1,2 $F_{su,\text{ upper level}}$ of a specific test loading level in Test Range 4 (R4) (see Table 3 and Table 9) are suitable for all static and cyclic tests of this document carried out at this specific test loading level and at all lower levels.

The use of different sets of end attachments, individually designed to the specific requirements of the test loading conditions and Test Ranges (R) of the static and cyclic tests of this document (see EXAMPLE) and/or to the specific requirements of the ankle-foot devices or foot units submitted for test, requires the proof test of end attachments to be applied to each of these sets. In this case each set shall satisfy the stiffness requirements of the proof test of end attachments at values of test force F_{pa} relating as shown in Table 13 to the highest value of test force F_{su}, F_{sp} or F_{cmax} (see Table 3 and Table 9) to be applied during the test for which this set has been designed.

EXAMPLE A particular reason for the use of a specific set of (light-weight) end attachments for the cyclic test is the reduction of inertia effects caused by the mass of (heavy-weight) universal end attachments suitable for all tests.

It is not necessary to repeat the proof test of end attachments if earlier results for previously tested relevant combinations of end attachments are available and are suitable.

Table 13 — Option for end attachments of specific design

Intended use of end attachments	Test force to be applied
For the static ultimate strength test	F_{pa} = 1,2 $F_{su, upper level}$
For the static proof test	F_{pa} = 1,2 F_{sp}
For the cyclic test	F_{pa} = 1,2 F_{sp} = 2,1 F_{cmax} [a]
[a] The value of test force to be applied to end attachments intended to be used for cyclic tests takes into account that each test sample having passed the cyclic test is subjected to a final static test without preceding re-alignment. The latter condition can hardly be met if the procedure requires the exchange of end attachments, which would be the case if the set-up of the test sample for the cyclic test contained end attachments specifically designed for cyclic tests only.	

13.2.2.2 Test procedure

13.2.2.2.1 Carry out the proof test on end attachments, consisting of non-prosthetic extension pieces and any appropriate top load application adaptor or lever, as required, by measuring their stiffness in the manner specified in 13.2.2.2.2 to 13.2.2.2.10.

Assemble the non-prosthetic components and the top load application adaptor or lever used in the test sample for the application of the test loading conditions specified in this document, together with a rigid dummy, replacing the ankle-foot device or foot unit.

The rigid foot dummy shall be designed to simulate the effective lever arms of a real ankle-foot device or foot unit. For orientation, the values of the bottom offsets f_{B1} (heel) and f_{B2} (forefoot) (see 6.3 and Figure 1) are specified in Table 4 for a range of foot lengths from L = 20 cm to L = 32 cm. For specific values of foot length not covered, Table 4 gives the Formulae for their calculation.

If the non-prosthetic extension pieces used have a means of adjustment, this shall be set to the worst structural condition in accordance with 10.6, i.e. the adjustment shall be directed away from the effective ankle-joint centre and from the load line so as to increase the effective lever arm.

If it is necessary to use additional non-prosthetic components to allow assembly of end attachments, the stiffness of these components shall not be less than the stiffness of the other non-prosthetic components when assembled in the test situation.

Record the details of the assembly of end attachments.

13.2.2.2.2 Within the range of adjustability required for the application of the relevant test loading condition(s), test loading level(s) and Test Ranges (R), set the top load application point P_T on the top load application adaptor or lever and the bottom load application point P_B on the rigid foot dummy (in the same direction) to their maximum distance from a line corresponding to the u-axis of the test sample in the test situation.

If the top load application adaptor or lever and/or the rigid foot dummy are used for the application of several test loading conditions and/or test loading levels, their ranges of adjustability shall allow the load application points to be set to the maximum distance required for the application of the test loading condition and/or test loading level and Test Range (R) with the highest values of offset at these points (see Tables 4 and 7).

Record the details of the adjustment of the top and bottom load application points P_T and P_B.

13.2.2.2.3 Mount the assembly in the test equipment or suitable device

a) with its u-axis extending parallel to the line of action of the moving part of the actuator of the test equipment when its top load application point P_T is matching the top load application point of the test equipment

or

b) with its top and bottom load application points P_T and P_B on the line of action of the moving part of the actuator of the test equipment.

For the orientation according to a), the values of the test forces F listed in Table 5 shall apply.

For the orientation according to b), the values of the test forces F_R in parentheses listed in Table 5 shall apply.

Record the orientation a) or b) in which the assembly is mounted in the test equipment and the test loading level to be applied, together with the corresponding values of test forces F or F_R.

13.2.2.2.4 Apply to the bottom and top load application points of the assembly the settling test force F_{set} or F_{Rset} (see 13.2.2.2.3) of the relevant (test loading condition and) test loading level and Test Range (R), specified in Table 5.

Maintain this force, F_{set} or F_{Rset}, at the prescribed value for (30 ± 3) s and then remove it.

13.2.2.2.5 Apply to the bottom and top load application points of the assembly the stabilizing test force F_{stab} or F_{Rstab} (see 13.2.2.2.3) specified in Table 5 and maintain it until the measurement specified below is completed.

Measure and record the displacement, δ of the moving load application point from its reference position in the test equipment as δ_1.

13.2.2.2.6 Increase the test force F smoothly at a rate of between 100 N/s and 10 kN/s to the proof test force F_{pa} or F_{Rpa} (see 13.2.2.2.3) of the relevant (test loading condition and) test loading level, specified in Table 5, and maintain it until the measurement specified below is completed.

Measure and record the displacement, δ of the moving load application point from its reference position in the test equipment as δ_2.

Record the application of a specific value of proof test force F_{pa} or F_{Rpa}, determined in accordance with the option described in 13.2.2.1.

13.2.2.2.7 Decrease the test F force to F_{stab} or F_{Rstab} and maintain it until the measurement specified below is completed.

Measure and record the displacement, δ of the moving load application point from its reference position in the test equipment as δ_3.

13.2.2.2.8 Calculate and record the deflection, d_1, at F_{pa} or F_{Rpa} and the permanent deformation, D_2, at F_{stab} or F_{Rstab} as given in Formulae (2) and (3):

$$D_1 = \delta_2 - \delta_1 \quad (2)$$

$$D_2 = \delta_3 - \delta_1 \quad (3)$$

13.2.2.2.9 Do not use the end attachment if the calculated values exceed the following limits:

maximum deflection at F_{pa} or F_{Rpa}: D_1 = 2 mm.

maximum permanent deformation at F_{stab} or F_{Rstab}: D_2 = 1 mm.

13.2.2.2.10 Record the results.

13.3 Jig

A jig can be used to facilitate the setting-up of test samples before mounting them in the test equipment.

13.4 Test equipment

13.4.1 Test equipment to perform static heel and forefoot loading

13.4.1.1 The test equipment shall be capable of producing static test forces at a loading rate of between 100 N/s and10 kN/s up to the values specified in Table 9 for the relevant test procedure, test loading condition, test loading level and Test Range (R).

The test equipment shall allow the adjustment of the position of the top load application point P_T to the f- and u-offsets relevant to the foot length L of the ankle-foot device or foot unit of the test sample, specified in Table 7 and illustrated in Figures 4 and 5. (For further background information see A.2.2.3.)

The connection between the test equipment and the test sample at the top load application point P_T shall allow rotation of the test sample about each of the 3 spatial axes (see also Figure 5).

13.4.1.2 The test equipment shall incorporate a foot platform or foot platforms capable of supporting the ankle-foot device or foot unit when the static test forces referred to in 13.4.1.1 are applied to the test sample (see Figure 5).

13.4.1.3 The test equipment shall allow the adjustment of the foot platform(s) to the values of tilting angle for heel and forefoot loading, β_1 and β_2, specified in Table 8.

NOTE Test equipment other than that addressed, described or referred to in this document (see paragraphs 3 and 4 of 15.1) can use a foot platform fixed horizontally and apply the specified values of tilting angle to the test sample.

13.4.1.4 The foot platform(s) of the test equipment shall (each) have sufficient length to allow simultaneous heel and forefoot support.

13.4.1.5 Test equipment using different foot platforms for the support of the ankle-foot device or foot unit of the test sample at heel and forefoot loading shall be so designed that

a) the foot platform used at heel loading supports the forefoot, if heel loading by the test force F_1 deforms the test sample to such an extent that forefoot support is necessary to avoid unrealistic conditions of loading, and

b) the foot platform used at forefoot loading supports the heel, if forefoot loading by the test force F_2 deforms the test sample to such an extent that heel support is necessary to avoid unrealistic conditions of loading.

13.4.1.6 The foot platform used at heel loading shall be equipped with a heel block, which satisfies the following requirements (see also EXAMPLE, NOTE and Figure 5).

a) The heel block shall provide a thickness corresponding to the recommended heel height h_r of the ankle-foot device or foot unit of the test sample.

b) The top surface of the heel block shall be designed as follows:

   1) it shall approach the contour of the foot sole of the unloaded ankle-foot device or foot unit of the test sample, the heel block thus filling most of the free space between foot sole and platform (bottom) surface;

   2) it shall be composed of a plane rear (posterior) section and a cylindrical front (anterior) section with a tangential transition to the plane section;

3) the radius of the cylindrical front section of the top surface shall be greater than a quarter of the foot length L; the maximum value of the radius shall be limited by the requirements of b) 1) and/or d).

c) The position of the heel block relative to the position of the ankle-foot device or foot unit in the test set-up shall be determined as follows:

1) the line of transition from the plane rear section to the cylindrical front section of the top surface of the heel block shall intersect the f-u-plane perpendicularly;

2) the point of intersection shall lie on the u-axis, unless an offset from the u-axis is specified by the manufacturer/submitter in the test submission document [see 12.3.2 e)].

d) The front edge of the heel block shall not extend to the forefoot by more than half of the foot length L, when positioned in accordance with c).

e) The heel block shall be made of material with a compressive stress (strength) of at least 50 MPa.

EXAMPLE For a foot of length L = 27 cm and a recommended heel height of h_r = 10 mm, a heel block with a cylindrical front section defined by a radius of R = 120 mm has been shown to be appropriate.

NOTE For the provision of specific heel blocks, see Clause 11.

13.4.2 Test equipment to perform cyclic loading

The test equipment to perform cyclic loading may also be used to perform static loading. In this case it is required to keep the foot platform in the relevant static position. A mechanical lock can be used to facilitate this adjustment and to avoid overloading of the tilting drive mechanism (see Figure 5).

13.4.2.1 The test equipment shall be capable of producing pulsating (compression) test forces F_c up to the magnitudes and rates of loading/unloading specified in Tables 9, 10 and 11 for the relevant test loading condition, test loading level and Test Range (R).

The test equipment shall allow the adjustment of the position of the top load application point P_T to the f- and u-offsets relevant to the foot length L of the ankle-foot device or foot unit of the test sample, specified in Table 7 and illustrated in Figures 4 and 5. For further background information see A.2.2.3.

The connection between the test equipment and the test sample at the top load application point P_T shall allow rotation of the test sample about each of the 3 spatial axes (see also Figure 5).

13.4.2.2 The test equipment shall incorporate a tiltable foot platform capable of supporting the ankle-foot device or foot unit of the test sample when the pulsating test force referred to in 13.4.2.1 is applied (see Figure 5).

13.4.2.3 The test equipment shall allow the adjustment of the position of the tilting axis TA of the foot platform (see Figure 5) to the values of f_{TA} and u_{TA} relevant to the foot length L of the ankle-foot device or foot unit of the test sample, specified in Table 7. For further background information see D.3.2 and D.3.3.

13.4.2.4 The foot platform shall support the ankle-foot device or foot unit at values of tilting angle β oscillating through the range from heel contact to toe-off specified in Table 11 and illustrated in Figure 6.

NOTE Test equipment other than that addressed, described or referred to in this document (see paragraphs 3 and 4 of 15.1) can use a foot platform fixed horizontally and apply the specified values of tilting angle to the test sample.

13.4.2.5 The foot platform shall be equipped with a heel block that satisfies the same requirements as the heel block of test equipment to perform static heel and forefoot loading (see 13.4.1.6).

13.4.2.6 In addition, the test equipment shall satisfy the following requirements:

a) The test equipment shall be capable of lifting the test sample off the foot platform for the period of unloading corresponding to the swing phase of walking, during which the foot platform returns to its starting position for the next loading cycle (see Figure 5).

NOTE 1 The example illustrated in Figure 5 produces a lifting force F_{lift}, the magnitude of which depends on the design of the test equipment and the mass of the test sample set-up.

b) The test equipment shall incorporate a means to ensure that the foot of the test sample contacts the foot platform in the correct position for the next loading cycle.

NOTE 2 This is important, since foot contact on the platform in an incorrect position will change the test loading conditions. For example, foot contact on the platform in an incorrect position in the *f*-*u*-plane will change the relationship between the test force *F* applied to the test sample in the top load application point P_T and the forces acting between foot and platform, comprising the perpendicular and tangential force components F_P and F_T and their resultant F_R [see A.2.2.1 a)]. Consequently, foot contact in incorrect position can impair the conformity of tests and the comparability of test results.

Appropriate means to ensure foot contact on the platform in the correct position are flexible elements, which act during the lift-off phase of the test sample to compensate dislocation of the foot that can have occurred during the previous loading cycle and to stabilize the foot in the correct position by resisting dislocation in the manner specified below [see also Figure 5].

1) Resistance to translatory dislocation of the foot in the *f*-*u*-plane

— either by stabilizing moments applied to the test sample in the top load application point P_T and acting about an axis perpendicular to the *f*-*u*-plane in each of the two opposing directions

or

— by stabilizing forces applied to the test sample at any appropriate *u*-level and acting along a line of application in the *f*-*u*-plane parallel to the *f*-axis in each of the two opposing directions.

2) Resistance to translatory dislocation of the foot perpendicular to the *f*-*u*-plane

— either by stabilizing moments applied to the test sample in the top load application point P_T and acting about an axis in the *f*-*u*-plane parallel to the *f*-axis in each of the two opposing directions

or

— by stabilizing forces applied to the test sample at any appropriate *u*-level and acting along a line of application perpendicular to the *f*-*u*-plane in each of the two opposing directions.

3) Resistance to rotatory dislocation of the foot about the long axis of the test sample

— either by stabilizing moments applied to the test sample in the top load application point P_T and acting about an axis parallel to the *u*-axis in each of the two opposing directions

or

— by stabilizing moments or force couples applied to the test sample at any appropriate *u*-level and acting about the long axis of the test sample in each of the two opposing directions.

The selection and arrangement of appropriate flexible elements and the magnitudes of the stabilizing moments or forces with which they resist to dislocation of the foot during the lift-off phase of the test sample depend on the design of the test equipment and the set-up of the test sample or the friction of their mechanical connection in the top load application point P_T, respectively. As a general rule, the stabilizing moments or forces should be as low as possible to avoid the test loading conditions to be affected. Balancing the mass of the end attachments above the Load Sensor support the elements to operate appropriately with lowest stabilizing moments or forces.

EXAMPLE Stabilizing forces of a magnitude of 1 N, applied at a u-level of 200 mm in the manner described in 1) and 2), and stabilizing force couples generating moments of magnitudes of 0,6 N·m as described in 3), have been shown to be appropriate if the tilting angle β(t) of the oscillating foot platform does not exceed the tolerance of ±1° in the instants of β_1, 0° and β_2.

13.4.2.7 The profiles of the tilting angle β of the oscillating foot platform and the pulsating test force F_c shall be applied in either of the ways specified in a) and b) and illustrated in Figures 6 and 7.

a) The profiles of tilting angle β and test force F_c are applied as synchronized functions of time β (t) and $F_c(t)$.

b) The profile of the tilting angle β is applied as a function of time β (t) and the profile of the test force F_c is applied as a function of the tilting angle $F_c(\beta)$.

Further matters related to the way of application of the profiles of tilting angle β and test force F_c are addressed in ISO/TR 22676. For further background information, see Annex D.

13.4.2.8 The profile of the tilting angle $\beta(t)$ is primarily specified by the instantaneous tilting positions β_1, β_{Fcmin} and β_2 (see Table 8) occurring at F_{1cmax} (1st maximum), F_{cmin} (intermediate minimum) and F_{2cmax} (2nd maximum) of the loading profile (see 13.4.2.9).

The profile of the tilting angle β (t) can also be specified with sufficient accuracy by a polynomial of 6th degree. For the period of 0 ms ≤ t ≤ 600 ms corresponding to a loading period of 600 ms (see NOTE 1).

The polynomial for R4 reads as given in Formula (4):

$$\beta(t) = -1{,}313\,09 \times 10^{-14} \times t^6 + 2{,}757\,30 \times 10^{-11} \times t^5 - 2{,}175\,95 \times 10^{-08} \times t^4 + 7{,}606\,52 \times 10^{-06} \times t^3 - 8{,}929\,8 \times 10^{-04} \times t^2 - 4{,}535\,31 \times 10^{-02} \times t - 20{,}153\,0 \quad (4)$$

The polynomial for R3 reads as given in Formula (5):

$$\beta(t) = -9{,}790\,67 \times 10^{-15} \times t^6 + 2{,}085\,30 \times 10^{-11} \times t^5 - 1{,}670\,28 \times 10^{-08} \times t^4 + 5{,}922\,39 \times 10^{-06} \times t^3 - 6{,}949\,70 \times 10^{-04} \times t^2 - 3{,}589\,25 \times 10^{-02} \times t - 16{,}620\,0 \quad (5)$$

The polynomial for R2 reads as given in Formula (6):

$$\beta(t) = -5{,}420\,78 \times 10^{-15} \times t^6 + 1{,}205\,81 \times 10^{-11} \times t^5 - 1{,}008\,43 \times 10^{-08} \times t^4 + 3{,}719\,69 \times 10^{-06} \times t^3 - 4{,}372\,41 \times 10^{-04} \times t^2 - 2{,}340\,666 \times 10^{-02} \times t - 11{,}877\,0 \quad (6)$$

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.) 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.

NOTE 2 For other test frequencies, preferably between 0,5 Hz and 3 Hz (see 16.4.1.7 and 16.4.1.8), Formulae 4 to 7 can be adapted by multiplying each coefficient of the polynomial by $(600\ \text{ms}/x\ \text{ms})^y$, the value of x corresponding to the loading period related to a different frequency, and the value of y corresponding to the exponent of the time t related to each coefficient, i.e. for the adaptation of the polynomial to a loading period of x = 900 ms, the coefficients were multiplied by $(600/900)^y = (2/3)^y$ for R4 as given in Formula (7):

$$\beta(t) = -1{,}419\,562 \times 10^{-14} \times (2/3)^6 + 2{,}505\,279 \times 10^{-11} \times (2/3)^5 - 1{,}618\,453 \times 10^{-08} \times (2/3)^4 + 4{,}251\,581 \times 10^{-06} \times (2/3)^3 - 1{,}006\,677 \times 10^{-04} \times (2/3)^2 - 1{,}733\,942 \times 10^{-02} \times (2/3) - 19{,}980\,95 \quad (7)$$

13.4.2.9 The pulsating test force $F_c(t)$ according to 13.4.2.7 a) and Figure 6 is primarily specified by the following data (see Table 9):

— The test force F_{1cmax} at the 1st maximum of the loading profile, occurring at 25 % of the loading period (see NOTE 1),

— the test force F_{cmin} at the intermediate minimum of the loading profile, occurring at 50 % of the loading period (see NOTE 1)

and

— the test force F_{2cmax} at the 2nd maximum of the loading profile, occurring at 75 % of the loading period (see NOTE 1).

NOTE 1 For a loading period of 600 ms, as shown in Figures 3 and 6 and Table 10 and Table 11, the percentiles 25 %, 50 % and 75 % of the loading period correspond to instants of 150 ms, 300 ms and 450 ms after the beginning of the loading period (see also NOTE 1 in 13.4.2.8).

The profile of the pulsating test force $F_c(t)$ can also be specified with sufficient accuracy by a polynomial of 6th degree. For the period of 0 ms ≤ t ≤ 600 ms corresponding to a loading period of 600 ms (see NOTE 1 in 13.4.2.8), the polynomial reads as given in Formula (8):

$$F_c(t) = F_{1cmax} \times 10^{-3} \times (5{,}123\,068\,422\,965\,52 \times 10^{-12} \times t^6 - 9{,}203\,737\,411\,041\,9 \times 10^{-9} \times t^5 + 5{,}988\,822\,251\,679\,48 \times 10^{-6} \times t^4 - 1{,}671\,019\,148\,992\,29 \times 10^{-3} \times t^3 + 1{,}646\,514\,971\,114\,25 \times 10^{-1} \times t^2 + 3{,}624\,956\,908\,832\,28 \times t) \quad (8)$$

NOTE 2 For the adaptation of Formula (8) to other loading periods related to different test frequencies, the method described in NOTE 2 of 13.4.2.8 applies.

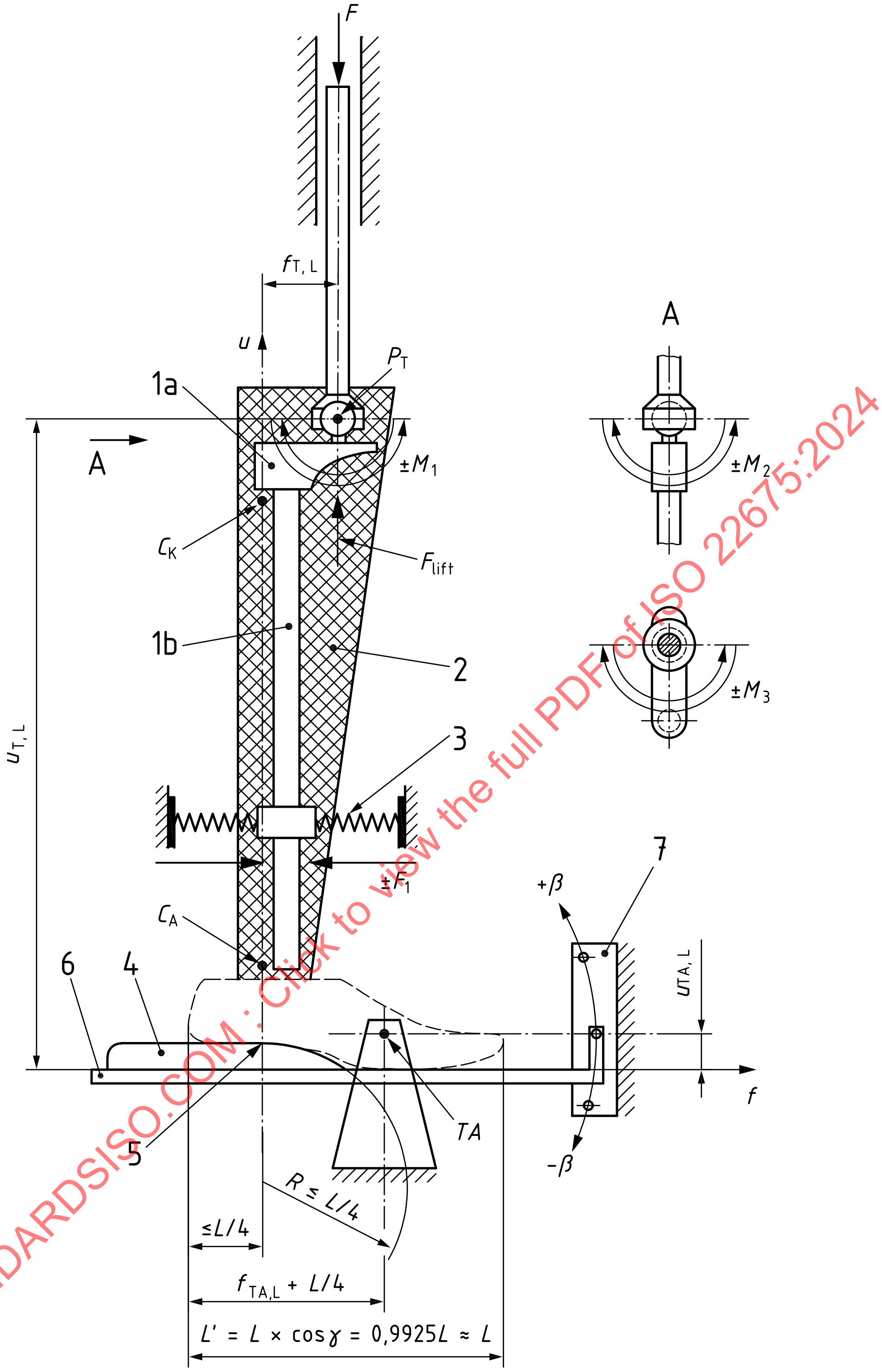
Further guidance on the application of the profile of the test force $F_c(t)$ is given in Table 10 and Table 11 and Figure 3.

13.4.2.10 The waveforms of the pulsating test force $F_c(t)$ or $F_c(\beta)$ and the tilting angle $\beta(t)$ of the oscillating foot platform generated by the test equipment shall be smooth with no overshoot spikes, characterized by a course corresponding to the descriptions given in 13.4.2.8 and 13.4.2.9.

13.4.2.11 The test equipment shall switch off, if the pulsating test force $F_c(t)$ or $F_c(\beta)$ and/or the tilting angle $\beta(t)$ of the oscillating foot platform exceed the tolerances specified in 14.3 f), g) and h), with the exception specified in 13.4.2.12.

13.4.2.12 If the test equipment control mechanism used to generate the pulsating test force $F_c(t)$ or $F_c(\beta)$ requires a number of cycles to achieve the prescribed loading profile, during this settling in period the waveform of the test force shall be smooth with no overshoot spikes, and the highest force applied to the test sample shall not exceed the maximum test force F_{1cmax} by more than 10 %.

NOTE Experience has shown that the repeated loading at values exceeding the maximum test force F_{1cmax} by more than 10 % can cause an early deterioration of the test sample.



Key

f, *u* axes of coordinate system

1 specific arrangement of end attachment consisting of extension piece '1b' and top load application lever "1a", providing specific position of top load application point P_T on test sample [see 10.5 d)]

2 reasonable area for the arrangement of alternative end attachments in consideration of the current spectrum of foot designs [see NOTE of 10.3.3 and Note 1 of 6.2 b)]

3 example of appropriate means to flexibly resist dislocation of the foot in the *f*-*u*-plane during the lift-off phase of the test sample to ensure contact of the foot on the foot platform in correct position for the next loading cycle [see 13.4.2.6 b)]

4 block of recommended heel height h_r with cylindrical shape of its top surface to provide a smooth transition towards the forefoot [see 13.4.1.6 and 13.4.2.5]

5 point of intersection of line of transition between plane rear section and cylindrical front section of top surface of heel block and u-axis [see 13.4.1.6 c) 2)]

6 tiltable foot platform:

— either fixed at the values of tilting angle β_1 and β_2 specified for static heel and forefoot loading (see 13.4.1.3)

or

— periodically oscillating with $\beta(t)$ within the range specified for progressive heel and forefoot loading from heel contact to toe-off (see 13.4.2.4)

7 means of locking the foot platform at the values of tilting angle β_1 and β_2 specified for static heel and forefoot loading (option – see NOTE of 13.4.2)

F test force $F_c(t)$ or $F_c(\beta)$, F_{sp} or F_{fin}, F_{su}

F_{lift} lifting force to lift the test sample off the foot platform during the period corresponding to the swing phase of walking [see NOTE of 13.4.2.6 a)]

$\pm F_1$ stabilizing forces at specific u-level according to 13.4.2.6 b) 1) (same effect as stabilizing moments $\pm M_I$ in P_T)

$\pm M_1$ stabilizing moments in P_T according to 13.4.2.6 b) 1) (same effect as stabilizing forces $\pm F_I$)

$\pm M_2$ stabilizing moments in P_T according to 13.4.2.6 b) 2) (corresponding stabilizing forces at specific u-level not shown)

$\pm M_3$ stabilizing moments in P_T according to 13.4.2.6 b) 3) (corresponding stabilizing moments or force couples at specific u-level not shown)

P_T top load application point, allowing rotation of the test sample about each of the 3 spatial axes (see 13.4.1.1, 13.4.2.1 and also Figure 4)

C_K effective knee-joint centre [see NOTE of 6.2 b)]

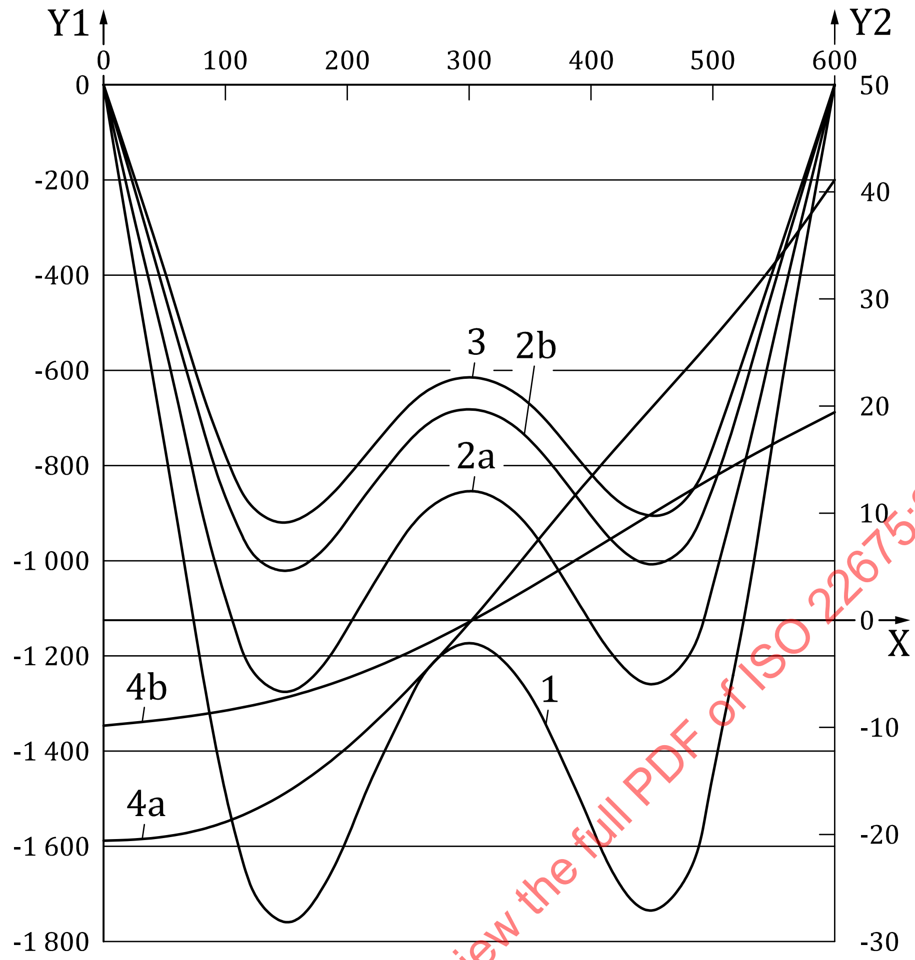
C_A effective ankle-joint centre (see 6.7.3)

TA tilting axis of foot platform (see 13.4.2.3)

L foot length [see 10.5 d) and Figure 4]

L' projection of foot length L on f-u-plane (see Figure 4)

Figure 5 — Diagrammatic view of test equipment according to 13.4.1 and 13.4.2 with test sample



Key

X time in ms

Y_1 force in N

Y_2 angle in degrees

1 test force *F* of test loading level P7

2a test force *F* of test loading level P5 R4

2b test force F of test loading level P5 R2

3 test force *F* of test loading level P3

4a tilting angle *β* R4 of foot platform (see Figure 5) – schematic

4b tilting angle *β* R2 of foot platform – schematic

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).

Figure 6 — Profiles of test force $F_c(t)$ and tilting angles $\beta(t)$ as synchronized functions of time, determining examples of loading conditions of the cyclic test of this document

14 Accuracy

14.1 General

Details of methods used to measure accuracy shall be recorded.

The test equipment, any jig used for the setting-up of test samples and any devices used to measure loads and dimensions shall be calibrated at least annually and whenever any part is replaced. Records of the calibration shall be maintained.

14.2 Accuracy of equipment

In order to meet the accuracy of procedure specified in 14.3, the test equipment, any jig used for the setting-up of test samples and any measuring devices should be capable of measuring a) to d) to the accuracy specified.

a) linear dimensions of the jig to an accuracy of ±0,2 mm; linear dimensions of test equipment to an absolute accuracy of ±0,5 mm or a relative accuracy of ±0,2 mm;

b) angular dimensions to an accuracy of ±1°;

c) test forces to an accuracy of ±1 % of the highest value required in the test;

d) the frequency of cyclic tests to an accuracy of within 5 % of the test frequency used.

14.3 Accuracy of procedure

a) Linear dimensions, except segment lengths, shall be initially set and finally adjusted with a tolerance of ±1 mm;

b) Segment lengths shall be set with a tolerance of ±2 mm;

c) Angular dimensions, except the angular toe-out position of feet, shall be set with a tolerance of ± 2°;

d) The angular toe-out position of feet shall be set with a tolerance of ±3°;

e) Static test forces shall be applied with a tolerance of ±2 % of the highest value prescribed for the test;

f) The pulsating test force $F_c(t)$ or $F_c(\beta)$ shall be applied with a tolerance of ±3 % of the value prescribed for F_{c1max} at the instants of:

— the 1st maximum F_{c1max} at t_1 = 150 ms and $\beta_1 = \beta_{(150)}$;

— the intermediate minimum F_{cmin} at t_{Fcmin} = 300 ms and β_{Fcmin} = 0°;

— the 2nd maximum F_{c2max} at t_2 = 450 ms and $\beta_2 = \beta_{(450)}$;

g) The tilting angle β (t) of the oscillating foot platform shall be applied with a tolerance of ±2° at the instants of

— $\beta_1 = \beta_{(150)}$ at t_1 = 150 ms;

— $\beta_{Fcmin} = \beta_{(300)}0°$ at t_{Fcmin} = 300 ms;

— $\beta_2 = \beta_{(450)}$ at t_2 = 450 ms.

h) The frequency of cyclic tests shall be controlled with a tolerance of ±10 % of the test frequency used.

15 Test principles

15.1 General

The static and cyclic test procedures for prosthetic ankle-foot devices and foot units addressed and specified in this document use static and cyclic strength tests that simulate the loading conditions typical of normal use as described in a) to d).

The static tests relate to the worst loads generated in any activity. The cyclic tests relate to normal walking activities where loads occur regularly with each step.

The description of the test principles given in a) to d) is closely related to a specific type of test equipment as described in 13.4.1 and 13.4.2, which is considered to require the lowest complexity possible (see also 16.1.1, 16.1.2 and Annex D).

This relationship between test principle and test equipment is, however, not imperative. Moreover, any other type of test equipment can be used, provided it is capable of applying the forces and displacements in accordance with the requirements specified in Clauses 7, 8, 13, 14, 15 and 16.

a) The test sample, consisting of the ankle-foot device or foot unit and the end attachments required for the test sample set-up, is set up in the test equipment in a position determined by its suspension in the top load application point P_T and the placement of its foot on the foot platform, allowing deflection/deformation under load.

b) The range of angular movement from heel contact to toe-off in the progression of the limb during the stance phase of walking, characterized by the (lower) leg angle in the sagittal plane as a function of time, or any specific instant of this angular movement is simulated by corresponding tilting of the foot platform of the test equipment as a cyclical oscillation within a given range of tilting angle or at fixed values of tilting angle (see 16.1.2).

c) The loading exerted on the ankle-foot device or foot unit of the lower limb prosthesis by the amputee during the stance phase of walking is simulated by a single test force, applied at the top load application point P_T of the test sample, while this is supported by the tiltable foot platform of the test equipment.

d) The top load application point P_T is the point of intersection of the lines of action of the resultant reference forces F_{R1} and F_{R2}, determining the directions of the static and the maximum cyclic heel and forefoot reference loading.

   According to the concept applied to the static and cyclic test procedures of this document, the position of the top load application point P_T, determined by its f- and u-coordinates, is only dependent on the foot length L of the ankle-foot device or foot unit submitted for test. It is not dependent on the test loading level. This allows the application of the static and cyclic test procedures of this document at any of the test loading levels specified to test samples of ankle-foot devices or foot units of any size of foot.

   NOTE For further background information, see Annex A.

15.2 Static test procedure

The static test procedure consists of a proof test (see 16.2) and an ultimate strength test (see 16.3). This test procedure is carried out to determine the performance of the load bearing structures under typical severe loading conditions that can occur during use by users as occasional single events.

Shock absorption capacity quantified by the ultimate strength test (see 16.3) is determined by carrying out the following:

a) Apply the test force, and increase it smoothly until the test sample fails, the test force is falling below $F_{su\ lower\ level}$ during the test or the test sample shows sufficient deflection to demonstrate shock absorption capacity (see below).

b) Derive the deformation rate at $F_{su\ lower\ level}$ (see NOTE), i.e. gradient of line (r).

c) Calculate the intersection point of the deformation rate line through $F_{su,\ lower\ level}$ at $F_{su,\ upper\ level}$, i.e. point (i) derived from line (r).

d) Calculate the amount of energy theoretically absorbed under the deformation rate line between its intersection with $F_{su,\ lower\ level}$ and with $F_{su,\ upper\ level}$, based on the theoretical force value, i.e. the cross hatched area (a).

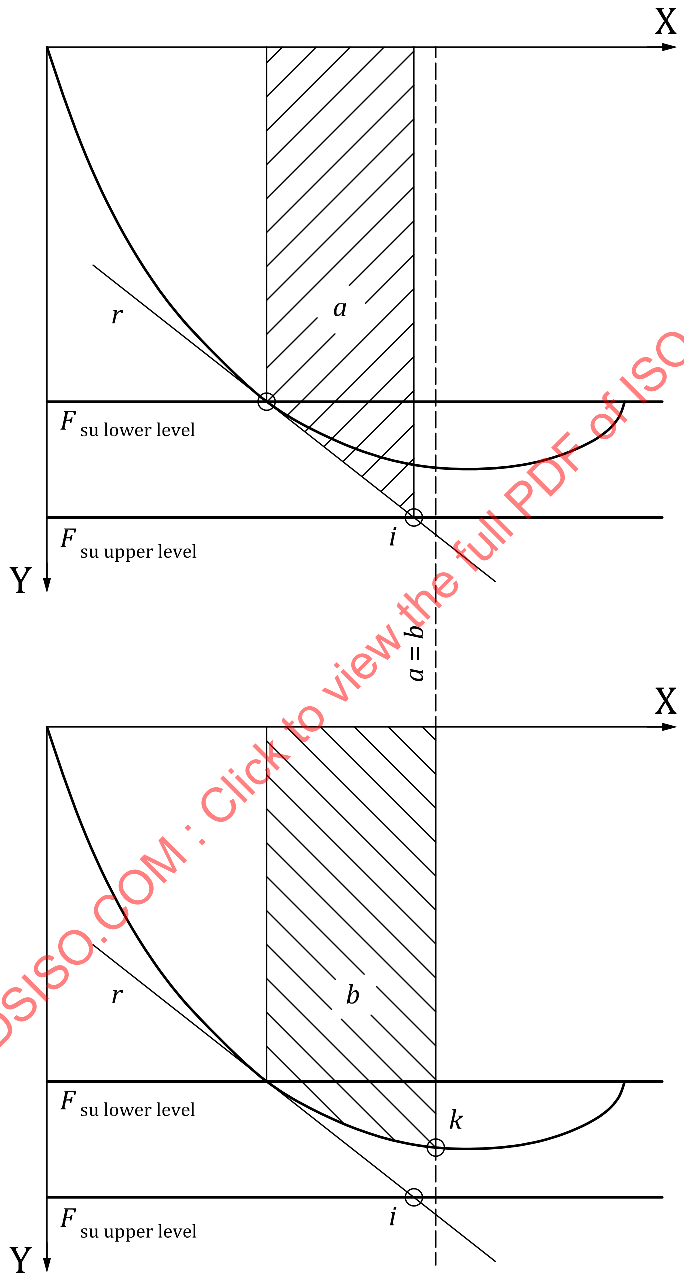
e) Calculate the real energy absorbed under the force-displacement-curve between $F_{su,\ lower\ level}$ and the earliest end of the test, point (k) based on the absolute force value, i.e. the cross hatched area (b).

f) The energy integration shall not be continued after the test force is falling below $F_{su,\ lower\ level}$ during the test, i.e. stop the test at point (m) on Figure 8 and Figure 9.

Shock absorption capacity is demonstrated if the real energy absorbed, area (b), exceeds the theoretically absorbed energy, area (a), see Figure 7.

Shock absorption capacity is not demonstrated if the real energy absorbed, area (b), is lower than the theoretically absorbed energy, area (a), see Figure 8 and Figure 9.

NOTE The method to derive the deformation rate can be for example graphical or numerical. The test lab is responsible to use an appropriate method derive the representative deflection rate (for example considering the signal noise) i.e. a tangent on the load-over-deflection curve in $F_{\text{su, lower level}}$.



Key

X deflection

Y force

a theoretically absorbed energy

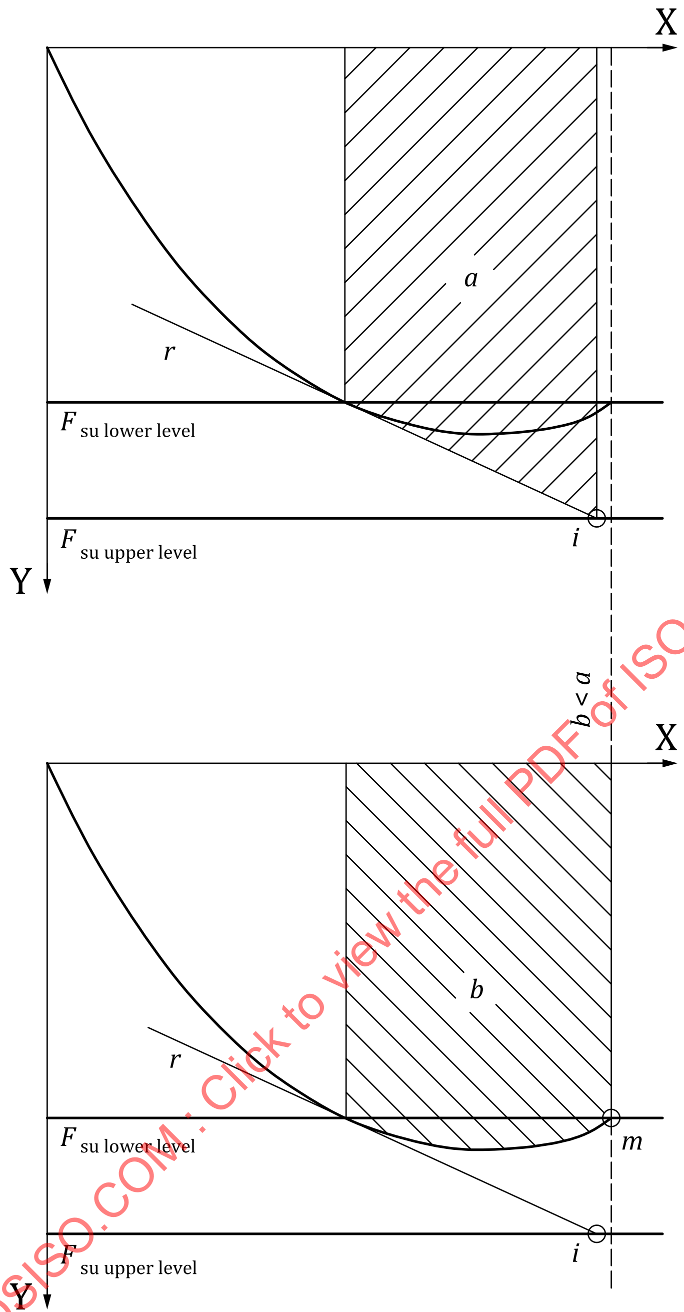
b real absorbed energy

i point of intersection

k earliest point of end of test

r deformation rate line

Figure 7 — Force-Deflection curve and related areas of shock absorption capacity



Key

X deflection

Y force

a theoretically absorbed energy

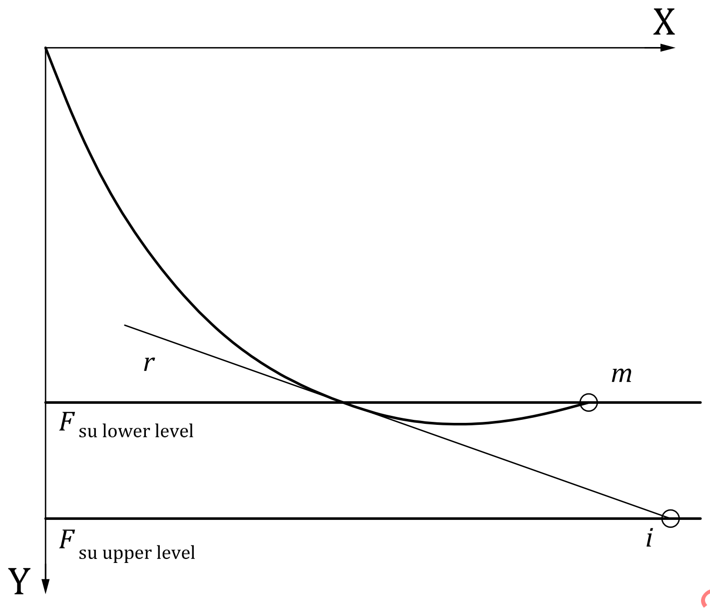
b real absorbed energy

i point of intersection

m latest point of end of test

r deformation rate line

Figure 8 — Force-Deflection curve and related insufficient area of shock absorption capacity



Key

X deflection

Y force

i point of intersection

m latest point of end of test

r deformation rate line

Figure 9 — Force-Deflection curve of shock absorption capacity test, test is stopped before point of intersection is reached

15.3 Cyclic test procedure

The cyclic test procedure (see 16.4) consists of repeated applications of a prescribed load to a test sample with loading conditions typical of normal walking, followed by a final static test (see 16.4.1.11) for which the loading and unloading procedures of the static proof test (see 16.2) apply.

16 Test procedures

16.1 Test loading requirements

16.1.1 Preparation for test loading

The preparation for test loading shall proceed as described in a) to d).

NOTE 1 For test equipment other than that addressed, described or referred to in this document (see paragraphs 3 and 4 of 15.1), the steps of preparation for test loading may differ from those described in a) and b).

a) For the static test procedure [see 15.2 and 16.1.2 a)] prepare the test equipment as follows.

1) Set the foot platform to a position that allows it to support the entire foot of the test sample when this is mounted in the test equipment in accordance with d).

NOTE 2 This is to ensure that

— for heel loading, the foot platform supports the forefoot, if heel loading by the test force F_1 deforms the test sample to such an extent that forefoot support is necessary to avoid unrealistic conditions of loading, and

— for forefoot loading, the foot platform supports the heel, if forefoot loading by the test force F_2 deforms the test sample to such an extent that heel support is necessary to avoid unrealistic conditions of loading.

2) Set the foot platform at one of the tilting angles, β_1 or β_2 (see Table 8).

3) Mount the specific heel block on the foot platform and position it so that

— the line of transition from the plane rear section to the cylindrical front section of its top surface intersects the *f*-*u* plane perpendicularly [see 13.4.1.6 c) 1)], and

— the point of intersection lies on the *u*-axis of the test sample [see d)] or is offset from the *u*-axis [see 13.4.1.6 c) 2)] as specified by the manufacturer/submitter in the test submission document [see 12.3.2 e)].

4) If appropriate (see NOTE 3), set the top load application point, P_T horizontally, to a distance from the tilting axis, TA, determined by the difference of their *f*-offsets ($f_{TA, L} - f_{T, L}$) relevant to the foot length *L* of the test sample (see Table 7 and Figure 5).

NOTE 3 The static test procedure is carried out with the foot platform set to a fixed tilting angle [see a) 2)], hence, the position of the test sample set-up in the test equipment set with step d) 2) will not be changed by oscillation of the foot platform typical of the cyclic test procedure. Therefore, the position of the tilting axis, TA of the foot platform determined by the offsets $f_{TA, L}$ and $u_{TA, L}$ is less important than for the cyclic test procedure. This aspect is relevant in particular, if the static and the cyclic test procedures are carried out on different test equipment.

5) Set the top load application point, P_T vertically, to a position that allows the offset $u_{T, L}$ relevant to the foot length *L* of the test sample (see Table 7) to be established when setting it up in the test equipment [see d)], the offset $u_{T, L}$ to be measured from the *u*-level of that point on the contact surface of the foot platform tilted at β_1 or β_2 (see Table 8), at which the posterior heel edge or the point of the foot of the test sample will be positioned upon its correct setting-up in the test equipment [see d), Figure 10 and NOTE 4], and which provides sufficient travel for the moving part of the actuator.

NOTE 4 As illustrated in Figure 10, in the setting-up described in the foregoing paragraph the straight line passing through the top load application point P_T parallel to the *u*-axis intersects the contact surface of the foot platform at a distance ($u_T + \Delta u_T$). This distance can be calculated by factoring the value of $u_{T, L}$ relevant to the foot length *L* as specified in Figure 10 for static heel and forefoot loading at β_1 or β_2. The vertical setting of the top load application point at this distance is considered to be one appropriate way of preparing the test equipment for static loading as required.

b) For the cyclic test procedure [see 15.3 and 16.1.2 b)], prepare the test equipment as follows.

1) Establish a distance between the tilting axis, TA, and the contact surface of the foot platform corresponding to the value of $u_{TA, L}$ relevant to the foot length *L* (see Table 7, Figure 5 and D.3.2.2).

2) Set the foot platform to a position which allows it to support the entire foot of the test sample when this is mounted in the test equipment in accordance with d).

3) Temporarily fix the foot platform in its neutral tilting position ($\beta = 0$) so as to simulate the ground.

4) Mount the specific heel block on the foot platform and position it so that

— the line of transition from the plane rear section to the cylindrical front section of its top surface intersects the *f*-*u* plane perpendicularly [see 13.4.1.6 c) 1)], and

— the point of intersection lies on the *u*-axis of the test sample [(see d)] or is offset from the *u*-axis [see 13.4.1.6 c) 2)] as specified by the manufacturer/submitter in the test submission document [see 12.3.2 e)].

5) Set the top load application point, P_T horizontally, to a distance from the tilting axis, TA, determined by the difference of their *f*-offsets ($f_{TA, L} - f_{T, L}$) relevant to the foot length *L* of the test sample (see Table 7 and Figure 5).

6) Set the top load application point, P_T vertically, to a position that allows the offset $u_{T, L}$ relevant to the foot length, *L* of the test sample (see Table 7) to be established when setting it up in the test

equipment [see d)], the offset $u_{T, L}$ to be measured from the horizontal contact surface of the foot platform, and which provides sufficient travel for the moving part of the actuator (see Figure 5).

c) Assemble the test sample to a fixed length, using end attachments consisting of extension pieces and any appropriate top load application adaptor or lever relevant to the test sample set-up (see 10.2 and 10.3 and Table 6), and align it to the values specified in Table 7 and Table 8 as described in 10.5 and illustrated in Figure 4.

d) Set the test sample set-up in the test equipment

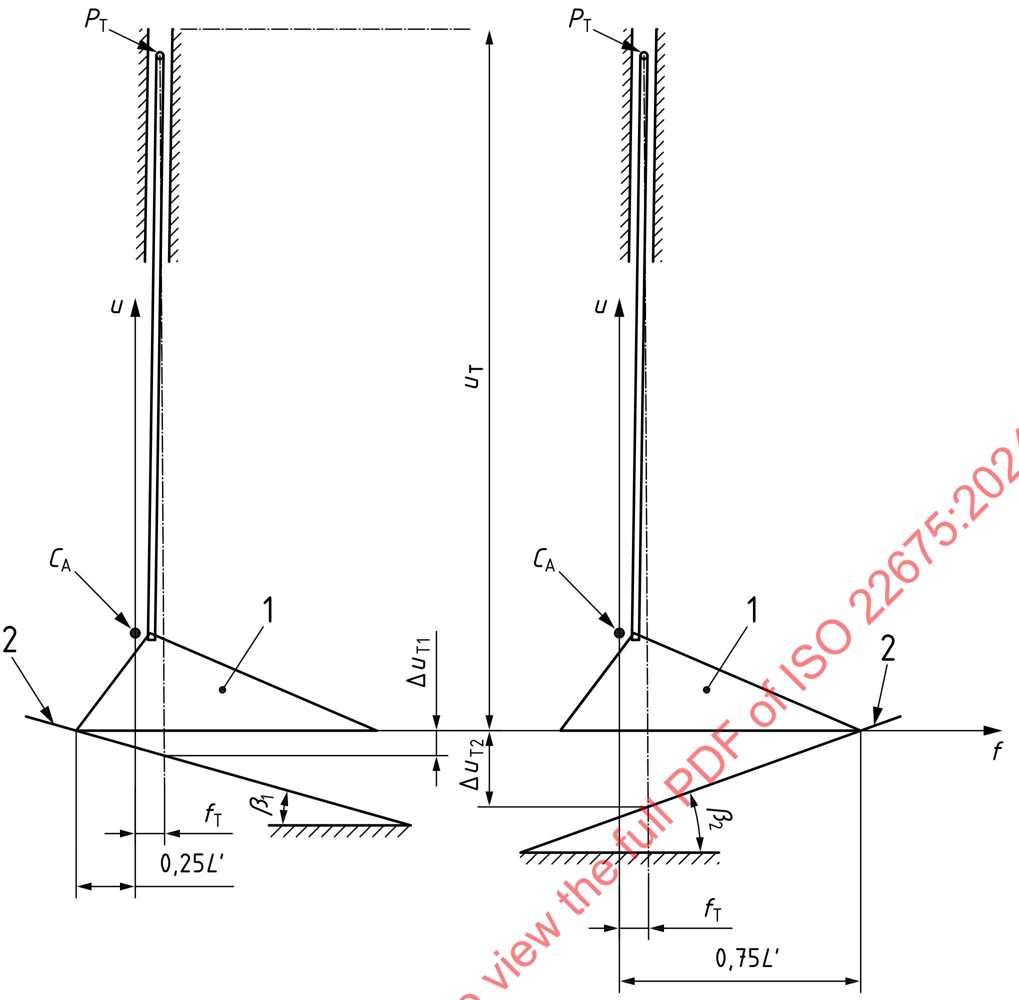
   1) with the ankle-foot device or foot unit placed on the foot platform in either of the ways referred to in a) and b) and in the toe-out position specified in Table 8 and illustrated in Figure 4, and

   2) with the *u*-axis extending parallel to the line of action of the moving part of the actuator at a horizontal distance from the tilting axis TA of the foot platform determined by $f_{TA, L}$ relevant to the foot length *L* of the test sample (see Table 7) when the top load application point, P_T of the test sample is matching the top load application point, P_T of the test equipment (see Figure 5).

   For some designs of ankle-foot devices and foot units. it is not possible to set up a test sample in accordance with these requirements. Special test set-ups may then be used in certain cases.

e) Arrange the means to resist dislocation of the test sample during its lift-off phase, in accordance with 13.4.2.6 b) and Figure 5. Adjust the means so that the foot of the test sample contacts the foot platform for the next loading cycle in the position determined by the test set-up according to d).

f) Do not alter the set-up described in a) to e) if the test sample deflects under the test loading conditions specified in Clause 8 during the tests specified in 16.2, 16.3 and 16.4.



Key

f, u axes of coordinate system

1 symbolic view of foot

2 foot platform

P_T top load application point [see 16.1.1 a) 5) and 6)]

C_A effective ankle-joint centre (see 6.7.3)

f_T Forward offset top load application point

Static heel loading at β_1

$\Delta u_{T1} = (0{,}25\ L' + f_T) \cdot \tan \beta_1 = 0{,}04\ u_T$

$u_T + \Delta u_{T1} = 1{,}04\ u_T$

Static forefoot loading at β_2

$\Delta u_{T2} = (0{,}75\ L' - f_T) \cdot \tan \beta_2 = 0{,}11\ u_T$

$u_T + \Delta u_{T2} = 1{,}11\ u_T$

NOTE L' is the projection of the foot length L on the f-u plane. $L' = L \cdot \cos \tau = 0{,}992\ 5\ L \approx L$ (see Figure 4).

Figure 10 — Preparation for test loading of static test procedure

16.1.2 Test loading conditions

The test loading shall be applied in different conditions, described in a) and b).

For test equipment other than that addressed, described or referred to in this document (see paragraphs 3 and 4 of 15.1), the application of the test loading may differ from that described in a) and b).

a) The static tests shall apply separate heel and forefoot loading to the test sample of ankle-foot device or foot unit in directions and at magnitudes relating to the maxima occurring early and late in the stance phase of normal walking respectively.

   With the test sample set-up according to 16.1.1, these loading conditions are determined by the values of the test forces F_1 and F_2 specified in Table 9, to be applied at the top load application point, P_T, and by the tilting angles β_1 and β_2 of the foot platform, specified in Table 8.

   The conditions of heel and forefoot loading specified for the static tests shall also apply for the instants of maximum heel loading (1st maximum) and maximum forefoot loading (2nd maximum) during the cyclic test addressed in b).

b) The cyclic test shall apply progressive loading to the sample of ankle-foot device or foot unit in directions and at magnitudes representative of the full stance phase of walking from heel contact to toe-off.

   With the test sample set-up according to 16.1.1, this loading condition is determined by the profile of the test force F_c, to be applied at the top load application point, P_T, and by the profile of the tilting angle, β of the foot platform, the profiles of test force, F_c and tilting angle, β to be applied either as synchronized functions of time $F_c(t)$ and β (t), or the profile of the tilting angle β to be applied as a function of time β (t) and the profile of the test force F_c to be applied as function of the tilting angle $F_c(\beta)$ (see 13.4.2.7 and Figures 6 and 7).

   The profile of the test force $F_c(t)$ is determined by the instantaneous values of test force F_{1cmax} (1st maximum), F_{cmin} (intermediate minimum) and F_{2cmax} (2nd maximum), specified in Table 9, by additional “thresholds” illustrated in Figure 3 and specified in Table 10, by discrete values specified in 30 ms time increments in Table 11 and also by Formula (8).

   The profile of the tilting angle, β (t), is determined by the instantaneous values of tilting angle, β_1, β_{Fcmin} and β_2 at the instants of F_{1cmax} (1st maximum), F_{cmin} (intermediate minimum) and F_{2cmax} (2nd maximum), specified in Table 8, by discrete values specified in 30 ms time increments in Table 11 and also by Formulae 4 to 7.

NOTE The lines of application of the static and maximum cyclic heel and forefoot reference loading of Test Range 4 (R4) are intended to approach those determining the sagittal plane loading of the corresponding test loading conditions I and II of the principal structural tests of ISO 10328:2016, while the values of tilting angle of the foot platform are actually identical with those specified for heel and forefoot loading of the separate structural tests on ankle-foot devices and foot units of ISO 10328:2016 (for further background information, see Annex A).

16.2 Static proof test

16.2.1 Test method

16.2.1.1 The static proof test for ankle-foot devices and foot units shall be conducted by applying the test force initially to the heel and subsequently to the forefoot of the same test sample, as described in 16.2.1.2 to 16.2.1.10, or vice versa.

The static proof test for ankle-foot devices and foot units may be carried out as part of the alternative static ultimate strength test.

A flowchart for this test is shown in Figure 11.

16.2.1.2 Prepare and align a test sample from the batch specified in Table 12, for this test, in accordance with 9.4, Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8.

If a test sample that has completed the cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.4.2, re-align it in accordance with Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (see also 16.2.1.11). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the tilting angles β_1 and β_2 of the foot platform and the test forces F_1 and F_2, determining the conditions of heel and forefoot loading.

Record whether a special jig is used.

16.2.1.3 Prepare the test equipment in accordance with 16.1.1 a).

For the test in heel loading, set the tilting angle of the foot platform to β_1, for the Test Range (R) specified in Table 8.

Record the individual settings for the preparation of the test equipment and the arrangement of the foot platform for heel loading, including the positioning of the specific heel block.

16.2.1.4 Mount the test sample in the test equipment in accordance with 16.1.1 d).

16.2.1.5 Apply to the heel of the test sample the test force F_1 and increase it smoothly at a rate of between 100 N/s and10 kN/s to the proof test force F_{1sp} of the relevant test loading level, specified in Table 9.

Maintain this force, F_{1sp}, at the prescribed value for (30 ± 3) s and then decrease the test force F_1 to zero.

If the test sample sustains the static heel loading at F_{1sp} for the prescribed time, record this and proceed with 16.2.1.7.

If the test sample fails to sustain the static heel loading at F_{1sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force, F_{1sp}, has been maintained and decide on the continuation of the test procedure in consideration of the statement given below (but see 16.2.1.11). Record the decision.

The occurrence of failure in the test procedure in one direction of loading prevents compliance with the performance requirements of this test being claimed for the test sample (see 16.2.3). For this reason, the test shall be terminated, unless otherwise stated in the test submission document or agreed upon between the test laboratory/facility and the manufacturer/submitter (see 12.3.3).

16.2.1.6 If the test sample fails to satisfy the performance requirement of 16.2.2 in the test procedure of heel loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.2.1.7 For the test in forefoot loading, set the tilting angle of the foot platform to β_2, specified in Table 8.

If appropriate, remove the test sample from the test equipment during the setting and arrangement of the foot platform and subsequently remount it.

Record the individual settings for the arrangement of the foot platform for forefoot loading, including the positioning of the specific heel block.

16.2.1.8 Apply to the forefoot of the test sample that has completed the test procedure of heel loading without failing (see 16.2.1.5) the test force, F_2 and increase it smoothly at a rate of between 100 N/s and 10 kN/s to the proof test force F_{2sp} of the relevant test loading level, specified in Table 9.

Maintain this force, F_{2sp}, at the prescribed value for (30 ± 3) s and then decrease the test force, F_2 to zero.

If the test sample sustains the static forefoot loading at F_{2sp} for the prescribed time, record this.

If the test sample fails to sustain the static forefoot loading at F_{2sp} for the prescribed time, record this together with the highest value of test force reached or the time for which the prescribed value of the proof test force F_{2sp} has been maintained (but see 16.2.1.11).

16.2.1.9 If the test sample fails to satisfy the performance requirement of 16.2.2 in the test procedure of forefoot loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.2.1.10 Decide and record whether or not the test sample has passed the test procedure of heel loading (16.2.1.4 and 16.2.1.5) and the test procedure of forefoot loading (16.2.1.7 and 16.2.1.8), checking the results of 16.2.1.5 and 16.2.1.8 against the performance requirement of 16.2.2.

16.2.1.11 If a test sample that has already completed, without failing, the cyclic test procedure for ankle-foot devices and foot units (see 16.2.1.2) fails to satisfy the performance requirement of 16.2.2 in heel loading (see 16.2.1.4 and 16.2.1.5) or in forefoot loading (see 16.2.1.7 and 16.2.1.8), repeat the complete test (see 16.2.1.2 to 16.2.1.9) on a substitute test sample and record the failure and the repetition, including all specific records called for.

16.2.2 Performance requirement

In order to pass the static proof test for ankle-foot devices and foot units, a test sample shall sustain successive static heel and forefoot loading by the proof test forces F_{1sp} and F_{2sp} at the prescribed values and inclinations for (30 ± 3) s each.

16.2.3 Compliance conditions

In order to claim that the ankle-foot device or foot unit submitted for test according to 9.1 to 9.3 complies with the performance requirement of the static proof test for ankle-foot devices and foot units in accordance with 16.2.2 at a specific test loading level, tests of this type, each successively applying heel loading and forefoot loading to the same test sample, shall be passed by two test samples from the prescribed batch, the prescribed batch including the substitute test sample allowed by 16.2.1.11 (see 9.3 and Table 12).

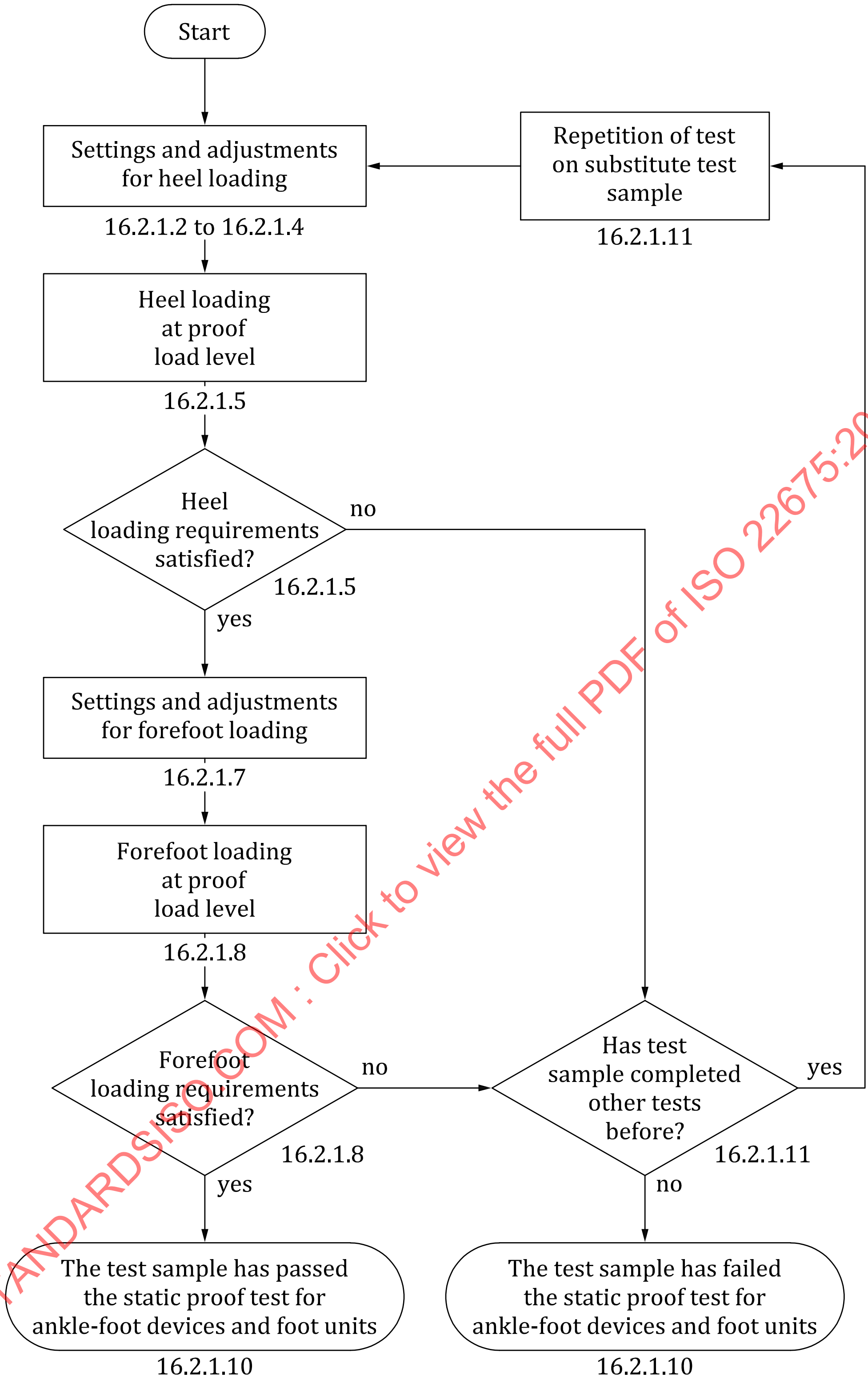


Figure 11 — Flowchart for the static proof test specified in 16.2.1

16.3 Static ultimate strength test

16.3.1 Test method

16.3.1.1 The static ultimate strength tests for ankle-foot devices and foot units shall be conducted on different test samples, loading the first on the heel and the second on the forefoot, as described in 16.3.1.2 to 16.3.1.14, or vice versa.

A test sample that satisfies the requirements of this test in one direction of loading, can be used for this test in the other direction of loading (but see 16.3.1.16).

A flowchart for this test is shown in Figure 12.

16.3.1.2 Prepare and align a test sample from the batch specified in Table 12 for this test in accordance with 9.4, Clause 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8.

If a test sample that has completed the static proof test for ankle-foot devices and foot units without failing is used for this test in accordance with 9.4.2, re-align it in accordance with Clauses 10 and 11 and 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (see also 16.3.1.15). Record the re-use of the test sample.

If a test sample that has completed the cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.4.2, re-align it in accordance with (Clauses 10 and 11, and 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (see also 16.3.1.15). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the tilting angle β_1 of the foot platform and the test force F_1, determining the condition of heel loading. Record whether a special jig is used.

16.3.1.3 Prepare the test equipment in accordance with 16.1.1 a).

For the test in heel loading, set the tilting angle of the foot platform to β_1, specified in Table 8.

Record the individual settings for the preparation of the test equipment and the arrangement of the foot platform for heel loading, including the positioning of the specific heel block.

16.3.1.4 Mount the test sample in the test equipment in accordance with 16.1.1 d).

16.3.1.5 Apply to the heel of the test sample the test force, F_1 and increase it smoothly at a rate of between 100 N/s and 10 kN/s until the test sample fails, or the test force, F_1 attains the value of the ultimate test force $F_{1\text{su, upper level}}$ of the relevant test loading level, specified in Table 9, without failure of the test sample.

Record the highest value of the test force F_1 reached during the test, the rate of loading and whether failure has occurred. If expressly requested by the manufacturer/submitter or if requested in the test submission document [12.3.4 a)], continue the static ultimate strength test after the test sample has withstood the ultimate test force, $F_{1\text{su, upper level}}$ until failure actually occurs, and record the value of the load at failure.

Take into account that in this case the end attachments used need a higher value of stiffness and ensure that the values of their deflection and permanent deformation keep within the limits specified in 13.2.2.2.9 at a higher proof load than is specified in Table 6 for the test loading level to be applied.

16.3.1.6 Check the results of step 16.3.1.5 against the performance requirements of 16.3.2 and record the findings.

If the test sample completes the test procedure of heel loading without failing, proceed with 16.3.1.8.

If the test sample fails, decide on the continuation of the test procedure in consideration of the statement given below (but see 16.3.1.15). Record the decision.

The occurrence of failure in the test procedure in one direction of loading prevents compliance with the performance requirements of this test being claimed for the test sample (see 16.3.3). For this reason, the test shall be terminated, unless otherwise stated in the test submission document or agreed between the test laboratory/facility and the manufacturer/submitter (see 12.3.3).

16.3.1.7 If the test sample fails to satisfy the performance requirement of 16.3.2 in the test procedure of heel loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.3.1.8 Prepare and align a fresh test sample from the batch specified in Table 12 for this test in accordance with 9.4, Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (but see 16.3.1.1 and 16.3.1.16).

If a test sample that has completed the static proof test for ankle-foot devices and foot units without failing is used for this test in accordance with 9.4.2, re-align it in accordance with Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (see also 16.3.1.15). Record the re-use of the test sample.

If a test sample that has completed the cyclic test procedure for ankle-foot devices and foot units (including the final static test) without failing is used for this test in accordance with 9.4.2, re-align it in accordance with Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8 (see also 16.3.1.15). Record the re-use of the test sample.

Record the test loading level to be applied, together with the corresponding values of the tilting angle, β_2 of the foot platform and the test force, F_2, determining the condition of forefoot loading. Record whether a special jig is used.

16.3.1.9 For the test in forefoot loading, set the tilting angle of the foot platform to β_2, specified in Table 8.

Record the individual settings for the arrangement of the foot platform for forefoot loading, including the positioning of the specific heel block.

16.3.1.10 Mount the test sample in the test equipment in accordance with 16.1.1 d).

16.3.1.11 Apply to the forefoot of the test sample the test force F_2 and increase it smoothly at a rate of between 100 N/s and 10 kN/s until the test sample fails, or the test force F_2 attains the value of the ultimate test force $F_{2\text{su, upper level}}$ of the relevant test loading level, specified in Table 9, without failure of the test sample.

Record the highest value of the test force, F_2 reached during the test, the rate of loading and whether failure has occurred. Make specific reference if the test force F_2 is to be applied at a higher rate of loading.

If expressly requested by the manufacturer/submitter or if requested in the test submission document [12.3.4 a)], continue the static ultimate strength test after the test sample has withstood the ultimate test force $F_{2\text{su, upper level}}$ until failure actually occurs, and record the value of the load at failure.

Take into account that in this case the end attachments used need a higher value of stiffness and ensure that the values of their deflection and permanent deformation keep within the limits specified in 13.2.2.2.9 at a higher proof load than is specified in Table 5 for the test loading level to be applied.

16.3.1.12 Check the results of step 16.3.1.11 against the performance requirements of 16.3.2 and record the findings.

16.3.1.13 If the test sample fails to satisfy the performance requirement of 16.3.2 in the test procedure of forefoot loading, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.3.1.14 Decide form and record whether or not the test sample referred to in 16.3.1.2 has passed the test procedure of heel loading (16.3.1.3 to 16.3.1.5) and the test sample referred to in 16.3.1.8 has passed the test procedure of forefoot loading (16.3.1.9 to 16.3.1.11), taking account of the findings of 16.3.1.6 and 16.3.1.12.

16.3.1.15 If a test sample that has already completed, without failing, the static proof test and/or the cyclic test procedure for ankle-foot devices and foot units (see 16.3.1.2), fails to satisfy either of the performance requirements of 16.3.2 in heel loading (16.3.1.3 to 16.3.1.5) or in forefoot loading (16.3.1.9 to 16.3.1.11), repeat the test on a substitute test sample in the failed direction of loading and record the failure and the repetition, including all specific records called for.

16.3.1.16 If a test sample that has already completed, without failing, the static ultimate strength test for ankle-foot devices and foot units in one direction of loading (see 16.3.1.1 and 16.3.1.6), fails this test in the other direction of loading (see 16.3.1.12), repeat the test on a substitute test sample in the failed direction of loading and record the failure and the repetition, including all specific records called for.

16.3.2 Performance requirements

In order to pass the static ultimate strength test for ankle-foot devices and foot units, a test sample shall satisfy one of the following performance requirements:

a) the test sample shall sustain either static heel loading by the ultimate test force F_{1su} at the value and inclination prescribed for $F_{1su,\ upper\ level}$ or static forefoot loading by the ultimate test force F_{2su} at the value and inclination prescribed for $F_{2su,\ upper\ level}$ without failing

or

b) if the mechanical characteristics of the test sample prevent the requirement of a) to be satisfied for heel- or forefoot loading, the test sample shall demonstrate shock absorption capacity (see 15.2) in the related loading direction.

16.3.3 Compliance conditions

In order to claim that the ankle-foot device or foot unit submitted for test according to 9.1 to 9.3 complies with the performance requirements of the static ultimate strength test for ankle-foot devices and foot units in accordance with 16.3.2 at a specific test loading level, the following shall apply.

If the test forces F_1 and F_2 have been applied at a rate of between 100 N/s and 10 kN/s , tests of this type, each separately applying heel loading and forefoot loading to different test samples, shall be passed in accordance with 16.3.2 in each of these directions of loading by two test samples from the prescribed batch, the prescribed batch including the substitute test samples allowed by 16.3.1.15 and 16.3.1.16 (see 9.3 and Table 12).

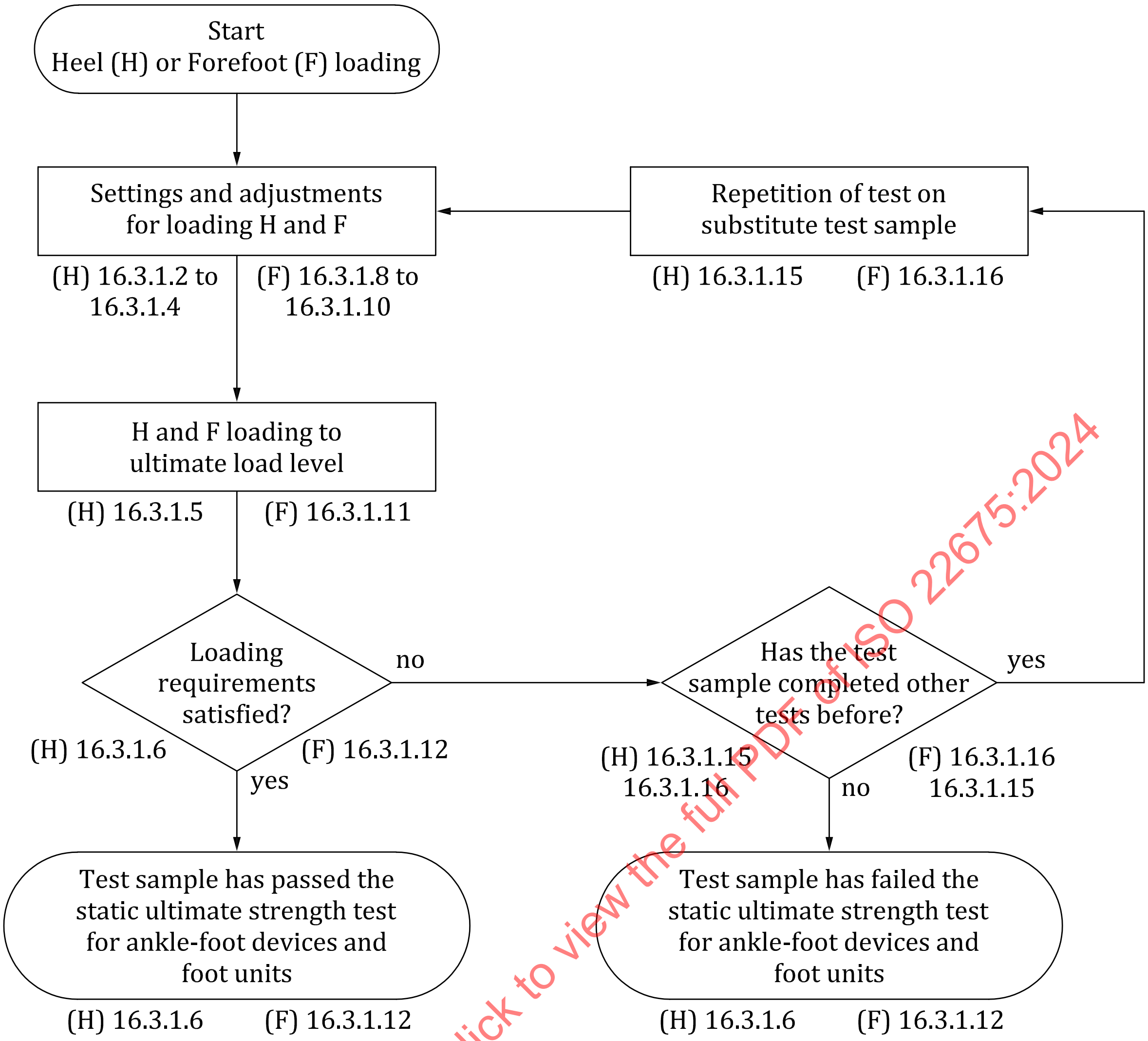


Figure 12 — Flowchart for the static ultimate strength test specified in 16.3.1

16.4 Cyclic test

16.4.1 Test method

16.4.1.1 The cyclic test for ankle-foot devices and foot units shall be conducted on a test sample, continuously loading on the foot from heel contact to toe-off by repeated application of synchronized profiles of tilting angle and test force, followed by final static loading on the heel and the forefoot, as described in 16.4.1.3 to 16.4.1.12.

A flowchart for this test is shown in Figure 13.

16.4.1.2 The following requirements shall apply.

a) During the course of the cyclic test, specified parts shall be replaced when the number of cycles has reached a value at which such replacement is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b)]. All such replacements shall be recorded.

b) A test sample that completes the cyclic test without failing shall be subjected to final static heel and forefoot loading by the test forces F_{1fin} and F_{2fin}, successively applied at a rate of between 100 N/s and 10 kN/s and maintained for (30 ± 3) s for each loading case, with the foot platform set at the tilting angle, β_1 for heel loading and β_2 for forefoot loading.

c) A test sample that fails and/or a test sample that completes the cyclic test without failing shall, at the request of the manufacturer/submitter, be visually examined at the magnification specified in the test submission document [see 12.3.5 c)], and the presence, location and nature of any fractures and/or cracks recorded, together with the magnification used.

16.4.1.3 Prepare and align a test sample from the batch specified in Table 12 for this test in accordance with 9.4, Clauses 10 and 11, 12.2 and 16.1.1 c) and Tables 6, 7 and 8.

Record the test loading level to be applied and the Test Range (R) together with the corresponding profiles of the tilting angle $\beta(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\beta)$, determining the loading conditions at each instant of the loading cycle, and the prescribed number of cycles.

Record whether a special jig is used.

16.4.1.4 Prepare the test equipment in accordance with 16.1.1 b).

Record the individual settings for the preparation of the test equipment and the arrangement of the foot platform, including the positioning of the specific heel block.

16.4.1.5 Mount the test sample in the test equipment in accordance with 16.1.1 d).

Arrange and adjust the means to resist dislocation of the test sample during its lift-off phase in accordance with 16.1.1 e).

Record the individual settings.

16.4.1.6 Successively apply static heel loading as specified in a) and static forefoot loading as specified in b).

a) For static heel loading, set the tilting angle of the foot platform to β_1, specified in Table 8, and apply to the heel of the test sample the maximum test force F_{1cmax}, specified in Table 9.

b) For static forefoot loading, set the tilting angle of the foot platform to β_2, specified in Table 8, and apply to the forefoot of the test sample the maximum test force F_{2cmax}, specified in Table 9.

If the test sample sustains the successive static heel and forefoot loading at F_{1cmax} and F_{2cmax}, proceed with 16.4.1.7.

If the test sample fails to sustain the successive static heel and forefoot loading at F_{1cmax} and F_{2cmax}, record this together with the highest value of test force reached in each direction of loading and terminate the test.

16.4.1.7 Apply to the test sample simultaneously, the profiles of the tilting angle $\beta(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\beta)$ in accordance with the requirements of 13.4.2 and the values for the relevant test loading level, specified in Tables 8 to 11, at a frequency of between 0,5 Hz and 3 Hz in accordance with the test submission document [see 12.3.5 a)] for a series of cycles, to allow the test sample and the test equipment to “settle down”.

NOTE 1 The number of cycles required for the test to settle down will depend on the nature of the test sample and the test equipment control mechanism.

Start at any appropriate instant of the loading cycle.

Take care that during this settling-in period, the highest force applied to the test sample does not exceed the maximum test force F_{1cmax} by more than 10 % (see 13.4.2.12).

NOTE 2 Experience has shown that the repeated loading at values exceeding the maximum test force F_{1cmax} by more than 10 % can cause an early deterioration of the test sample.

Do not proceed with 16.4.1.8 until the test sample and the test equipment have settled down, and the profiles of the test force $F_c(t)$ or $F_c(\beta)$ and the tilting angle $\beta(t)$ of the oscillating foot platform have achieved the waveform specified in 13.4.2.10 and keep within the tolerances specified in 14.3 f), g) and h).

Record the frequency called for, together with the number of cycles required to settle down and whether the pulsating test force $F_c(t)$ or $F_c(\beta)$ and the tilting angle β (t) of the oscillating foot platform are applied in accordance with 13.4.2.10 and 14.3 f), g) and h).

If the frequency called for cannot be achieved, or does not allow the pulsating test force $F_c(t)$ or $F_c(\beta)$ and the tilting angle β (t) of the oscillating foot platform to be applied as specified, repeat the preceding steps of this subclause at a different frequency, preferably between 0,5 Hz and 3 Hz, to be agreed upon between the test laboratory/facility and the manufacturer/submitter.

Record any agreement on a frequency differing from the value called for.

If the pulsating test force $F_c(t)$ or $F_c(\beta)$ and/or the tilting angle $\beta(t)$ of the oscillating foot platform cannot be applied at any frequency agreed upon between the test laboratory/facility and the manufacturer/submitter, record this and terminate the test.

16.4.1.8 Apply to the test sample, simultaneously, the profiles of the tilting angle $\beta(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\beta)$ in accordance with the requirements of 13.4.2 and the values for the relevant test loading level, specified in Tables 8 to 11, at a frequency of between 0,5 Hz and 3 Hz in accordance with the test submission document [see 12.3.5 a)] or any agreement on a frequency differing from the value called for therein, preferably between 0,5 Hz and 3 Hz (see 16.4.1.7), for the prescribed number of cycles specified in Table 9.

Inspect the waveforms of the applied test force $F_c(t)$ or $F_c(\beta)$ and the tilting angle $\beta(t)$ of the oscillating foot platform. Terminate the test if the waveforms do not conform with 13.4.2.10.

Record the frequency applied, together with the results of the inspection of the waveform and the decision on the continuation of the test.

16.4.1.9 During the course of the cyclic test, replace any parts which would be replaced in normal service. Proceed as follows.

Stop the test equipment when the number of cycles of load has reached a value at which the exchange/replacement of these parts is indicated in accordance with the manufacturer's/submitter's service instructions and/or the test submission document [see 12.3.5 b) and 16.4.1.2 a)]. Record the number of cycles at shutdown.

Exchange/replace the specified parts in accordance with the manufacturer's/submitter's service instructions and/or the test submission document.

Restart the test from 16.4.1.3 or 16.4.1.7, depending on the mechanical properties of these parts and the complexity of the dis- and re-assembling of the test sample necessary for their exchange/replacement.

Record the details of the exchange/replacement and the resulting conditions of the restart, together with the number of the corresponding clause.

16.4.1.10 Continue the test until failure occurs or the prescribed number of cycles specified in Table 9 has been reached. Record the number of cycles at shutdown and whether failure has occurred.

16.4.1.11 Subject a test sample that completes the cyclic test without failing, to the final static test force F_{1fin}, applied to the heel with the foot platform set at the tilting angle β_1, and subsequently to the final static force F_{2fin}, applied to the forefoot with the foot platform set at the tilting angle β_2, in accordance with the values for the relevant test loading level, specified in Table 9, applied at a rate of between 100 N/s and

10 kN/s. For each loading case, maintain the load at the prescribed value for (30 ± 3) s and record the results [see 16.4.1.2 b)].

If the test sample fails to sustain the successive final static heel loading at F_{1fin} and forefoot loading at F_{2fin} for the prescribed time in either of the directions of loading, record this together with the highest value of test force reached in each direction of loading or the time for which the prescribed values of the final static test forces F_{1fin} and F_{2fin} have been maintained.

16.4.1.12 Decide and record whether the test sample has passed or failed the test procedure specified in 16.4.1.2 to 16.4.1.11, checking the results of steps 16.4.1.6, 16.4.1.10 and 16.4.1.11 against the performance requirements of 16.4.2.

16.4.1.13 If the test sample fails to satisfy any of the performance requirements of 16.4.2, inspect it to detect the nature and, if possible, the location of any damage and record the results.

16.4.1.14 At the request of the manufacturer/submitter, visually examine a test sample that fails and/or a test sample that completes the cyclic test for ankle-foot devices and foot units and the final static test without failing, to detect the presence, location and nature of any fractures and/or cracks [see 16.4.1.2 c)].

Carry out the examination at the magnification specified in the test submission document [see 12.3.5 c)] or decided according to circumstances in agreement with the manufacturer/submitter.

Record the magnification used and the information obtained, taking account of the manufacturer's/submitter's instructions concerning the documentation of test results [see 12.3.5 c)].

16.4.2 Performance requirements

In order to pass the cyclic test for ankle-foot devices and foot units, a test sample shall satisfy the following performance requirements:

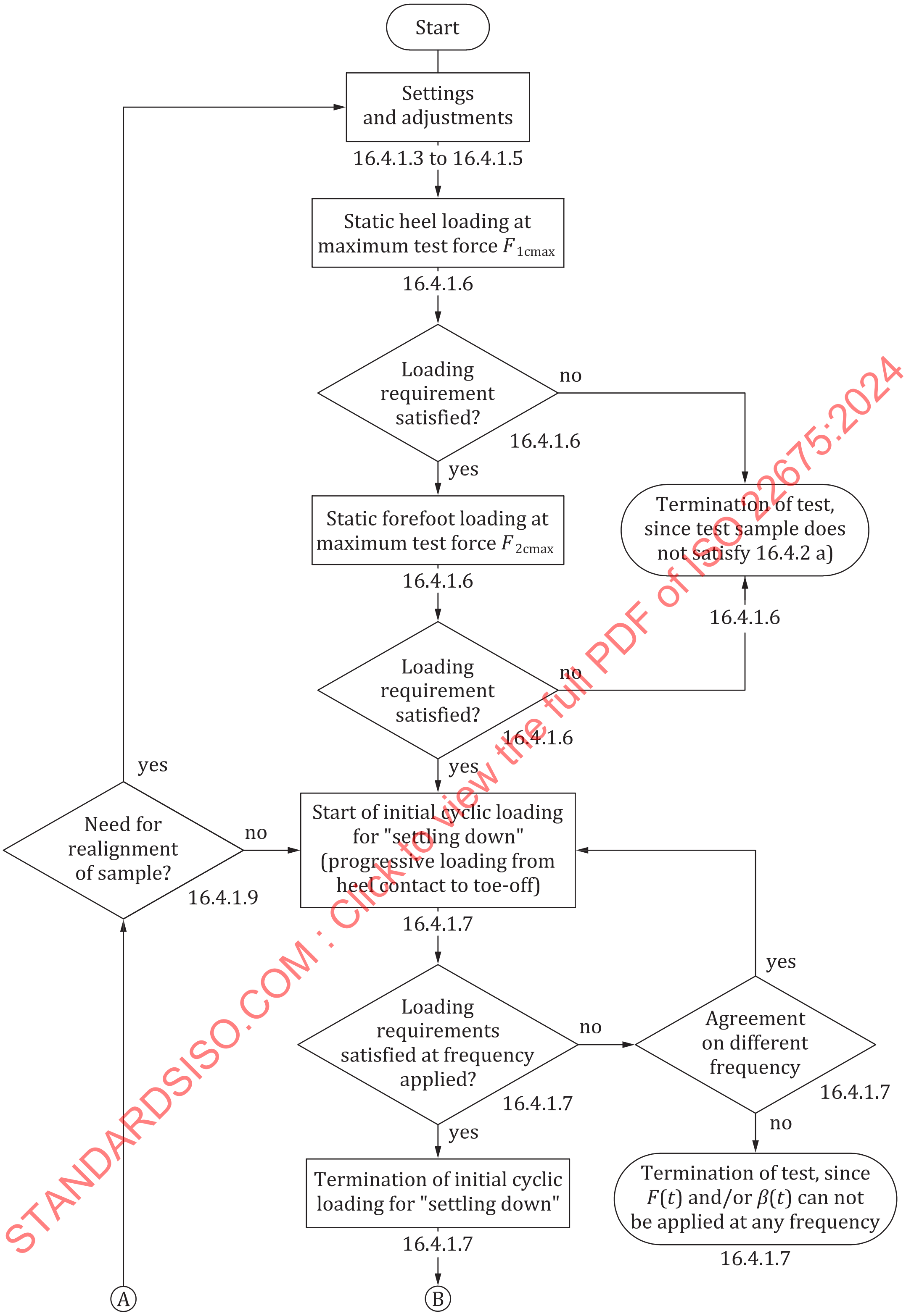
a) the test sample shall sustain successive static heel and forefoot loading by the maximum test forces F_{1cmax} and F_{2cmax} at the prescribed values and inclinations;

b) the test sample shall sustain cyclic loading by the pulsating test force $F_c(t)$ or $F_c(\beta)$ at the prescribed levels and ranges for the prescribed number of cycles;

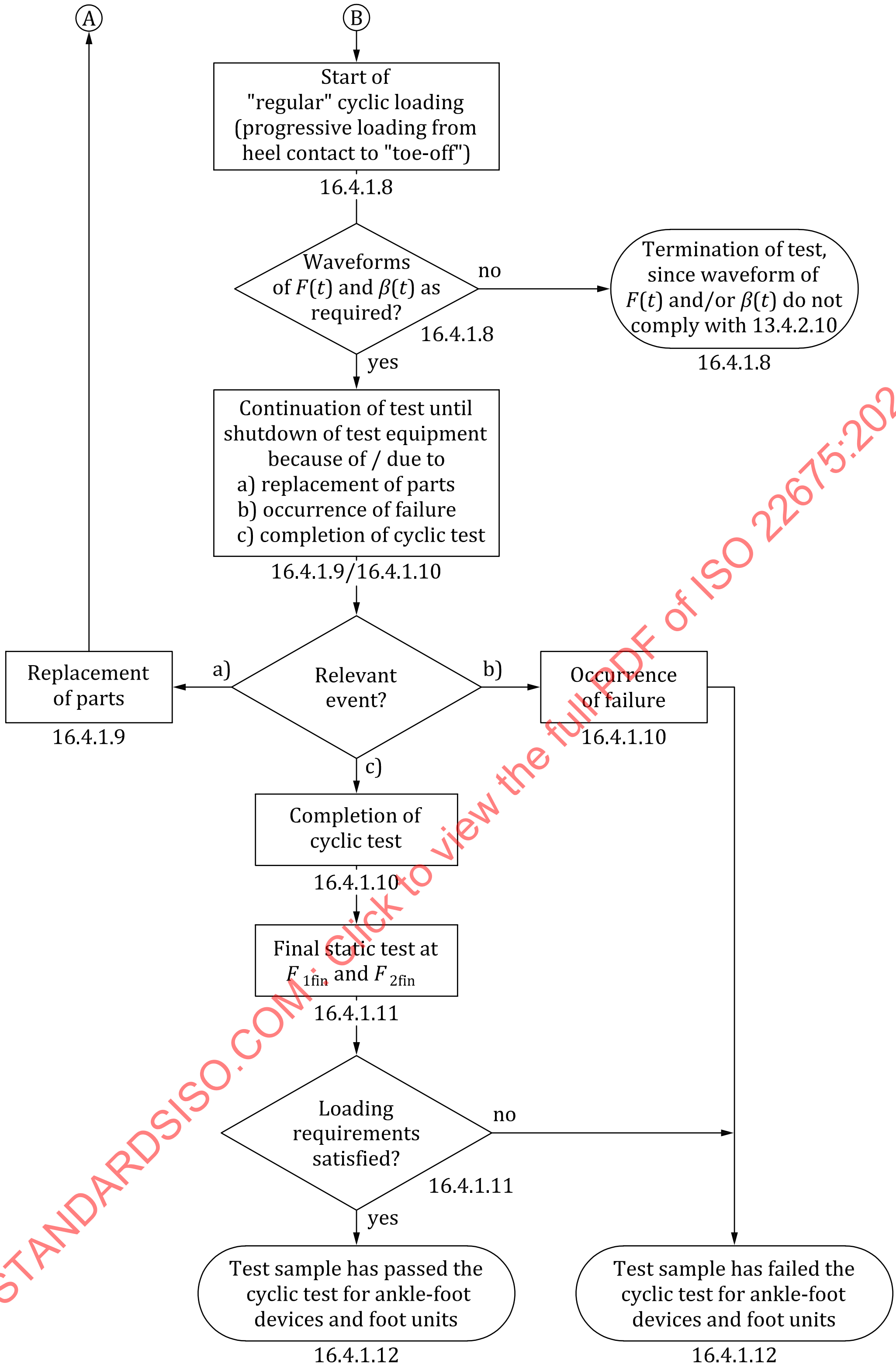
c) the test sample shall sustain successive static heel and forefoot loading by the final static test forces F_{1fin} and F_{2fin} at the prescribed values and inclinations for (30 ± 3) s each.

16.4.3 Compliance conditions

In order to claim that the ankle-foot device or foot unit submitted for test according to 9.1 to 9.3 complies with the performance requirements of the cyclic test for ankle-foot devices and foot units in accordance with 16.4.2 at a specific test loading level, in a specific Test Range (R), tests of this type shall be passed by two test samples from the prescribed batch (see 9.3 and Table 12).



a) Flowchart for the cyclic test specified in 16.4.1 to allow the test sample and the test equipment to "settle down".



b) Flowchart for the cyclic test specified in 16.4.1 – "regular" cyclic loading

Figure 13 — Flowchart for the cyclic test

16.5 Separate static test in torsion

16.5.1 General

The requirements of this subclause shall apply to test samples of all prosthetic devices/structures submitted for test.

16.5.2 Purpose of test

Users can apply twisting loads to their prostheses, which exceed the levels of the twisting moments (induced torque) generated by the test loading conditions of the other strength tests, specified in this document.

16.5.3 Test method

16.5.3.1 Prepare (or check and, if necessary, correct) the assembly of a test sample from the batch specified in Table 12 for this test in accordance with the manufacturer's assembly instructions and 9.4, Clause 10, 11.4, 11.5, 11.6 and 12.2.

Record the values of the tightening torque(s) of bolts of clamped connections specified in the test submission document (see 11.1 and 12.2) and of the twisting moments to be applied.

16.5.3.2 Set up and mount the test sample as specified in 13.4.1 at a plate angle β of 0°.

To avoid slippage between a functional insert of an ankle foot device and the footshell, footwear can be applied in this test, which represents typically used footwear for this type of ankle foot device. Using representative footwear requires the heel-block to be removed from the tilting plate. The ankle foot device remains in the position and orientation as specified in 13.4.1.

To avoid slippage between the sole of the foot and the plate, or the sole of the footwear and the plate, the plate can be equipped with a rough surface such as sand paper to increase friction.

Record the set-up, including the mid-positions adjusted. If the plate is equipped with a rough surface, record the type of surface and the method of fixation. If a representative footwear is used for this test, this footwear shall be stored together with the ankle foot device after test.

16.5.3.3 The axis of torque application is perpendicular to the tilting plate and runs through P_T.

16.5.3.4 Increase the vertical load between a rate of 100 N/s and 10 kN/s smoothly until the vertical load on the level of the Final Static test force F_{1fin} as specified in Table 9 is reached. Maintain this load during the following application of the twisting moment within a range of ±10 % of the specified vertical load.

Record the angular position of the axis of torque application γ_{T1}, at a twisting moment of 0 Nm about the axis of torque.

16.5.3.5 Apply a twisting moment of 50 Nm about the axis of torque between a rate of 10 Nm/s and 100 Nm/s. Maintain this twisting moment for 3 s and record the angular position γ_{T2} of the axis of torque application, immediately before the transition to the next torque level starts.

Calculate and record the maximum angular movement $\Delta\gamma_1$as given in Formula (9):

$$\Delta\gamma_1 = \mathrm{I}\gamma_{T1} \text{-} \gamma_{T2}\mathrm{I} \quad (9)$$

If $\Delta\gamma_1$ exceeds 135°, stop the test and inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

16.5.3.6 Reduce the twisting moment to 0 Nm in the rate applied in 16.5.3.5. Reduce the vertical load in the reversed rate of 16.5.3.4 to 50 N. Maintain the twisting moment for 30 s and record the angular position γ_{T3} of the axis of torque application, immediately before the transition to the next torque level starts.

Calculate and record the maximum angular movement $\Delta\gamma_2$ as given in Formula (10):

$$\Delta\gamma_2 = \mathrm{I}\gamma_{T1} - \gamma_{T3}\mathrm{I} \tag{10}$$

If $\Delta\gamma_2$ exceeds 7°, stop the test and inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

NOTE If any slippage of the clamped connections and/or the any damage occurs in the high torque phase, this will show up in the $\Delta\gamma_2$ value.

16.5.3.7 Increase the vertical load as described in 16.5.3. Apply a twisting moment of -50 Nm in the reversed torque rate of 16.5.3.5. Maintain this twisting moment for 3 seconds and record the angular position γ_{T4} of the axis of torque application, immediately before the transition to the next torque level starts.

Calculate and record the maximum angular movement $\Delta\gamma_3$ as given in Formula (11):

$$\Delta\gamma_3 = \mathrm{I}\gamma_{T3} - \gamma_{T4}\mathrm{I} \tag{11}$$

If $\Delta\gamma_3$ exceeds -135° stop the test and inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

16.5.3.8 Reduce the twisting moment to 0 Nm in the rate applied in 16.5.3.5. Reduce the vertical load in the reversed rate of 16.5.3.4 to 50 N. Maintain the twisting moment for 30 s and record the angular position γ_{T5} of the axis of torque application, immediately before the vertical load is removed.

Calculate and record the maximum angular movement $\Delta\gamma_4$ as given in Formula (12):

$$\Delta\gamma_4 = \mathrm{I}\gamma_{T3} - \gamma_{T5}\mathrm{I} \tag{12}$$

If $\Delta\gamma_4$ exceeds 7°, stop the test and inspect it to detect any slippage of the clamped connections and/or the nature and, if possible, the location of any damage and record the results.

NOTE If any slippage of the clamped connections and/or the any damage occurs in the high torque phase, this will show up in the $\Delta\gamma_4$ value.

16.5.3.9 Remove the vertical load.

Note and record the loading time taken for this separate static test in torsion.

16.5.4 Performance requirements

In order to pass the separate static test in torsion, a test sample shall satisfy the following performance requirement:

The values of the remaining angular displacement, excluding slipping, $\Delta\gamma_2$ and $\Delta\gamma_4$ shall not exceed 7°.

If any individual prosthetic component fails to satisfy this requirement, this constitutes a failure only in the prosthetic assembly and alignment simulated in the test sample set-up.

16.5.5 Compliance conditions

In order to claim that the prosthetic device/structure submitted for test according to 9.1 to 9.3 complies with the performance requirements of the separate static test in torsion according to 16.5.4, tests of this type shall be passed by two test samples from the prescribed batch (see 9.4).

17 Test laboratory/facility log

17.1 General requirements

17.1.1 The test laboratory/facility carrying out the tests specified in this document and indicated in the test submission document shall ensure that all records called for in this document are entered in the test laboratory/facility log.

17.1.2 The submitter of test samples and the identification of the test submission document shall be clearly indicated and the date or dates of receipt be recorded.

17.1.3 The identification of the test report or reports (such as serial number) shall be clearly indicated and the dates of preparation and submission be recorded.

17.2 Specific requirements

According to the instructions of this document (see NOTE), specific records shall be entered in the test laboratory/facility log for

a) the identification (number) of the test equipment used and the reference (number) of the end attachments, jig and measuring devices (if used),

b) the selection, type, preparation, identification and alignment of test samples,

c) the conduct of specific tests, selected in accordance with this document and the test submission document, and

d) any unusual features observed during the test(s).

NOTE Detailed instructions on records to be entered in the test laboratory/facility log are given in the relevant clauses of this document.

In addition, Annex C offers a summary of these records for general information and guidance of test laboratory/facility staff and submitters (see 18.3).

18 Test report

18.1 General requirements

18.1.1 The test laboratory/facility shall prepare a test report for the test(s) conducted and shall provide at least one copy to the submitter of the test sample.

NOTE The test laboratory/facility can maintain another copy of the test report with the test log. This will simplify the reply to possible further inquiries of the manufacturer/submitter.

18.1.2 The test report shall be signed and dated on behalf of the test laboratory/facility by a designated person.

18.1.3 The test laboratory/facility shall clearly indicate a name and address for communication.

18.1.4 The test laboratory/facility shall provide a unique and traceable identification and date for the test report (such as serial number), including identification of each page and the total number of pages of the report. The test laboratory/facility shall maintain a record of such identification and date.

18.1.5 The submitter of the test sample, the manufacturer, if known, and the test laboratory/facility identification shall be clearly indicated.

18.1.6 The date of receipt of test samples and date(s) of preparation of the test report shall be clearly indicated.

18.2 Specific requirements

18.2.1 For each type of test conducted (see 9.3), the test report shall specifically refer to this document, the clauses related to the specific type of test performed, and the test loading condition or direction of loading, the test loading level applied, the Test Range (R) applied and which special test set-ups were used.

18.2.2 For each ankle-foot device or foot unit for which an appropriate batch or batches of test samples have been submitted for test, the test report shall state the tests in which compliance with requirements of this document has been demonstrated. The test report shall also state the tests conducted, in which compliance has not been demonstrated.

18.3 Options

18.3.1 The test report shall include any additional information, specifically requested in the test submission document (see 12.1.2).

18.3.2 Upon request of the submitter, the test laboratory/facility shall copy from the test log to the test report any further records of samples and test results called for. Annex C gives details of the records which can be entered in the test laboratory/facility log.

19 Classification and designation

19.1 General

A prosthetic ankle-foot device or foot unit

a) for which compliance with the requirements of this document is claimed (see 9.1 and 9.2) for a specific test loading level (P) (see 7.2) and a specific Test Range (R), and

b) which is suitable for lower limb amputees with a body mass not exceeding a specific value of maximum body mass, *m*, in kg according to the manufacturer's written instructions on the intended use of that device,

shall be classified and designated as shown below.

ISO 22675 - "P" - "R"- "*m*" kg

19.2 Example of classification and designation

The example below illustrates the classification/designation for an ankle-foot device or foot unit that complies with the requirements of ISO 22675 for test loading level 4 (P4) and the Test Range 3 (R3).

ISO 22675 - P4 – R3 - 80 kg

The classification/designation requires the manufacturer to specify, with justification, the conditions of use in their written instructions on the intended use of the prosthetic ankle-foot device or foot unit (see 7.2.4).

Compliance also can be claimed for ankle foot devices for amputees, whose body mass is not specified by the P-levels, as defined in 9.5. Applying 9.5, the related body mass is the value for the "body mass value right to the mass symbol" on the indicator.

20 Identifier

20.1 General

Each prosthetic ankle-foot device or foot unit

a) for which compliance with the requirements of this document is claimed (see 9.1 and 9.2) for a specific test loading level "P" (see 7.2.3) and specific Test Range (R) (see 7.2.4)

b) which is suitable for lower limb amputees with a body mass not exceeding a specific value of maximum body mass "*m*" kg according to the manufacturer's written instructions on the intended use of that device,

shall be identified in accordance with the classification/designation specified in 19.1.

The statements on the identifier shall be given independent of any specific information on the intended use of the prosthetic ankle-foot device or foot unit supplied by the manufacturer with the device. The symbol ISO 7000-1641 and IEC 60417-5665 shall be marked on the identifier layout.

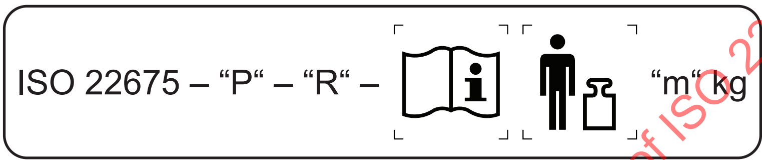


Figure 14 — General concept for the identifier layout

The series of symbols (operating instructions, body weight) shall allow reference to a brief statement on the identifier, that the value "*m*" stated, specifies the body mass limit not to be exceeded and that further important information on the specific conditions of use is given in the manufacturer's written instructions on the intended use of the device.

20.2 Identifier layout

The layout of the identifier shall conform to Figure 14 and Figure 15.

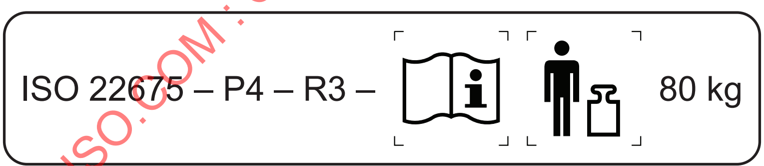


Figure 15 — Identifier layout

20.3 Identifier placement

The identifier shall be placed in the instructions for use in the format **"ISO 22675 - "P" - "R"- "*m*" kg"** or **ISO 22675 - P4 – R3 - 80 kg** or on the device or on the packaging for each unit or on the sales packaging in the format of Figure 14 and Figure 15. If individual packaging of each unit is not practicable, the identifier shall be placed in the information leaflet supplied with one or more devices.

Annex A
(informative)

Reference data for the specification of the test loading conditions and test loading levels of this document

A.1 Background statement

The test loading levels P5, P4 and P3 according to 7.2 correspond to the test loading levels P5, P4 and P3 according to 7.2 of ISO 10328:2016. These are based on data acquired at the time of development of ISO 10328:1996[1)], measured on lower limb prostheses of the types used at that time and listed according to the body mass of the amputees whose locomotion was measured. The data used comprised information presented at the Philadelphia meeting in 1977 and additional data subsequently contributed by several countries.

The test loading level P5 is based on data from all amputees including a few whose body mass exceeded 100 kg. The test loading levels P6 and P7 is based on locomotion data from amputees of whose body mass is less than 125 kg and 150 kg, respectively and obtained from simulations and field observations. P8 is extrapolated from these two levels to amputees whose body mass is less than 175 kg. The test loading levels P4 and P3 are based on locomotion data from amputees whose body mass is less than 80 kg and 60 kg, respectively.

The method of classing/relating the test loading levels with/to specific ranges of body mass of amputees on whose locomotion data these are based should, however, not obscure the fact that these locomotion data are also determined by the influence of all other factors, on which the loads developed in a prosthesis during use depend (see NOTE 1) but only within the range that was possible with respect to the lifestyle and activity level of the amputees and the performance of the ankle-foot devices and foot units available at the time of data acquisition (see NOTE 2). All of these factors should therefore be taken into account together with the body mass, when specifying the conditions of use of a specific ankle-foot device or foot unit that complies with the requirements of this document for a specific test loading level [see 5.2 b)].

NOTE 1 Besides the general physical parameters and locomotion characteristics of the amputee already addressed in 7.2.1, other specific factors on which the loads developed in a prosthesis during use depend are the individual character of use of the prosthesis by the amputee, determined by their lifestyle and activity level, the performance of the prosthesis provided by the mechanical characteristics of the components and their prosthetic assembly and alignment, occasional events such as, for example, tripping or stumbling, and environmental conditions in which the prosthesis will be used.

NOTE 2 The range of influence of these factors can change in course of time, due to changes in the lifestyle and activity level of amputees and improvements in the performance of ankle-foot devices and foot units.

A.2 Specification of the test loading conditions for the different test loading levels

A.2.1 General

Although the concept of the tests on ankle-foot devices and foot units of this document differs from that of the corresponding tests of ISO 10328:2016, the relevant values of loads and dimensions are adopted where possible. Nevertheless, a few adaptations are unavoidable.

These and other matters relevant to the specification of the test loading conditions and test loading levels of this document are dealt with in detail in ISO/TR 22676. For further information see Annex D.

1) Withdrawn.

Subclauses A.2.2 to A.2.4 present information on selected items from ISO/TR 22676 modified to the actual content of this document including Ranges.

A.2.2 Directions of static and maximum cyclic heel and forefoot reference loading

A.2.2.1 Basic relationships and conditions

The specification of the directions of static and maximum cyclic heel and forefoot reference loading is based on the relationships of a) and the conditions of b) to d). Introducing Ranges and related angular profiles in this document, limits the description below to the relation between ISO 10328 and this document, before the Ranges were implemented. The principle of deriving that relation still is applicable, as in ISO 10328 also Ranges are introduced.

a) According to Figure A.1, for any instant of loading there is a given relationship between the test force F and the forces at the foot platform, comprising the tangential (A-P) force component, F_T, the perpendicular force component, F_P and their resultant, F_R. This relationship is determined by the angles β, ε and δ and their relation expressed in the Formulae (A.1) and (A.2)

The following equations apply:

$$\delta + \varepsilon = \beta \tag{A.1}$$

$$\varepsilon = \arctan\left(F_T/F_P\right) \tag{A.2}$$

b) The values of the tilting angles β_1 and β_2 of the foot platform for static and maximum cyclic heel and forefoot reference loading are consistent with those specified in ISO 10328:2016 for the separate structural tests on ankle-foot devices and foot units. These values are $\beta_1 = -15°$ for heel loading and $\beta_2 = 20°$ for forefoot loading (see subclause 17.2 of ISO 10328:2016 and Table 8). This is true before introduction of Ranges.

NOTE The $\beta_1$angle of -15° and β_2 angle of 20° is based on the table data of ISO 10328:2016.

c) The ratio F_T/F_P of the values of the tangential and the perpendicular force components at the foot platform according to Figure A.1 for static and maximum cyclic heel and forefoot reference loading at the tilting angles according to b) is roughly ±0,15.

NOTE This ratio is based on gait analysis data representative of normal level walking.

d) The offsets f_{A1} and f_{A2} of the ankle load reference points P_{A1} and P_{A2} (see 6.3 and Figure 1) relevant to heel and forefoot loading on an ankle-foot device or foot unit of foot length L = 26 cm are consistent with those specified in ISO 10328:2016 for the ankle load reference points P_{AI} and P_{AII} of test loading conditions I and II for test loading level P5. These are f_{AI} = − 32 mm and f_{AII} = 120 mm (see Table 6 of ISO 10328:2016).

A.2.2.2 Lines of action of the resultant reference forces F_{R1} and F_{R2}

The relationships of A.2.2.1 a) and the conditions of A.2.2.1 b) and c) allow the inclination of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading to be specified as follows:

— From Formula (A.2) and the condition according to A.2.2.1 c) $\varepsilon = \arctan(F_T/F_P) = \arctan(\pm 0{,}15) = \pm 8{,}5°$.

— From Formula (A.1) and the conditions according to A.2.2.1 b) $\delta_1 = \beta_1 - \varepsilon_1 = -15° + 8{,}5° = -6{,}5°$ and $\delta_2 = \beta_2 - \varepsilon_2 = 20° - 8{,}5° = 11{,}5°$.

Approaching these thresholds as far as possible in consideration of further aspects to be noted, the directions of static and maximum cyclic heel and forefoot reference loading on an ankle-foot device or foot unit of foot length L = 26 cm can be specified as follows:

— the direction of static and maximum cyclic heel reference loading is defined by a straight line which passes through the ankle reference point P_{A1} specified in A.2.2.1 d) and is inclined to the u-axis by δ_1 = – 6,18°;

— the direction of static and maximum cyclic forefoot reference loading is defined by a straight line which passes through the ankle reference point P_{A2}, specified in A.2.2.1 d) and is inclined to the u-axis by δ_2 = 11,14°.

A.2.2.3 Position of the top load application point P_T

For the tests on ankle-foot devices and foot units of this document, the top load application point P_T (see 6.3 and Figure 1) is the point of intersection of the lines of action of the resultant reference forces F_{R1} and F_{R2} of static and maximum cyclic heel and forefoot reference loading specified in A.2.2.2.

The coordinates f_T and u_T of the top load application point P_T are calculated by determining at first the functions $u_1(f)$ and $u_2(f)$ of these lines of action from Formula (A.3)

$$u(f) = f \tan (90 - \delta) + u_0 \tag{A.3}$$

and then determining their point of intersection by putting $u_1(f) = u_2(f)$.

For an ankle-foot device or foot unit of foot length L = 26 cm, this method provides the following results:

— the functions of the lines of action of the resultant reference forces F_{R1} and F_{R2} are $u_{1,26}(f) = 9{,}24f + 375{,}53$ and $u_{2,26}(f) = -5{,}08f + 689{,}39$;

— their point of intersection is located at $P_{T,26}$ {$f_{T,26}$ = 22; $u_{T,26}$ = 578}.

For lines of action of static and maximum cyclic heel and forefoot reference loading on ankle-foot devices or foot units of other foot lengths L, their inclination determined by the angles δ_1 and δ_2 will be the same (see NOTE) but the position of the top load application point $P_{T,L}$ determined by the coordinates $f_{T,L}$ and $u_{T,L}$ will be different, depending on the f_A-offsets of the related ankle load reference points P_{A1} and P_{A2}.

As is demonstrated in 3.2.3 of ISO/TR 22676:2006, these f_A-offsets can be expected to show a scaling that is proportional to the foot length L. This establishes a dependence of the position of the top load application point P_T on the foot length L in the following manner:

The position of the top load application point $P_{T,26}$, together with the posterior heel edge and the point of the foot of length L = 26 cm, determine the proportion of a reference triangle. According to the basic concept of the tests for ankle-foot devices and foot units of this document, this proportion should uniformly apply to all sizes of foot, independent of the test loading level.

The dependence of the position of the top load application point $P_{T,L}$ on the foot length L is illustrated in Figure A.2.

For feet of different lengths L, positioned within the coordinate system as illustrated in Figure A.2, the related top load application points $P_{T,L}$ are located on a straight line directed to the origin of the coordinate system. The distance D_{PT} between load application points $P_{T,L}$ relating to two successive values of foot length L has a fixed value determined by the equation

$$D_{PT} = \sqrt{\frac{\left(f_{T,26}^2 + u_{T,26}^2\right)}{26}} \tag{A.4}$$

which gives a value of D_{PT} = 22,2 mm.

The coordinates $f_{T, L}$ and $u_{T, L}$ determining the position of the top load application point $P_{T, L}$ are specified in Table 7 for a wide range of foot lengths L. In addition, Table 7 includes the equations that determine these coordinates for any other foot length.

The validity of this approach is demonstrated in detail in 3.2.3 of ISO/TR 22676:2006.

NOTE It lies within the concept of the tests of this document to specify the reference test loading conditions for static and maximum cyclic heel and forefoot reference loading in a manner generating the tangential and perpendicular forces F_T and F_P (see Figure A.1) at a fixed ratio independent of the foot lengths L. This requires fixed inclinations of the lines of action of the resultant reference forces F_{R1} and F_{R2} and, hence, fixed values of the angles δ_1 and δ_2 determining the inclinations.

A.2.3 Magnitudes of static and maximum cyclic heel and forefoot reference loading

The specification of the magnitudes of static and maximum cyclic heel and forefoot reference loading is based on the following general condition.

The specific values FR1x and FR2x of the resultant reference forces FR1 and FR2 according to this document (see Figure A.1) are consistent with the corresponding values F1x and F2x of the test forces F1 and F2 specified in ISO 10328:2016 for the separate tests on ankle-foot devices and foot units (see Tables 12 and D.3 of ISO 10328:2016). The specific values FR1x and FR2x of the resultant reference forces FR1 and FR2 are listed in Table A.1.

The specific values F1x and F2x of the test forces F1 and F2 related to the specific values FR1x and FR2x of the resultant reference forces FR1 and FR2 (see Figure A.1) are determined by equation (A.5), derived from the relationship described in A.2.2.1 a):

$$F_{1,2} = F_{R1,R2} \times \cos \delta_{1,2} \tag{A.5}$$

The specific values F1x and F2x of the test forces F1 and F2 calculated using Formula (A.5) for α_1 = − 6,18° and α_2 = 11,14° (see A.2.2.2) are listed in Tables 9.

Table A.1 — Magnitudes of resultant reference forces F_{R1x} and F_{R2x}

Resultant reference forces F_{R1x} and F_{R2x} of static and maximum cyclic heel and forefoot reference loading	Related test forces F_{1x} and F_{2x} of the separate tests on ankle-foot devices and foot units specified in ISO 10328 (see Tables 11 and D.3 of ISO 10328:2016 – modified combined view)												
	Symbol	Test loading level											
		P8		P7		P6		P5		P4		P3	
		Numerical values for heel loading (F_{1x}) and forefoot loading (F_{2x})											
		F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}
		N											
F_{R1sp} F_{R2sp}	F_{1sp} F_{2sp}	-3 200 –	– -3 200	-2 900 –	– -2 900	-2 490 –	– -2 490	-2 240 –	– -2 240	-2 065 –	– -2 065	-1 610 –	– -1 610
$F_{R1su, lower level}$ $F_{R2su, lower level}$	$F_{1su, lower level}$ $F_{2su, lower level}$	-4 450 –	– -4 450	-4 100 –	– -4 100	-3 760 –	– -3 760	-3 360 –	– -3 360	-3 098 –	– -3 098	-2 415 –	– -2 415
$F_{R1su, upper level}$ $F_{R2su, upper level}$	$F_{1su, upper level}$ $F_{2su, upper level}$	-5 700 –	– -5 700	-5 300 –	– -5 300	-4 880 –	– -4 880	-4 480 –	– -4 480	-4 130 –	– -4 130	-3 220 –	– -3 220
F_{R1cmax} F_{R2cmax}	F_{1cr} F_{2cr}	-2 050 –	– -2 050	-1 770 –	– -1 770	-1 530 –	– -1 530	-1 280 –	– -1 280	-1 180 –	– -1 180	-920 –	– -920
F_{R1fin} F_{R2fin}	F_{1fin} F_{2fin}	-3 200 –	– -3 200	-2 900 –	– -2 900	-2 490 –	– -2 490	-2 240 –	– -2 240	-2 065 –	– -2 065	-1610 –	– -1 610

A.2.4 Reference test loading conditions of static and cyclic tests

A.2.4.1 Static tests

According to the statements of A.2.2 and A.2.3, the reference test loading conditions for static (and maximum cyclic, see NOTE) heel and forefoot loading according to this document are determined by the parameters listed in a) to d).

a) The position of the top load application point P_T (= point of intersection P_i of the lines of action of the resultant reference forces F_{R1} and F_{R2}), determined by the coordinates f_T and u_T relevant to the foot length L of the test sample (see A.2.2.3). These are specified as offsets $f_{T,\,L}$ and $u_{T,\,L}$ in Table 7.

b) The direction of the lines of action of the resultant reference forces F_{R1} and F_{R2}, determined by the coordinates of the top load application point P_T [see a)] and their inclinations to the u-axis, determined by the angles $\delta_1 = -6{,}18°$ and $\delta_2 = 11{,}14°$ (see A.2.2.2).

c) The magnitudes of the resultant reference forces F_{R1} and F_{R2}, specified in Table A.1, and the related test forces F_1 and F_2 to be applied in the top load application point P_T [see a)] as illustrated in Figure A.1, determined by Formula (A.5) for $\delta_1 = -6{,}18°$ and $\delta_2 = 11{,}14°$. These are specified in Table 9.

d) The tilting angles β_1 and β_2 of the foot platform for static (and maximum cyclic) heel and forefoot loading. These are specified in Table 8.

The inclinations of the lines of action of the resultant reference forces F_{R1} and F_{R2} to the u-axis addressed in b) are only relevant to the reference test loading conditions of the static (and cyclic – see NOTE) tests performed at ISO 22675:2016 tilting angles (with introduction of Ranges they are modified), since the concept of this document allows each sample of ankle-foot device or foot unit to develop its individual performance under load corresponding to its individual design.

This will automatically determine the individual position of the bottom load application point P_{B1} on the heel or P_{B2} on the forefoot of the test sample (and with it the individual inclination of the load line) relating to the tilting position of the foot platform at β_1 or β_2 [see d)] and the individual magnitude of the resultant force F_{R1} or F_{R2}.

For this reason, the configuration of the test set-up for the preparation of test loading [see 16.1.1 a)] is determined only by the position of the top load application point P_T relevant to the foot length L of the test sample according to a) and the tilting angles β_1 and β_2 of the foot platform according to d).

NOTE References (in parentheses) to the cyclic tests take into account that the linear and angular dimensions determining the reference test loading conditions for static heel and forefoot loading are identical to those determining the reference test loading conditions for maximum cyclic heel and forefoot loading [see A.2.4.2 a)].

A.2.4.2 Cyclic test

According to A.2.2 and A.2.3, the reference test loading conditions for cyclic loading according to this document are determined by the parameters listed in a) and b).

a) The reference test loading conditions for maximum cyclic heel and forefoot loading are determined by the same linear and angular dimensions as the reference test loading conditions for static heel and forefoot loading (see A.2.4.1).

b) The reference test loading conditions for repeated foot loading progressing from heel contact to toe-off are determined by the parameters listed in 1) to 4).

   1) The position of the top load application point P_T [see A.2.4.1 a)].

   2) The progression of the resultant force F_R, characterized by the sequence of the instantaneous directions of its line of action, which are determined by the coordinates of the top load application point P_T [see A.2.4.1 a)] and the inclinations of the line of action to the u-axis at the related instantaneous values of angle δ (see Figure A.1).

3) The profile (curve) of the pulsating test force F_c, to be applied in the top load application point P_T [see A.2.4.1 a)] as illustrated in Figure A.1 as a function of time $F_c(t)$ as illustrated in Figure 6 or a function of tilting angle of the foot platform $F_c(\beta)$. The instantaneous values of F_c are determined by Formula (A.5) for the related instantaneous values of the resultant force F_R and the angle δ (see Figure A.1).

   The description and specification of the profile of the test force $F_c(t)$ or $F_c(\beta)$ is primarily based on the values F_{1cmax} (1st maximum of loading profile), F_{cmin} (intermediate minimum of loading profile) and F_{2cmax} (2nd maximum of loading profile), specified in Table 9.

   Further guidance on the description and specification of the profile of the test force F is given in Figure 3, Tables 10 and 11 and also by Formula (8).

4) The profile (curve) of the tilting angle $\beta(t)$ of the foot platform determining its periodical oscillation within the range of $-20° \leq \beta \leq 40°$ specified for the period between the instants of heel contact and toe-off (see Figure 6).

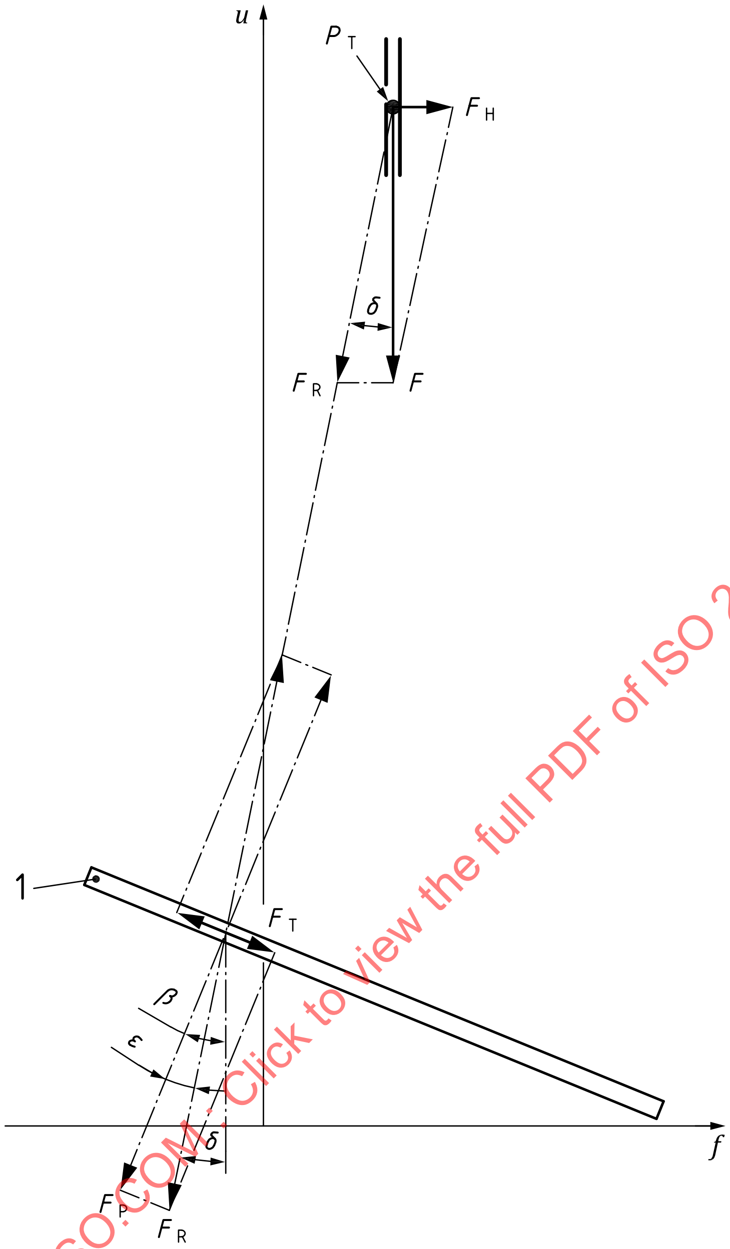
   The description and specification of the profile of the tilting angle $\beta(t)$ of the foot platform is primarily based on the values $\beta_1 = \beta_{(150)}$ (instant of 1st maximum F_{1cmax} of loading profile), $\beta_{Fcmin} = 0°$ (instant of intermediate minimum F_{cmin} of loading profile) and $\beta_{(450)}$(instant of 2nd maximum F_{2cmax} of loading profile), specified in Table 8.

   Further guidance on the description and specification of the profile of the tilting angle $\beta(t)$ is given by the Formulae 4 to 7).

The progression of the lines of action of the resultant force F_R addressed in b) 2) is only relevant to the reference test loading conditions for the cyclic test, since the concept of the tests of this document allows each sample of ankle-foot device or foot unit to develop its individual performance under load corresponding to its individual design.

This will automatically determine the individual position of the bottom load application point P_B on the foot of the test sample relating to the specific value of tilting angle $\beta(t_x)$ of the foot platform and the individual inclination and magnitude of the resultant force F_R.

For this reason, the configuration of the test set-up for the preparation of test loading [see 16.1.1 b)] is determined only by the position of the top load application point P_T relevant to the foot length L of the test sample according to b) 1) and an appropriate initial tilting position of the foot platform. According to 16.1.1 b) 3), an appropriate initial tilting position of the foot platform is determined by the temporary tilting angle $\beta = 0°$ relevant to the instant of the intermediate minimum F_{cmin} of the loading profile.

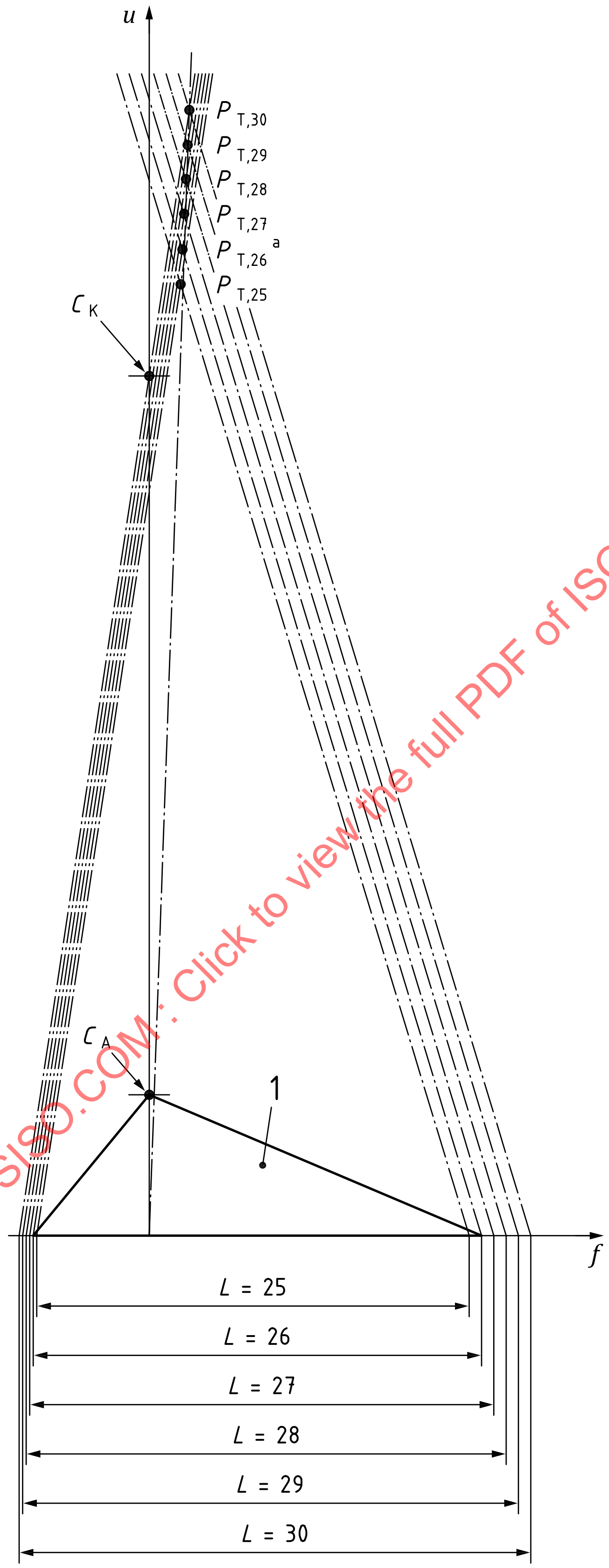


Key

1	foot platform
f, *u*	axes of coordinate system
P_T	top load application point
F	test force
F_H	force component transverse to line of application of test force F
F_R	resultant force
F_P	force component perpendicular to foot platform
F_T	force component tangential to foot platform
δ	inclination angle of line of action of resultant force F_R
ε	angle between resultant force F_R and force component F_P determining ratio F_T/F_P
β	tilting angle of foot platform

Figure A.1 — Illustration of different components of loading

Dimensions in centimetres



Key

f, *u* axes of coordinate system

1 symbolic view of foot

C_K effective knee-joint centre

C_A effective ankle-joint centre

a Top load application points relevant to indicated foot length L (Reference: $P_{T, 26}$ for L = 26 cm).

(see A.2.2.3)

Figure A.2 — Illustration of the dependence of the position of the top load application point P_T on the foot length L