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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

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Foreword

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

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 22675 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

Introduction

This International Standard offers alternatives to the structural tests on ankle-foot devices and foot units specified in 17.2 of ISO 10328:2006, 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 10328:2006;

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 International Standard is low, comparable to that of the test equipment required for the corresponding separate structural tests specified in ISO 10328. Apparently, basic components of both types of test equipment are similar and can be re-used in a modified design.

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

In order to allow continuity of testing by checking the test methods for ankle-foot devices and foot units specified in this International Standard against those specified in 17.2 of ISO 10328:2006, a transition period will be established, during which both test methods are valid. For practical reasons, this transition period will be adapted to the period of time after which the systematic review of ISO 10328:2006 and this International Standard is indicated. The systematic review of both standards is expected to result, among other outcomes, in the finding on whether the test methods specified in this International Standard have demonstrated their suitability.

NOTE Further guidance on the specification of the test loading conditions and test loading levels and on the design of appropriate test equipment is given in a separate document, published as a Technical Report (see Bibliography).

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

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of prosthetic ankle-foot devices and foot units with the strength requirements specified in 4.4 of ISO 22523:2006 (see NOTE 1). Prosthetic ankle-foot devices and foot units on the market, which have demonstrated their compliance with the strength requirements specified in 4.4 of EN 12523:1999 through submission to the relevant tests of ISO 10328:1996, need not be retested to this International Standard.

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

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

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

In addition, this International Standard specifies a static test procedure for prosthetic ankle-foot devices and foot units, consisting of a static proof test and a static ultimate strength test, distinguished, besides other features, (see NOTE 2) by the potential to generate heel and forefoot forces at lines of action conforming to those occurring at the instants of maximum heel and forefoot loading during the cyclic test.

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

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

According to the concept of the tests of this International Standard, each sample of ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

NOTE 1 ISO 22523 (formerly EN 12523) addresses those of the Essential Requirements listed in Annex I of the European Medical Device Directive 93/42/EEC that are applicable to external limb prostheses and external orthoses.

NOTE 2 The lines of action of the heel and forefoot forces generated by the static test procedure specified in this International Standard approach those determining the sagittal plane loading of the test loading conditions I and II for the principal structural tests specified in ISO 10328, 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.

2 Normative references

The following referenced documents are indispensable for the application 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 8549-1, *Prosthetics and orthotics — Vocabulary — Part 1: General terms for external limb prostheses and external orthoses*

ISO 10328:2006, *Prosthetics — Structural testing of lower limb prostheses — Requirements and test methods*

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

3 Terms and definitions

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

3.1
proof strength
static load representing an occasional severe event, which can be sustained by the ankle-foot device or foot unit and still allow it to function as intended

3.2
ultimate strength
static load representing a gross single event, which can be sustained by the ankle-foot device or foot unit but which could render it thereafter unusable

3.3
fatigue strength
cyclic load that can be sustained by the ankle-foot device or foot unit for a given number of cycles

3.4
batch
set of test samples of an ankle-foot device or foot unit submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this International Standard

4 Designations and symbols of test forces

The designations and symbols of all relevant test forces are listed in Table 1.

Table 1 — Designations and symbols of test forces

Designation	Symbol
Test forces	F, F_1, F_2
Settling test force Stabilizing test force Proof test force of end attachments	F_{set} F_{stab} F_{pa}
Static proof test force on heel/forefoot	F_{1sp}, F_{2sp}
Static ultimate test force on heel/forefoot	F_{1su}, F_{2su}
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	$F_c(t)$; $F_c(\gamma)$ F_{1cmax}, F_{2cmax} F_{cmin} F_{1fin}, F_{2fin}
NOTE Further details of the test forces listed are given in Table 3.	

5 Strength and related performance requirements and conditions of use

5.1 According to 4.4.1 of ISO 22523:2006, a prosthetic ankle-foot device or foot unit "*… shall have the strength to sustain the loads occurring during use by amputees […] in the manner intended by the manufacturer for that device according to his written instructions on its intended use*".

For the assessment of the conformity of ankle-foot devices and foot units with the above requirement (see also Scope), this International Standard provides means of determining different categories of strength. These are defined in 3.1 to 3.3 and listed in Table 2, together with the related performance requirements and the test methods for their verification.

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

The device shall

a) comply with the requirements of this International Standard (see 9.1 and 9.2) for a specific test loading level (see 7.2)

and

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

The conditions in a) and b) are regarded in both the classification and designation of ankle-foot devices and foot units according to Clause 19 and their labelling according to Clause 20.

NOTE The statement of the body mass limit not to be exceeded by amputees is part of the conditions of use to be specified, with justification, by the manufacturer in his written instructions on the intended use of a specific ankle-foot device or foot unit, taking account of all other factors affecting the loads expected to be exerted on that ankle-foot device or foot unit by amputees (see Clause A.1).

Table 2 — Categories of strength addressed in this International Standard, together with the related performance requirements and test methods for their verification

Category of strength	Related performance requirement [a]	Test method for verification
Proof strength (see 3.1)	Structure shall sustain static loading by the proof test forces F_{1sp} and F_{2sp} at the prescribed values for the prescribed time (see 16.2.2).	Static proof test (16.2.1), successively applying heel and forefoot loading.
Ultimate strength (see 3.2)	Structure shall sustain static loading by the ultimate test forces F_{1su} and F_{2su} at the prescribed values (see 16.3.2).	Static ultimate strength test (16.3.1), separately applying heel and forefoot loading.
Fatigue strength (see 3.3)	Structure shall sustain successively (see 16.4.2) 1) cyclic loading by the pulsating test force $F_c(t)$ or $F_c(\gamma)$ at the prescribed profile for the prescribed number of cycles and 2) final static loading by the final test forces F_{1fin} and F_{2fin} at the prescribed values for the prescribed time.	Cyclic test procedure (16.4.1), repeatedly applying a loading profile simulating the stance phase of walking, followed by final static heel and forefoot loading.

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

6 Coordinate system and test configurations

6.1 General

The test configurations of this International Standard are defined in a manner similar to that applied in ISO 10328.

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 c) 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.

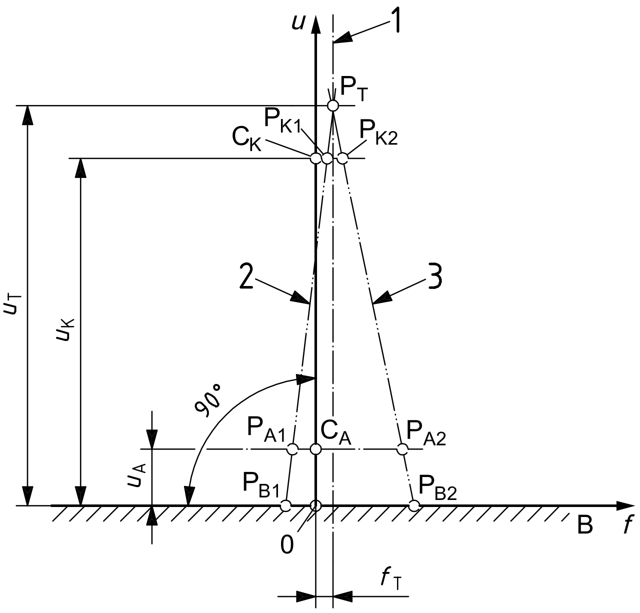
If a test sample is not in the vertical position, the axes of the coordinate system shall be rotated to correspond.

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

c) The f-axis extends from the origin 0 perpendicular to the u-axis (see Figure 1). Its positive direction is forward towards the toe (in the anterior direction).



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}.

IMPORTANT — In the subsequent clauses of this International Standard, the f-coordinates are also referred to as OFFSETS.

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

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

6.4 Test force F

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

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

6.5 Line of application of test force F

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

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

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

NOTE For further background information see also A.2.4.

6.7 Longitudinal axis of the foot and effective ankle joint centre

6.7.1 General

In order to align the test sample within the coordinate system (see 6.1 and 6.2) it is necessary to locate

a) the longitudinal axis of the foot (see 6.7.2);

b) the effective ankle-joint centre (see 6.7.3).

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

6.7.2 Longitudinal axis of the foot

Unless otherwise specified by the manufacturer/submitter, the longitudinal axis of the foot shall be taken to pass through the centre of the widest part of the forefoot and equidistant between the medial and lateral borders of the foot at a quarter of the length of the foot from the most posterior part of the foot with the foot placed as specified in 6.7.3.3 and illustrated in Figure 2.

6.7.3 Effective ankle-joint centre, C_A

6.7.3.1 Locate the effective ankle-joint centre C_A as described in 6.7.3.2 to 6.7.3.4.

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

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

6.7.3.3 Place the foot on a horizontal surface with a block of the manufacturer's/submitter's recommended heel height h_r placed under the heel of the foot (see Figure 2).

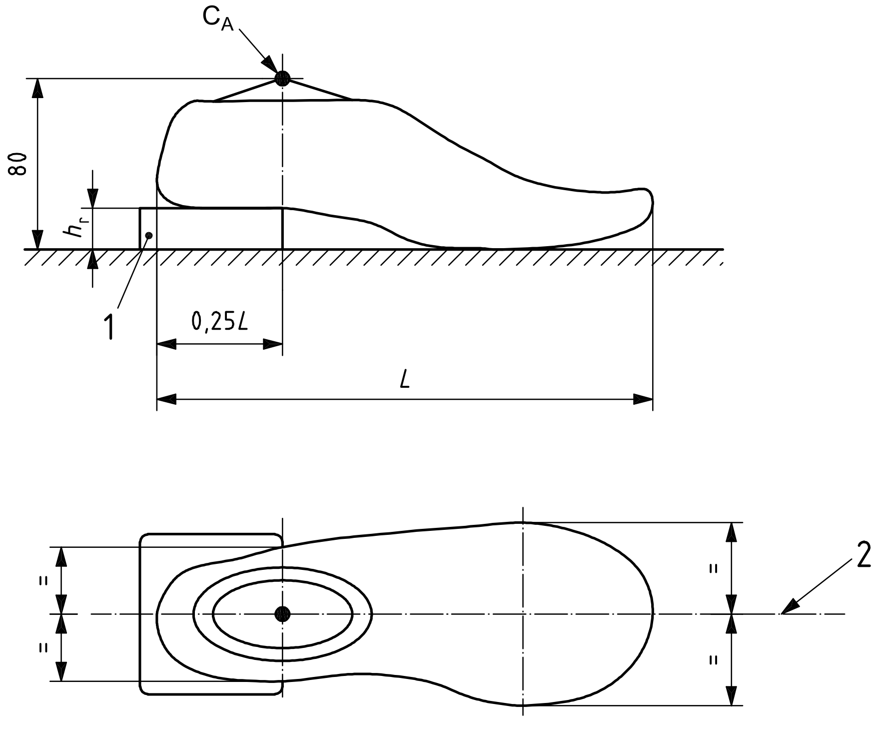
6.7.3.4 The effective ankle-joint centre C_A lies

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

b) 80 mm above the bottom surface;

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

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)

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

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

7 Test loading conditions and test loading levels

7.1 Test loading conditions

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

The single test loading condition of the cyclic test is characterized by a specific profile of pulsating test force, $F_c(t)$ or $F_c(\gamma)$, 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, $\gamma(t)$.

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 a specific tilting angle, γ.

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 Tables 3 to 11 of Clause 8. Further information is given in Clauses 15 and 16.

NOTE For further information see Annex A.

7.2 Test loading levels

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

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

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

NOTE 2 The values of the dimensions and loads of test loading levels P3, P4 and P5 are specified in separate tables in Clause 8. As an interim measure, pending validation, it is suggested that the values of the dimensions and loads specified in C.3 and Table C.2 are appropriate for test loading level P6. Further test loading levels will be defined, if necessary.

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;

— dimensions such as segmental lengths, foot lengths and coordinates (offsets);

— cycles (prescribed number of loading cycles)

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

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

Table 3 — Test forces and relevant references

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

[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 (see 13.2.2)

Parameter	**Dimension**	**Value**												
Foot length L	cm	20	21	22	23	24	25	**26**	27	28	29	30	31	32
$f_{B1, L}$ [a]	mm	$f_{B1, L} = f_{B1, 26} \cdot (L/26)$												
		– 32	– 33	– 35	– 36	– 38	– 39	– **41**	– 43	– 44	– 46	– 47	– 49	– 50
$f_{B2, L}$ [a]	mm	$f_{B2, L} = f_{B2, 26} \cdot (L/26)$												
		105	110	115	120	126	131	**136**	141	146	152	157	162	167

[a] The values of $f_{B, 26}$ are determined by the condition $(f_{B, 26} - f_{T, 26}) / u_{T, 26} = (f_{A, 26} - f_{T, 26}) / (u_{T, 26} - u_{A, 26})$. For the values of $f_{A, 26}$ see A.2.2.1 d); for the values of $u_{A, 26}$ and $u_{T, 26}$ see Tables 6 and 7.

Table 5 — Test forces of the proof test of end attachments for test loading levels P5, P4 and P3 (see 13.2.1)

End attachments for				**Stabilizing test force**, F_{stab}; (F_{Rstab}) [b]	**Settling test force**, F_{set}; (F_{Rset}) [b]	**Proof test force**, F_{pa}; (F_{Rpa}) [b]
Test procedure	**Test loading level**	**Test loading condition**				
		Heel loading F_1 at $\gamma = -15°$	Forefoot loading F_2 at $\gamma = 20°$	N	N	N
All tests [a]	P5	•		50	1 018; (1024)	5 345; (5 376)
			•		1 005; (1024)	5 275; (5 376)
	P4	•			939; (944)	4 927; (4 956)
			•		926; (944)	4 863; (4 956)
	P3	•			732; (736)	3 842; (3 864)
			•		722; (736)	3 791; (3 864)

NOTE For the additional test loading level P6 the test forces are specified in Table C.1.

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

For sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard and/or to the specific requirements of the ankle-foot devices or foot units submitted for test, particular conditions apply (see the OPTION described in 13.2.2.1).

[b] The relationship between the values of F_x and F_{Rx} (placed in parentheses) is determined by equation (A.5), using the values of α_1 and α_2 specified in A.2.3. The values of F_{Rx} are calculated from the relevant values listed in Table A.1 (see A.2.3), using the factors specified in Table 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)	—
			$u_{T, 26} - u_A = 498$ [$u_{T, L} - u_A = 578 \cdot (L/26) - 80$]
$u_C = 250$ [c]	$(u_K - u_A)_{\text{Any foot length}} = 420$	—	—
		$(u_C - u_A) = 170$	
u_A	—	—	—
	$u_{A, \text{Any foot length}} = 80$	$u_{A, \text{Any foot length}} = 80$	$u_{A, \text{Any foot length}} = 80$
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)		

NOTE The total length and the segmental lengths also apply to the additional test loading level P6 specified in Annex C [see C.3 a)].

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

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

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

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

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

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

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

Subject	Test procedure		Foot length L [a, b] cm												
			20	21	22	23	24	25	26	27	28	29	30	31	32
			Related values of f- and u-offsets of P_T [c] and TA [d]												
		Direction and location	Numerical value mm												
Position of top load application point, P_T [c]	All tests	$f_{T,L}$	$f_{T,L} = f_{T,26} \cdot (L/26)$												
			17	18	19	19	20	21	**22**	23	24	25	25	26	27
		$u_{T,L}$	$u_{T,L} = u_{T,26} \cdot (L/26)$												
			445	467	489	511	534	556	**578**	600	622	645	667	689	711
Position of tilting axis TA of foot platform [d]	All tests	$f_{TA,L}$	$f_{TA,L} = 0{,}365 \cdot L$												
			73	77	80	84	88	91	**95**	99	102	106	110	113	117
		$u_{TA,L}$	$u_{TA,L} = 0{,}1 \cdot L$												
			20	21	22	23	24	25	**26**	27	28	29	30	31	32

NOTE The specified dimensions also apply to the additional test loading level P6, specified in Annex C [see C.3 a)].

[a] The foot length L is specified in cm, taking into account that in many countries the foot size determining the foot length is measured in cm.

[b] The selection of appropriate sizes of ankle-foot devices and foot units for test purposes is not limited by the range given in this table. The formulae allow the calculation of f- and u-offsets of P_T and TA relating to any foot length L.

[c] See 6.3 and Figures 1, 4 and 5. (For further information see 16.1.1 and A.2.2.3.)

[d] See 13.4.2.3 and Figure 5. (For further information see 16.1.1, E.3.2 and E.3.3.)

Table 8 — Angles of toe-out position of foot and specific tilting positions of foot platform, 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	—	τ	7
Fixed tilting positions of foot platform (see 13.4.1.3)	Static proof test and static ultimate strength test	Heel loading, F_1	γ_1	– 15
		Forefoot loading, F_2	γ_2	20
Instantaneous tilting positions of foot platform (see 13.4.2.8)	Cyclic test	1st maximum value, F_{1cmax}	γ_1	– 15
		Intermediate minimum value, F_{cmin}	γ_{Fcmin}	0
		2nd maximum value, F_{2cmax}	γ_2	20

NOTE The specified dimensions also apply to the additional test loading level P6, specified in Annex C [see C.3 a)].

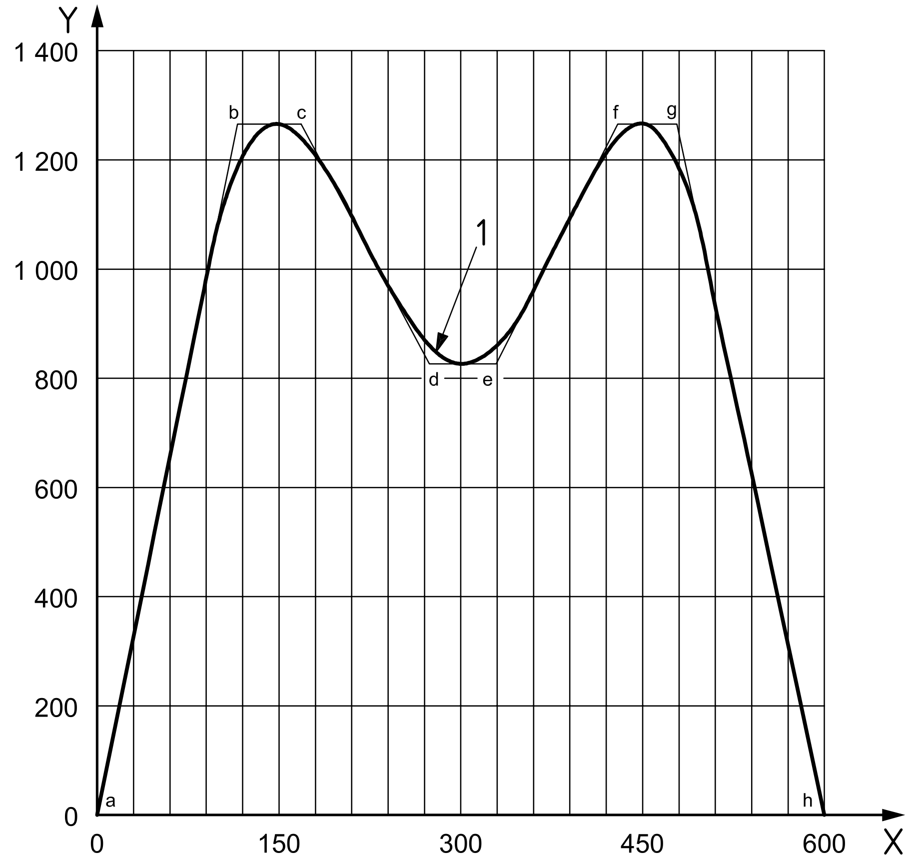
[a] The positive direction of the angles τ and γ is shown in Figures 4 or 5, respectively.

Table 9 — Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading levels P5, P4 and P3 (see 16.2, 16.3 and 16.4)

Test procedure and test force			Unit	Test loading level (P_x) [a] and test loading condition (F_{1x}; F_{2x})					
				P5		P4		P3	
				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}	N	2 227	—	2 053	—	1 601	—
		F_{2sp}		—	2 198	—	2 026	—	1 580
	Static ultimate test force	$F_{1su, lower level}$	N	3 340	—	3 079	—	2 401	—
		$F_{2su, lower level}$		—	3 297	—	3 039	—	2 369
		$F_{1su, upper level}$		4 454	—	4 106	—	3 201	—
		$F_{2su, upper level}$	N	—	4 396	—	4 052	—	3 159
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax}	N	1 273	—	1 173	—	915	—
	Intermediate minimum value of pulsating test force	F_{cmin}	N	850		784		611	
	2nd maximum value of pulsating test force	F_{2cmax}	N	—	1 256	—	1 158	—	903
	Final static test force	F_{1fin} (= F_{1sp})	N	2 227	—	2 053	—	1 601	—
		F_{2fin} (= F_{2sp})		—	2 198	—	2 026	—	1 580
	Prescribed number of cycles		1	2×10^6					

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

[a] For the additional test loading level P6 the values of the test forces and the prescribed number of cycles are specified in Table C.2.



Key

X time in milliseconds

Y force in newtons

1 test force F

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

NOTE 2 The reference points a to h are specified in Table 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			
	ms	ms	**P5**	**P4**	**P3**	**Symbol**	**Value relevant to test loading level**		
							P5	P4	P3
a	0					$F_c(t_a)$	0	0	0
		115	11,1	10,2	8,0				
b	115					F_{1cmax}	1 273	1 173	915
		51							
c	166					F_{1cmax}	1 273	1 173	915
		103	− 4,1	− 3,8	− 2,9				
d	269					F_{cmin}	850	783	611
		62							
e	331					F_{cmin}	850	783	611
		102	4,0	3,7	2,9				
f	433					F_{2cmax}	1 256	1 166	903
		51							
g	484					F_{2cmax}	1 256	1 166	903
		116	− 10,8	− 9,9	− 7,9				
h	600					$F_c(t_h)$	0	0	0

NOTE The loading period of 600 ms corresponds to the average stance phase time of a typical walking cycle of 1 second 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 tilting angle $\gamma(t)$ and 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	Tilting angle $\gamma(t)$ of foot platform degree	Pulsating test force $F_c(t)$ (Value relevant to test loading level) P5 N	P4 N	P3 N
0	**− 20,0**	**0**	**0**	**0**
30	− 19,5	331	306	238
60	− 19,0	663	612	477
90	− 18,0	996	919	716
120	− 16,5	1 221	1 126	878
150	**− 15,0**	**1 273**	**1 173**	**915**
180	− 13,0	1 215	1 120	873
210	− 10,5	1 092	1 007	785
240	− 7,5	969	893	697
270	− 4,0	880	811	632
300	**0**	**850**	**783**	**611**
330	4,0	879	810	632
360	8,0	966	891	694
390	12,0	1 086	1 003	781
420	16,0	1 204	1 110	866
450	**20,0**	**1 256**	**1 158**	**903**
480	24,0	1 198	1 105	861
510	28,0	971	895	698
540	32,0	643	593	463
570	36,0	321	296	231
600	**40,0**	**0**	**0**	**0**

NOTE The loading period of 600 ms corresponds to the average stance phase time of a typical walking cycle of 1 second 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 increments between each instant after heel contact, for which values of tilting angle and test force are specified in this table, can easily be adapted by linear scaling.

9 Compliance

9.1 General

In order to claim compliance with this International Standard 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 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 International Standard shall be certified by the test laboratory/facility only for the specific prosthetic assembly and alignment simulated in the set-up of the batch of test samples of the ankle-foot device or foot unit which have been subjected to this test (see 9.3).

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

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

9.2.1 Arrangements for testing

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

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

b) If the type of connecting part is intended to be allowed for use in combination with any type of ankle-foot device or foot unit, then batches of samples of this part shall be subjected to the principal structural tests specified in ISO 10328 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 International Standard for each specified assembly of connecting part and ankle-foot device or foot unit passing the tests of this standard, as certified by the test laboratory/facility (see 2nd paragraph of 9.1).

b) In the case of 9.2.1 b), the manufacturer/submitter can claim compliance with ISO 10328 for the “universal” connecting part passing the principal structural tests of that standard, as certified by the test laboratory/facility (see 2nd paragraph of 9.1).

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

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

The minimum number of tests required for each type of test in the prescribed loading conditions in order to claim compliance with this International Standard is shown in Table 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 may 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 may vary, and since test samples that have completed a specific test without failing may be used for another test (see 9.4, 16.2.1 and 16.3.1).

9.4 Multiple use of test samples

9.4.1 General

Test samples, which have demonstrated compliance with the requirements of any of the tests specified in this International Standard, may be subjected to other tests of this International Standard, 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 International Standard 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 International Standard can not be claimed if the test sample has previously been subjected to the static ultimate strength test of this International Standard.

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

For different reasons the intended use of a particular design of ankle-foot device or foot unit may require the tests of this standard to be applied at a particular test loading level not specified in this International Standard, derived from the next lower regular test loading level of this International Standard by increasing its test loads by x %.

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

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

Reference to this International Standard may also be given by stating that the prescribed batch (or batches) of test samples of ankle-foot device or foot unit submitted for test has/(have) been tested

a) following this International Standard

or, in a more specific manner,

b) by applying the tests of this International Standard at test loads set x % above test loading level P_y.

Table 12 — Number of tests and test samples required to claim compliance with this International Standard

Type of test	Test loading condition and manner of application	Minimum [a] number of tests required	Batch [b] of test samples allowed for each type of test		
			Regular test samples	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	2	2	1	16.3.1.15 and 16.3.1.17 (option)
	and				
	Direction of forefoot loading	2	2	1	16.3.1.15 and/or 16.3.1.16, and 16.3.1.17 (option)
Cyclic test (see 16.4.1)	Continuous loading from heel contact to toe-off, repeatedly applied to each test sample, followed by final static tests on heel and forefoot	2	2	—	—

[a] The term *minimum* indicates that the repetition of tests on allowed substitute test samples may be necessary to satisfy the compliance conditions.

[b] For the definition of *batch* see 3.4.

[c] The number of possible substitute test samples is related to each occasion at which any of the conditions of the relevant subclauses listed under "Reference" applies.

10 Test samples

10.1 Selection of test samples

10.1.1 General

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

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

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

For the purposes of this International Standard, the size of the foot selected shall provide the worst-case loading (see NOTE) that is possible for that type of foot when subjected to the test loading conditions of the static and cyclic tests specified in Clause 8.

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

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

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

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

10.2 Types of test sample

10.2.1 Complete structure

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

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

10.2.2 Partial structure

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

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

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

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 column C of Table 7 and also marks the reasonable area for the arrangement of alternative end attachments in consideration of the current spectrum of foot designs.

10.3.4 The ankle-foot device or foot unit, selected in accordance with 10.1.2, shall be submitted assembled by the manufacturer/submitter at least to the part connected to the remainder of the prosthesis such as an ankle unit, alignment device, pylon base, compliant structure or exoskeletal member. The type and identification of the part connected shall be recorded.

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

10.4 Identification of test samples

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

10.5 Alignment of test samples

The alignment of the test sample of an ankle-foot device or foot unit within the coordinate system shall be set in accordance with 6.1 to 6.3, 6.7.2, 6.7.3, 10.6, 14.3 a) and d), Tables 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 $\tau = 7°$ 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 International Standard shall be conducted in the worst-case alignment position

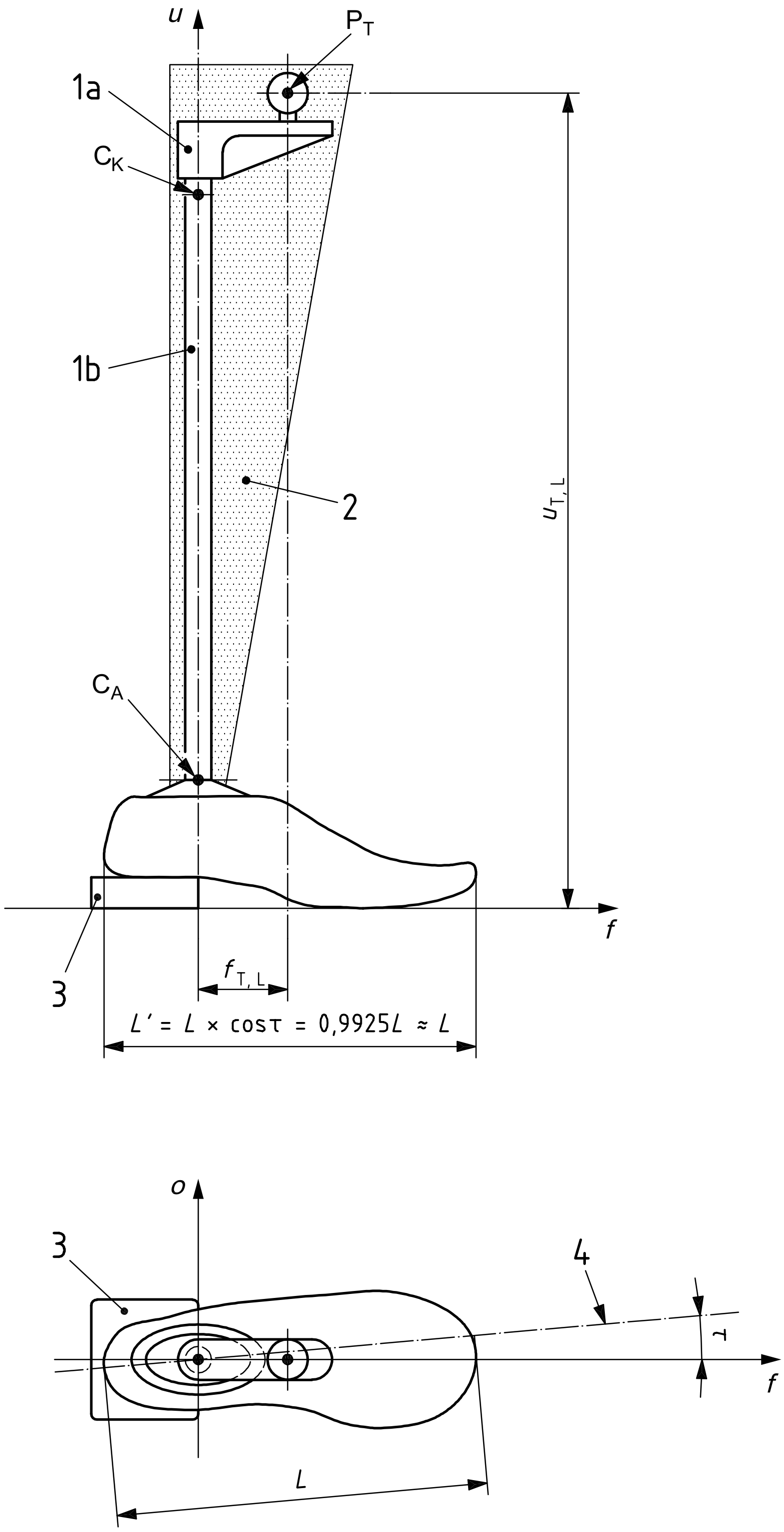
— if the part required to connect the ankle-foot device or foot unit submitted for test to the remainder of the test sample is a prosthetic component normally used for its connection to a prosthetic structure, such as an ankle-unit, ankle attachment, alignment device or pylon base (see 9.2)

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).



For legend and key to Figure 4 see facing page (23).

Key

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)

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)

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 International Standard 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) and test loading levels [Clauses 7 and 8 (and Annex C)];

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 for 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 in accordance with 16.3.1.1, 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 International Standard, 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 specified in this International Standard. End attachments which satisfy the stiffness requirements of this test for proof test forces F_{pa} = 1,2 $F_{su,\ upper\ level}$ of a specific test loading level (see Tables 3, 9 and C.2) are suitable for all static and cyclic tests of this International Standard carried out at this specific test loading level and at all lower levels.

OPTION — If it is intended to use different sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard (see EXAMPLE) and/or to the specific requirements of the ankle-foot devices or foot units submitted for test, the proof test of end attachments shall 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 Tables 3, 9 and C.2) 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 International Standard, 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 the meaning of 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) and test loading level(s), 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 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 or Table C.1 apply.

For the orientation according to b) the values of the test forces F_R in parentheses listed in Table 5 or Table C.1 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, specified in Table 5 or Table C.1.

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 or Table C.1, 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 250 N/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 or Table C.1 (but see the OPTION described in 13.2.2.1), 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 follows:

$$D_1 = \delta_2 - \delta_1 \quad (1)$$

$$D_2 = \delta_3 - \delta_1 \quad (2)$$

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 (optional)

A jig may 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 and 250 N/s (but see NOTE) up to the values specified in Table 9 or Table C.2 for the relevant test procedure, test loading condition and test loading level.

NOTE For the alternative static ultimate strength test according to Annex B, increased loading rates of between 1 kN/s and 5 kN/s are considered to be appropriate.

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, γ_1 and γ_2, specified in Table 8.

NOTE Test equipment other than that addressed, described or referred to in this International Standard (see paragraphs 3 and 4 of 15.1) may 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

NOTE The test equipment to perform cyclic loading may also be used to perform static loading. In this case it is recommended that means be provided to lock the foot platform in the relevant position to facilitate its 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 and test loading level.

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 E.3.2 and E.3.3.)

13.4.2.4 The foot platform shall support the ankle-foot device or foot unit at values of tilting angle γ 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 International Standard (see paragraphs 3 and 4 of 15.1) may 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 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 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 may 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 may 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 NOTE and EXAMPLE in 3) as well as 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.

NOTE 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.

EXAMPLE In a specific arrangement of test equipment and test sample, stabilizing forces of magnitudes between 10 N and 15 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 between 0,6 N·m and 0,9 N·m, applied at the same u-level in the manner described in 3), have been shown to be appropriate.

13.4.2.7 The profiles of the tilting angle γ 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 γ and test force F_c are applied as synchronized functions of time $\gamma(t)$ and $F_c(t)$.

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

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

13.4.2.8 The profile of the tilting angle $\gamma(t)$ is primarily specified by the instantaneous tilting positions γ_1, γ_{Fcmin} and γ_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 $\gamma(t)$ can also be specified with sufficient accuracy by a polynomial of 5th degree. For the period of 0 ms $\leqslant t \leqslant$ 600 ms corresponding to a loading period of 600 ms (see NOTE 1), the polynomial reads:

$$\gamma(t) = 2{,}450\,74 \times 10^{-12} \times t^5 - 3{,}759\,84 \times 10^{-9} \times t^4 + 1{,}775\,19 \times 10^{-6} \times t^3 - 1{,}084\,09 \times 10^{-4} \times t^2 + 2{,}072\,17 \times 10^{-2} \times t - 20{,}041 \qquad (3)$$

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), Equation (3) 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 had to be multiplied by $(600/900)^y = (2/3)^y$ as follows: $2{,}450\,74 \times 10^{-12} \times (2/3)^5$; $3{,}759\,84 \times 10^{-9} \times (2/3)^4$ etc.

Further guidance on the application of the profile of the tilting angle $\gamma(t)$ is given in Table 11.

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 Tables 10 and 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 of 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 $\leqslant t \leqslant$ 600 ms corresponding to a loading period of 600 ms (see NOTE 1 of 13.4.2.8), the polynomial reads:

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

NOTE 2 For the adaptation of Equation (4) to other loading periods related to different test frequencies, the method described in NOTE 2 of 13.4.2.8 applies.

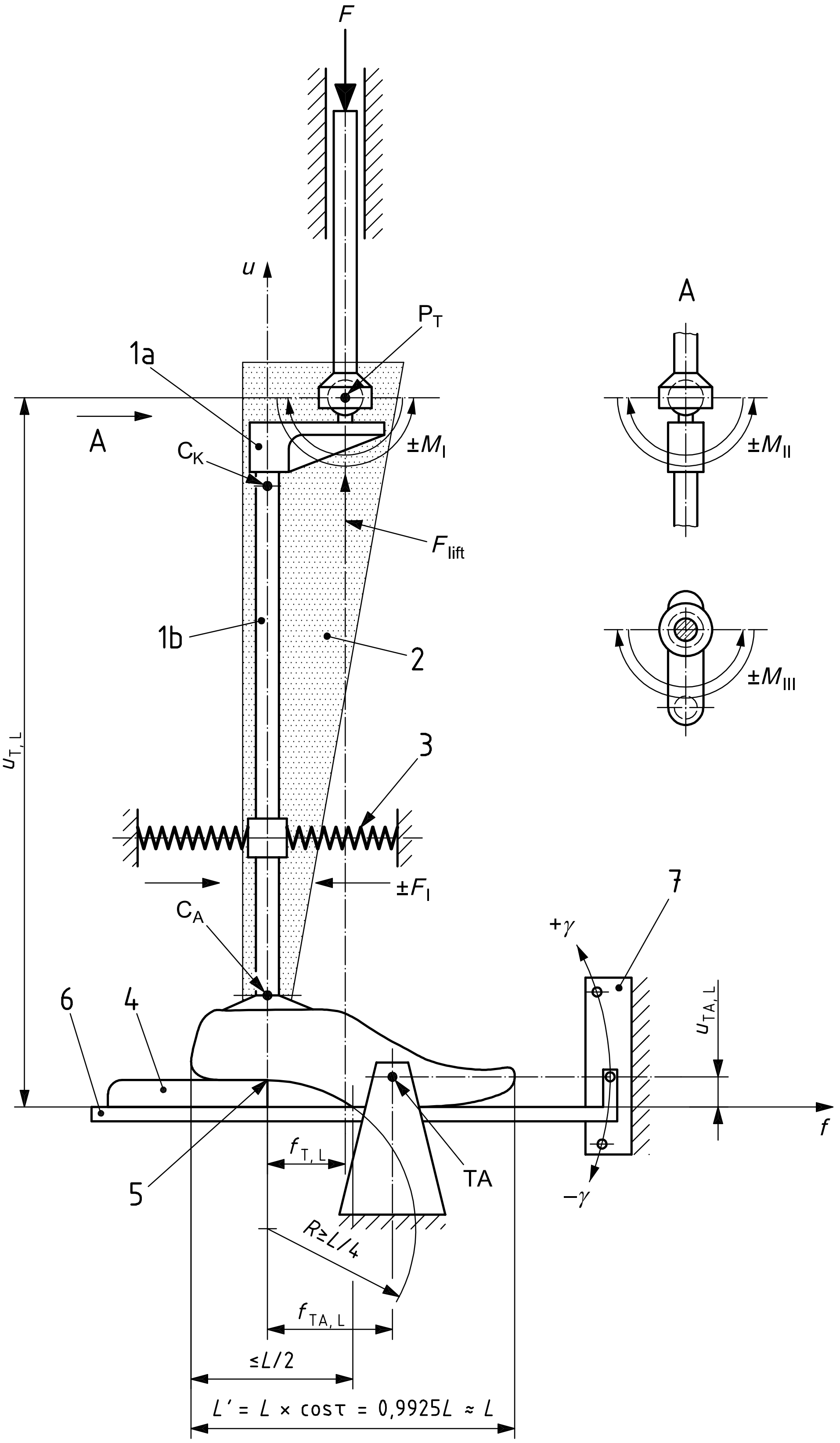
Further guidance on the application of the profile of the test force $F_c(t)$ is given in Tables 10 and 11 and Figure 3.

13.4.2.10 The waveforms of the pulsating test force $F_c(t)$ or $F_c(\gamma)$ and the tilting angle $\gamma(t)$ 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 $F_c(\gamma)$ and/or the tilting angle $\gamma(t)$ 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 $F_c(\gamma)$ 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.



For legend and key to Figure 5 see facing page (35).

Key

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]

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 γ_1 and γ_2 specified for static heel and forefoot loading (see 13.4.1.3)

or

— periodically oscillating with $\gamma(t)$ 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 γ_1 and γ_2 specified for static heel and forefoot loading (option – see NOTE of 13.4.2)

F test force $F_c(t)$ or $F_c(\gamma)$, 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)]

$\pm F_I$ 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)

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

$\pm M_{II}$ stabilizing moments in P_T according to 13.4.2.6 b) 2) (corresponding stabilizing forces at specific *u*-level not shown)

$\pm M_{III}$ 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)]

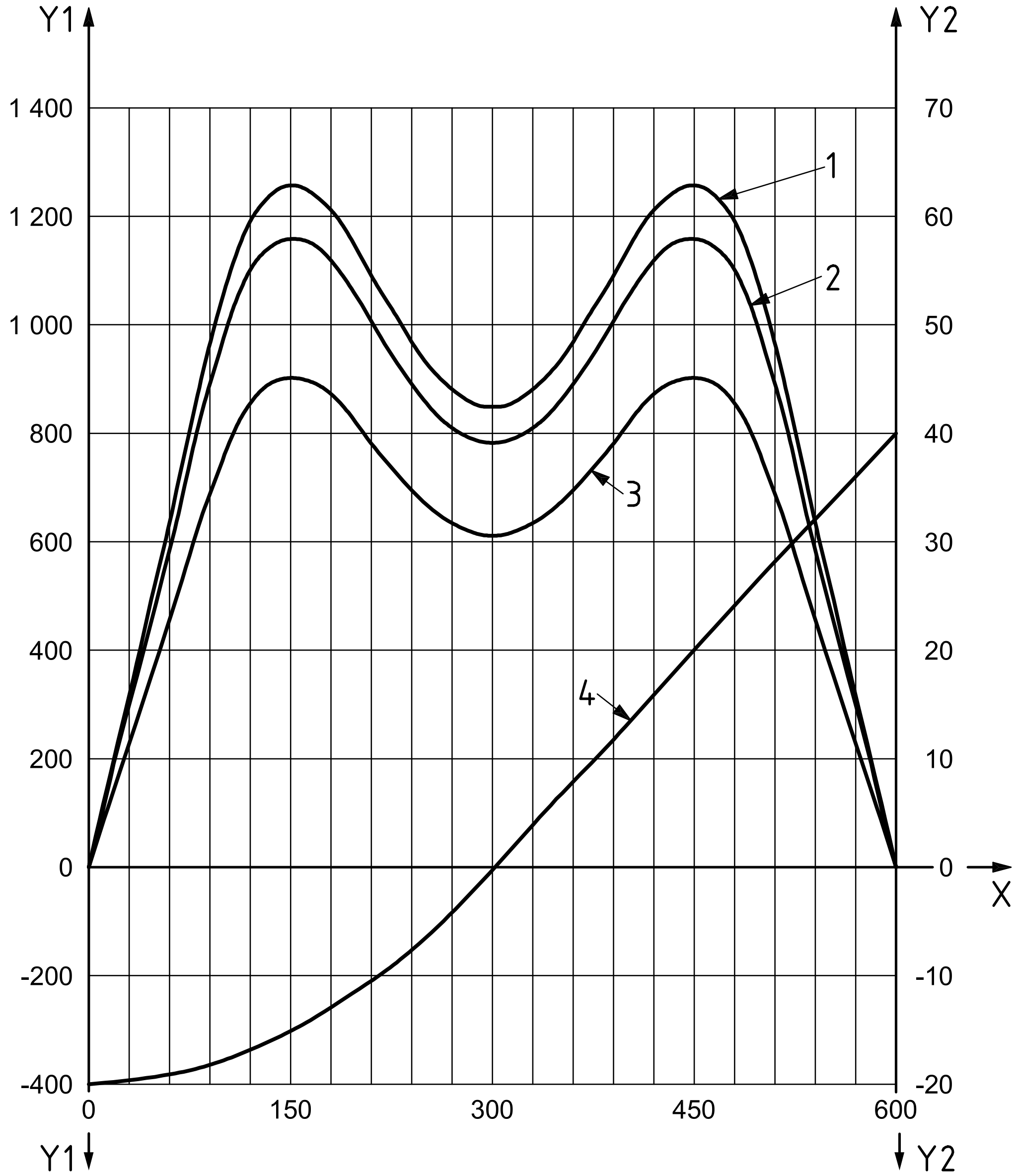
C_A effective ankle-joint centre (see 6.7.3)

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 milliseconds

Y_1 force in newtons

Y_2 angle in degrees

1 test force F of test loading level P5

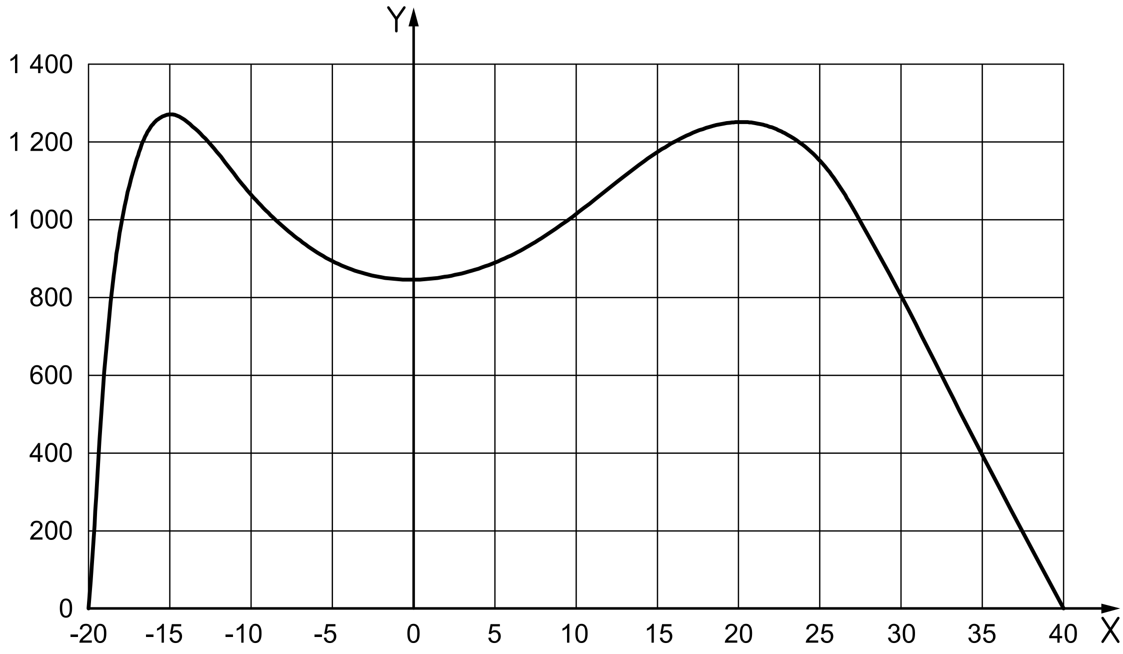
2 test force F of test loading level P4

3 test force F of test loading level P3

4 tilting angle γ of foot platform (see Figure 5)

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 angle $\gamma(t)$ as synchronized functions of time, determining the loading condition of the cyclic test of this International Standard



Key

X angle in degrees

Y force in newtons

Figure 7 — Test force $F_c(\gamma)$ of test loading level P5 as function of tilting angle $\gamma(t)$ of foot platform

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 to an accuracy of ± 0,2 mm;

b) angular dimensions to an accuracy of ± 0,2°;

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 1 % 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 ± 1°.

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 $F_c(\gamma)$ 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 γ_1 = – 15°;

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

— the 2nd maximum F_{c2max} at t_2 = 450 ms and γ_2 = 20°.

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

— γ_1 = – 15° at t_1 = 150 ms;

— γ_{Fcmin} = 0° at t_{Fcmin} = 300 ms;

— γ_2 = 20° 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 in the scope Clause 1 and specified in this International Standard 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 E.)

This relationship between test principle and test equipment is, however, not imperative. Moreover, any other type of test equipment may 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 International Standard, 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 International Standard 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 (16.2) and an ultimate strength test (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.

15.3 Cyclic test procedure

The cyclic test procedure (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 (16.4.1.11) for which the loading and unloading procedures of the static proof test (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 International Standard (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, γ_1 or γ_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 γ_1 or γ_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 8 and NOTE 4], and which provides sufficient travel for the moving part of the actuator.

NOTE 4 As illustrated in Figure 8, 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 8 for static heel and forefoot loading at γ_1 or γ_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 E.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 ($\gamma = 0$) 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 Tables 7 and 8 as described in 10.5 and illustrated in Figure 4.

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

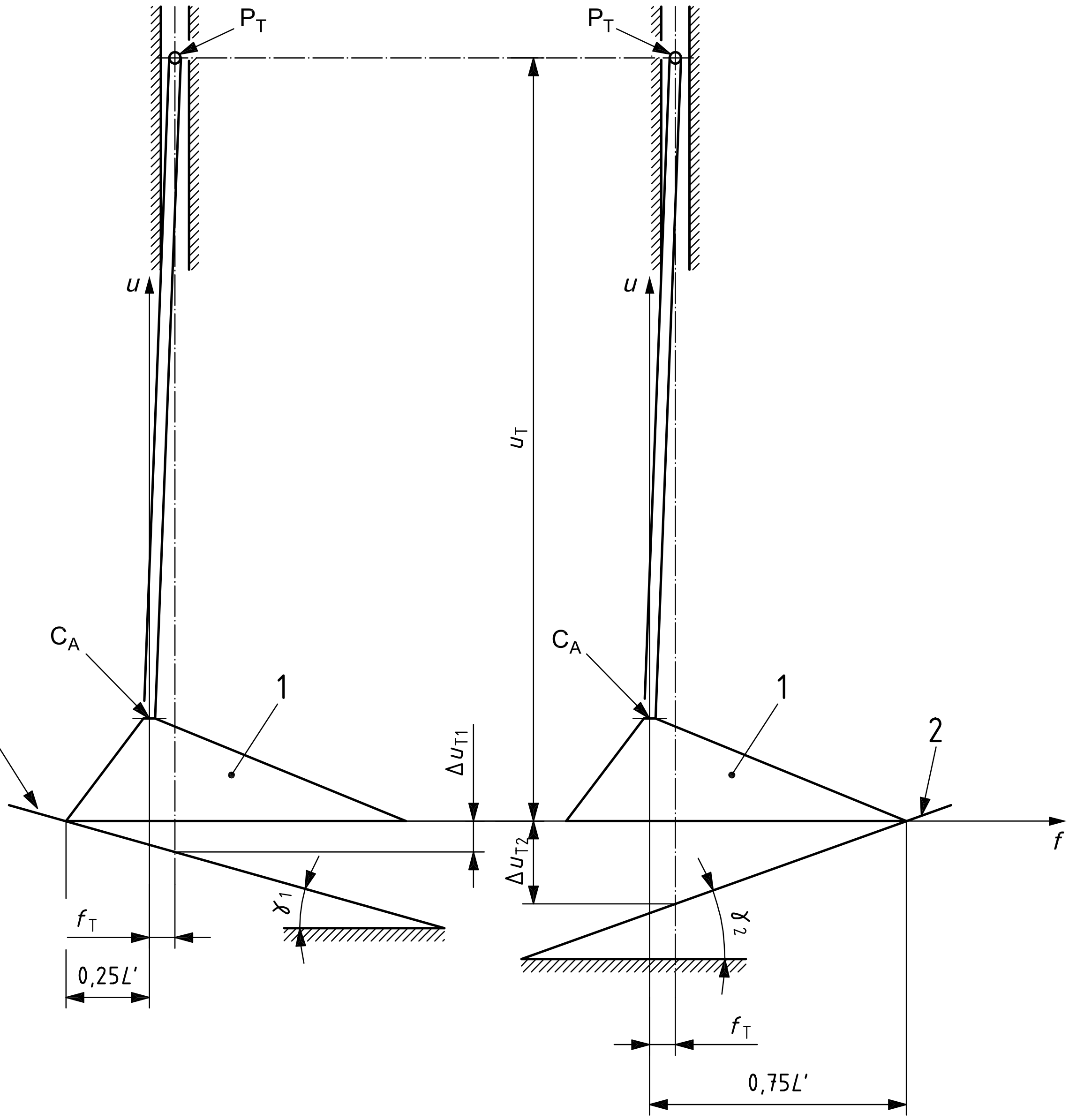
1) with the ankle-foot device or foot unit placed on the foot platform in either of the ways referred to in a) and b) and in the toe-out position specified in Table 8 and illustrated in Figure 4 and

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).

NOTE 5 For some designs of ankle-foot devices and foot units it may not be 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

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)

Static heel loading at γ_1	Static forefoot loading at γ_2
$\Delta u_{T1} = (0,25\ L' + f_T) \cdot \tan \gamma_1 = 0,04\ u_T$	$\Delta u_{T2} = (0,75\ L' - f_T) \cdot \tan \gamma_2 = 0,11\ u_T$
$u_T + \Delta u_{T1} = 1,04\ u_T$	$u_T + \Delta u_{T2} = 1,11\ u_T$

NOTE L' is the projection of the foot length L on the f-u plane. $L' = L \cdot \cos \tau = 0,9925\ L \approx L$ (see Figure 4).

Figure 8 — Preparation for test loading of static test procedure [see 16.1.1 a)]

16.1.2 Test loading conditions

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

NOTE 1 For test equipment other than that addressed, described or referred to in this International Standard (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 γ_1 and γ_2 of the foot platform, specified in Table 8.

   NOTE 2 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, γ of the foot platform, the profiles of test force, F_c and tilting angle, γ to be applied either as synchronized functions of time $F_c(t)$ and $\gamma(t)$, or the profile of the tilting angle γ to be applied as a function of time $\gamma(t)$ and the profile of the test force F_c to be applied as function of the tilting angle $F_c(\gamma)$ (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 equation (4) of 13.4.2.9.

   The profile of the tilting angle, $\gamma(t)$, is determined by the instantaneous values of tilting angle, γ_1, γ_{Fcmin} and γ_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 equation (3) of 13.4.2.8.

NOTE 3 The lines of application of the static and maximum cyclic heel and forefoot reference loading 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, 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 (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 specified in Annex B [see also 16.3.1, Clause B.1 and B.2 c)].

A flowchart for this test is shown in Figure 9.

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 γ_1 and γ_2 of the foot platform and the test forces F_1 and F_2, determining the conditions of heel and forefoot loading. Make specific reference if the additional test loading level P6 specified in Annex C is to be applied.

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 γ_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.

16.2.1.4 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 and 250 N/s to the proof test force F_{1sp} of the relevant test loading level, specified in Table 9 or Table C.2.

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 γ_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 250 N/s to the proof test force F_{2sp} of the relevant test loading level, specified in Table 9 or Clause C.2.

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 (16.2.1.4 and 16.2.1.5) or in forefoot loading (16.2.1.7 and 16.2.1.8), repeat the complete test (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 of this International Standard according to 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 (in the meaning of 16.2.2) 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).

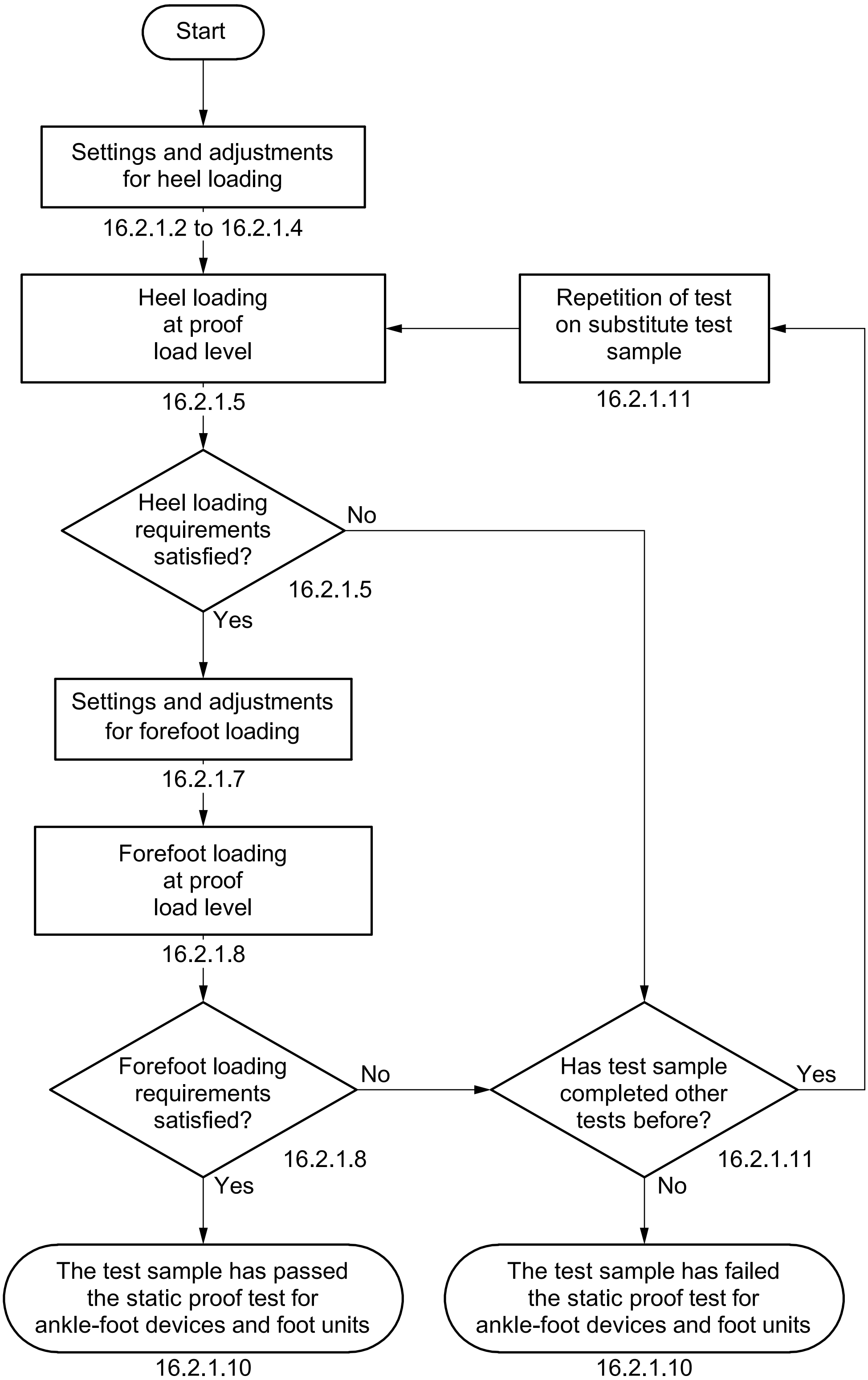


Figure 9 — Flowchart for the static proof test specified in 16.2.1

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, may be used for this test in the other direction of loading (but see 16.3.1.16).

For test samples of lower limb prostheses with material properties and/or construction features which render them unable to sustain the required ultimate test force at a rate of loading of between 100 N/s and 250 N/s, specified in 16.3.1.5 and 16.3.1.11, Annex B offers guidance on the application of an alternative static ultimate strength test, in which a higher rate of loading is applied to the test sample.

The higher rate of loading shall either be specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed upon between the manufacturer/submitter and the test laboratory/facility (see also 16.3.1.5 and 16.3.1.11) and may be applied to the initial test sample or to a substitute test sample, if the initial test sample has failed at a rate of loading of between 100 N/s and 250 N/s (see 16.3.1.17).

A flowchart for this test is shown in Figure 10.

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 γ_1 of the foot platform and the test force F_1, determining the condition of heel loading. Make specific reference if the additional test loading level P6 specified in Annex C is to be applied.

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 γ_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 250 N/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 or Table C.2, without failure of the test sample.

If appropriate, apply the test force F_1 at a higher rate of loading, specified by or agreed with the manufacturer/submitter in accordance with Annex B (see 16.3.1).

Record the highest value of the test force F_1 reached during the test, the rate of loading and whether failure has occurred. Make specific reference if the test force F_1 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 [12.3.3 a)], continue the static ultimate strength test after the test sample has withstood the ultimate test force, $F_{1su, upper level}$ 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 or Table C.1 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.

Take into account that, according to B.2 c), a test sample that has passed the test procedure specified in 16.3.1.2 to 16.3.1.5 with step 16.3.1.5 applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex B (see also 16.3.1.1), subsequently shall pass the static proof test for ankle-foot devices and foot units specified in 16.2.1 in the relevant direction of loading and at the relevant test loading level, in order to satisfy the requirements of the alternative static ultimate strength test of Annex B (see also 16.3.3).

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, γ_2 of the foot platform and the test force, F_2, determining the condition of forefoot loading. Make specific reference if the additional test loading level P6 specified in Annex C is to be applied.

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 γ_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 250 N/s until the test sample fails, or the test force F_2 attains the value of the ultimate test force $F_{2su,\ upper\ level}$ of the relevant test loading level, specified in Table 9 or Table C.2, without failure of the test sample.

If appropriate, apply the test force, F_2 at a higher rate of loading, specified by or agreed with the manufacturer/submitter in accordance with Annex B (see 16.3.1).

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 $F_{2su,\ upper\ level}$ 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 or Table C.1 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.

Take into account that, according to B.2 c), a test sample that has passed the test procedure specified in 16.3.1.8 to 16.3.1.11 with step 16.3.1.11 applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex B (see also 16.3.1.1), subsequently has to pass the static proof test for ankle-foot devices and foot units specified in 16.2.1 in the relevant direction of loading and at the relevant test loading level, in order to satisfy the requirements of the alternative static ultimate strength test of Annex B (see also 16.3.3).

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 and record whether or not the test sample referred to in 16.3.1.2 has passed the test procedure of heel loading (16.3.1.2 to 16.3.1.5) and the test sample referred to in 16.3.1.8 has passed the test procedure of forefoot loading (16.3.1.8 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 16.3.1 in heel loading (16.3.1.2 to 16.3.1.5) or in forefoot loading (16.3.1.8 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.

16.3.1.17 OPTION — If a test sample fails this test in one direction of loading at a rate of loading of between 100 N/s and 250 N/s, specified in 16.3.1.5 and 16.3.1.11, the test may be repeated on a substitute test sample in the failed direction of loading at an increased rate of loading in accordance with Annex B, specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter or agreed upon between the manufacturer/submitter and the test laboratory/facility. The failure and the repetition shall be recorded, 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, the maximum value of the ultimate test force F_{1su} or F_{2su} sustained by the test sample without loss of its structural integrity shall be either

— $\geqslant$ the value $F_{1su,\ lower\ level}$ prescribed for static heel loading

or

— $\geqslant$ the value $F_{2su,\ lower\ level}$ prescribed for static forefoot loading.

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 of this International Standard according to 16.3.2 at a specific test loading level, the following shall apply.

a) If the test forces F_1 and F_2 have been applied at a rate of between 100 N/s and 250 N/s, tests of this type, each separately applying heel loading and forefoot loading to different test samples, shall be passed (in the meaning of 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 (and also by 16.3.1.17 as an option) (see 9.3 and Table 12).

b) If the test forces F_1 and F_2 have been applied at a higher rate of loading in accordance with the alternative static ultimate strength test specified in Annex B (see 16.3.1.1 and 16.3.1.5 and 16.3.1.11), the compliance condition of a) shall apply provided that the same test samples also pass (in the meaning of 16.2.2) the static proof test for ankle-foot devices and foot units of this International Standard in the relevant direction of loading and at the relevant test loading level (see 16.3.1.6 and 16.3.1.12 and Annex B).

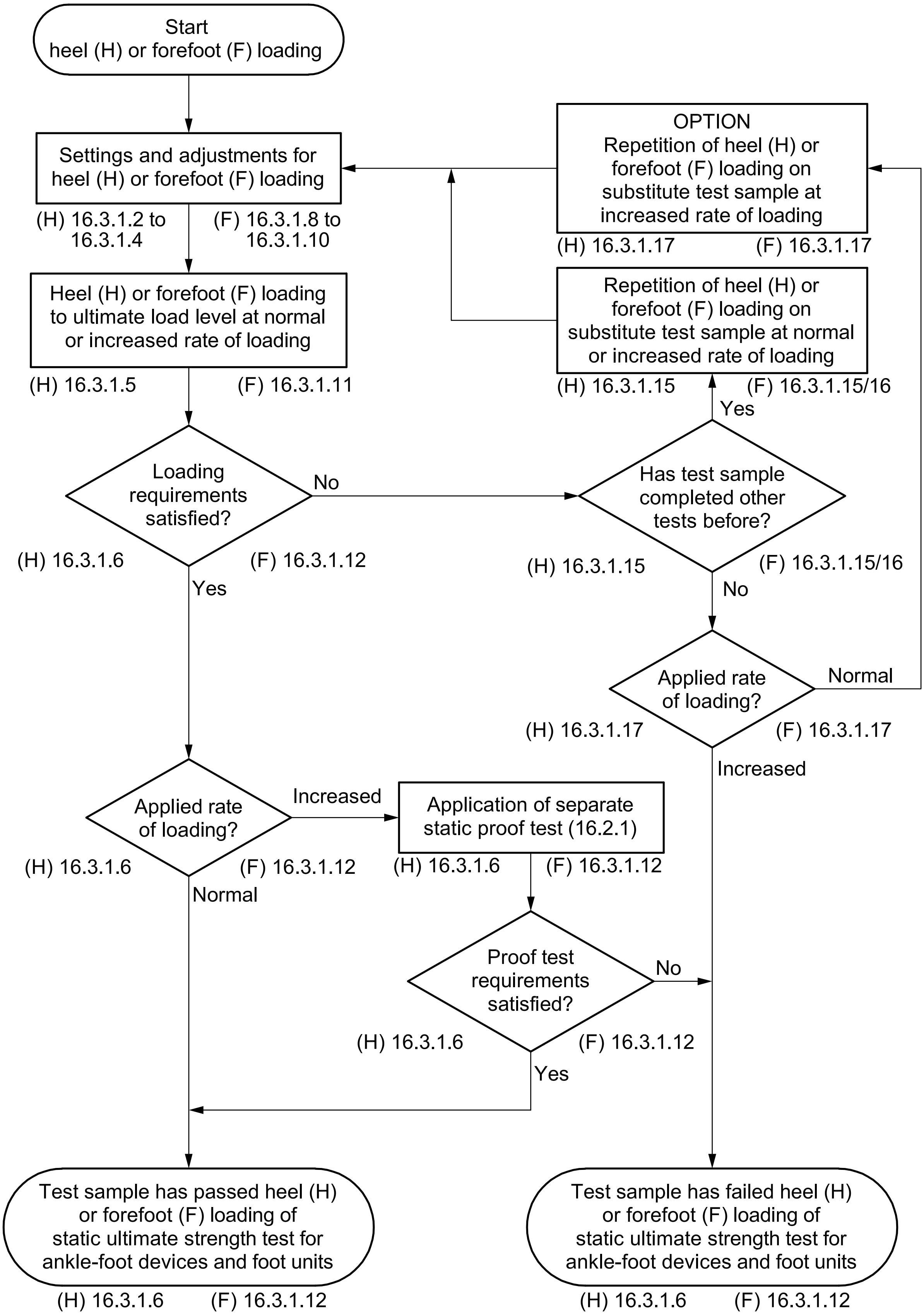


Figure 10 — Flowchart for the static ultimate strength test specified in 16.3.1

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 Figures 11 and 12.

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 250 N/s and maintained for (30 ± 3) s for each loading case, with the foot platform set at the tilting angle, γ_1 for heel loading and γ_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, together with the corresponding profiles of the tilting angle $\gamma(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\gamma)$, determining the loading conditions at each instant of the loading cycle, and the prescribed number of cycles. Make specific reference if the additional test loading level P6 specified in Annex C is to be applied.

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 γ_1, specified in Table 8, and apply to the heel of the test sample the maximum test force F_{1cmax}, specified in Table 9 or Table C.2.

b) For static forefoot loading, set the tilting angle of the foot platform to γ_2, specified in Table 8, and apply to the forefoot of the test sample the maximum test force F_{2cmax}, specified in Table 9 or Table C.2.

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 $\gamma(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\gamma)$ in accordance with the requirements of 13.4.2 and the values for the relevant test loading level, specified in Tables 8 to 11 and C.2, 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 $F_c(\gamma)$ and the tilting angle $\gamma(t)$ 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 $F_c(\gamma)$ and the tilting angle $\gamma(t)$ 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 $F_c(\gamma)$ and the tilting angle $\gamma(t)$ 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 $F_c(\gamma)$ and/or the tilting angle $\gamma(t)$ 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 $\gamma(t)$ of the oscillating foot platform and the pulsating test force $F_c(t)$ or $F_c(\gamma)$ in accordance with the requirements of 13.4.2 and the values for the relevant test loading level, specified in Tables 8 to 11 and C.2, 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 or Table C.2.

Inspect the waveforms of the applied test force $F_c(t)$ or $F_c(\gamma)$ and the tilting angle $\gamma(t)$ of the oscillating foot platform. Terminate the test if the waveforms do not comply 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 or Table C.2 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 γ_1, and subsequently to the final static force F_{2fin}, applied to the forefoot with the foot platform set at the tilting angle γ_2, in accordance with the values for the relevant test loading level, specified in Table 9 or Table C.2, applied at a rate of between 100 N/s and 250 N/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 $F_c(\gamma)$ 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 of this International Standard according to 16.4.2 at a specific test loading level, tests of this type shall be passed (in the meaning of 16.4.2) by two test samples from the prescribed batch (see 9.3 and Table 12).

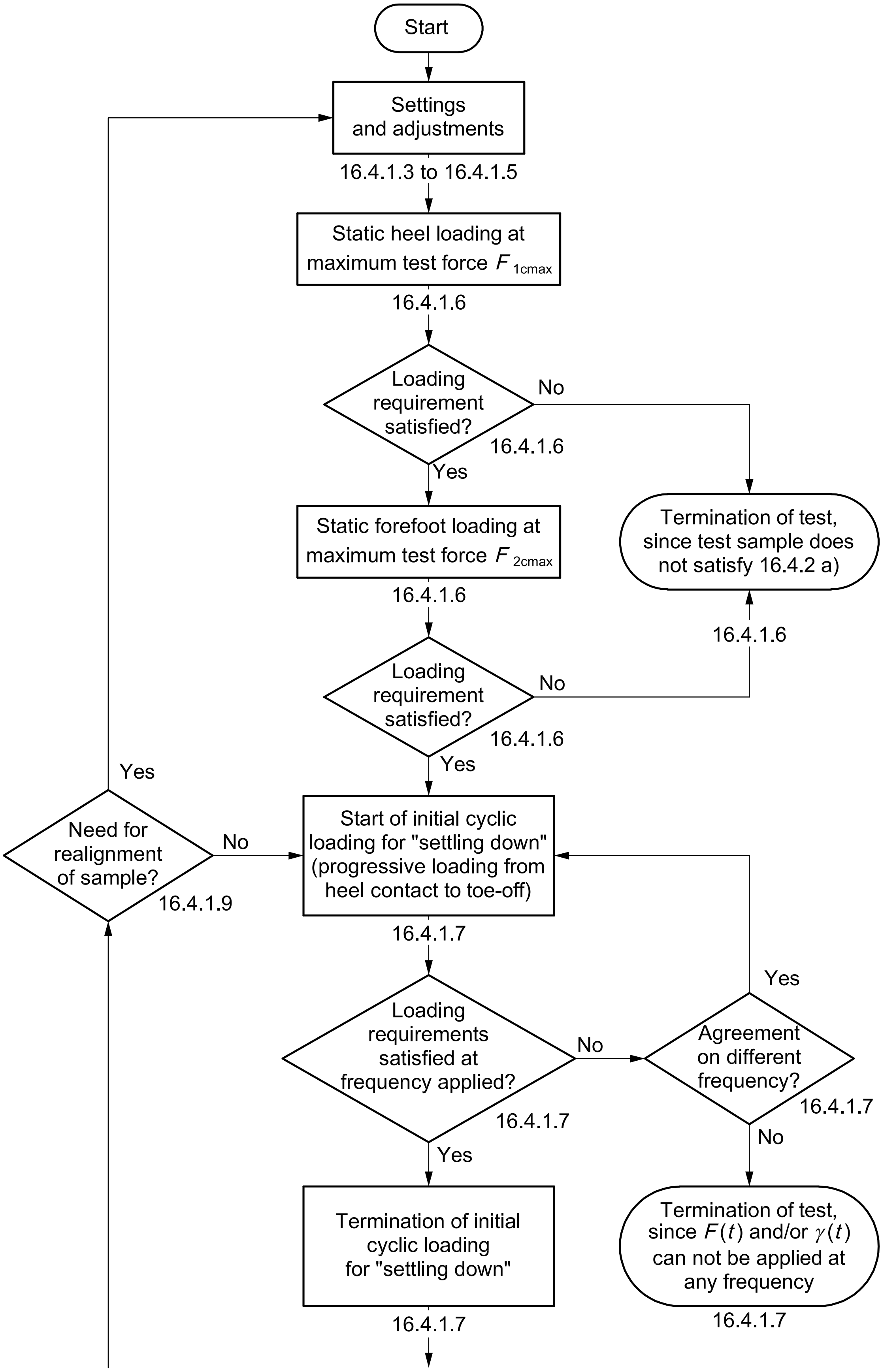


Figure 11 — Flowchart for the cyclic test specified in 16.4.1

Continued on Figure 12

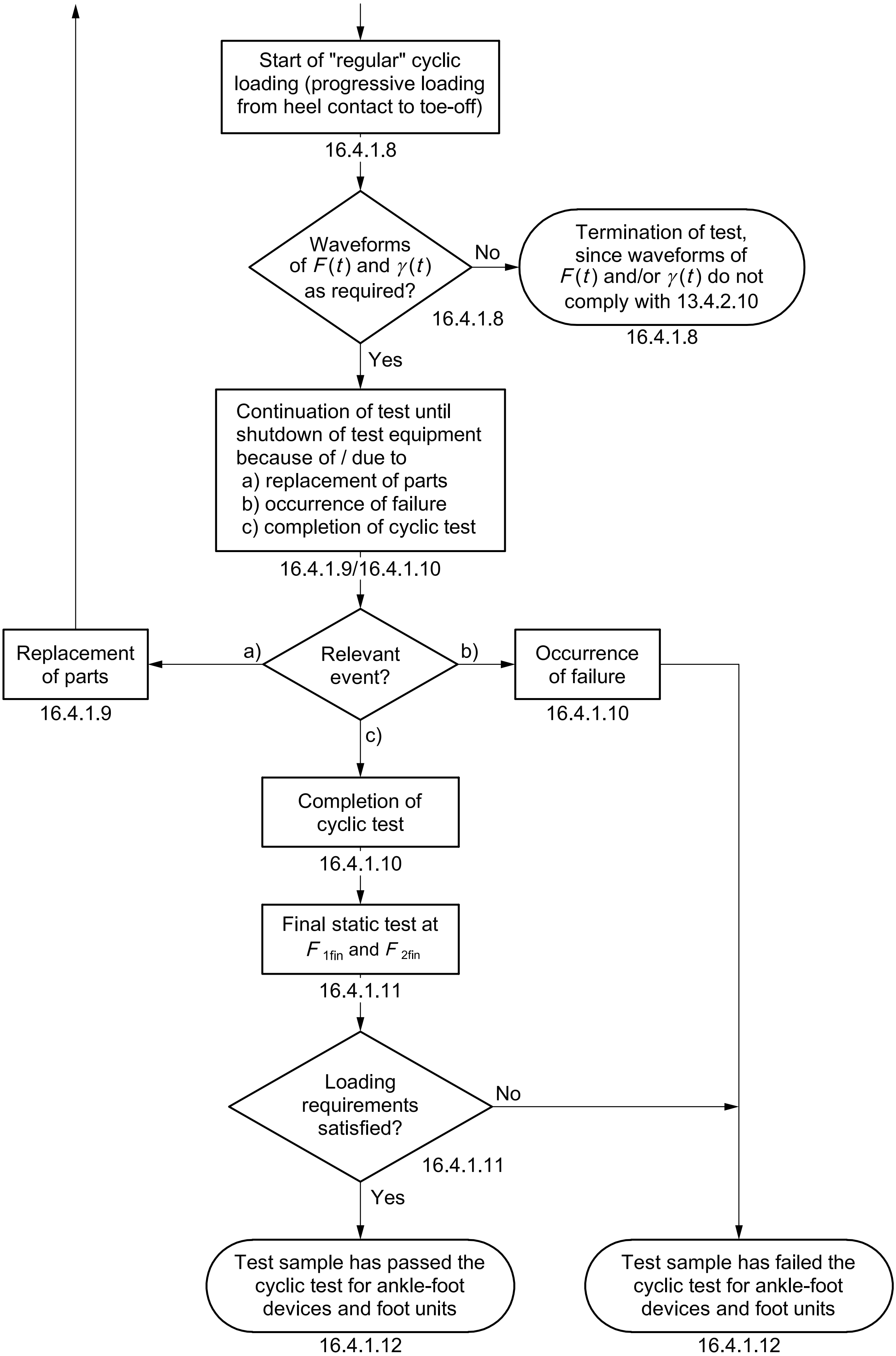


Figure 12 — Flowchart for the cyclic test specified in 16.4.1

Continued from Figure 11

17 Test laboratory/facility log

17.1 General requirements

17.1.1 The test laboratory/facility carrying out the tests specified in this International Standard and indicated in the test submission document shall ensure that all records called for in this International Sstandard 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 International Standard (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 International Standard 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 International Standard.

In addition, Annex D 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 should 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 International Standard, the clauses related to the specific type of test performed, and the test loading condition or direction of loading, the test loading level applied and which special test set-ups were used. This particularly applies to tests that are conducted at the additional test loading level P6 according to Annex C (see 16.2.1.2, 16.3.1.2 and 16.4.1.3), and to the alternative static ultimate strength test according to Annex B (see 16.3.1.1, 16.3.1.5 and 16.3.1.11).

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 International Standard 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 D gives details of the records which shall 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 International Standard is claimed (see 9.1 and 9.2) for a specific test loading level “P” (see 7.2) and

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 classified and designated as shown below.

ISO 22675 - "P" - "m" kg

19.2 Examples of classification and designation

EXAMPLES 1 to 3 illustrate variations of classification/designation for ankle-foot devices or foot units that comply with the requirements of ISO 22675 for one and the same test loading level (P4).

These examples are distinguished by different values of maximum body mass (70 kg, 80 kg, 90 kg), which indicate differences in the intended use of the devices concerned, depending on their individual design.

EXAMPLE 1 **ISO 22675 - P4 - 70 kg**

EXAMPLE 2 **ISO 22675 - P4 - 80 kg**

EXAMPLE 3 **ISO 22675 - P4 - 90 kg**

In consideration of the background information given in Annex A, the following can be stated:

a) The classification/designation according to EXAMPLE 1 is typical of an ankle-foot device or foot unit intended to be used for amputees, who are expected to load their lower limb prosthesis at a higher level than those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 70 kg, which is 10 kg below the maximum body mass of those amputees (80 kg).

b) The classification/designation according to EXAMPLE 2 is typical of an ankle-foot device or foot unit intended to be used for amputees, who are expected to load their lower limb prosthesis at the same level as those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 80 kg, which is identical with the maximum body mass of those amputees (80 kg).

c) The classification/designation according to EXAMPLE 3 is typical of an ankle-foot device or foot unit intended to be used for amputees, who are expected to load their lower limb prosthesis at a lower level than those amputees on whose locomotion data test loading level P4 is based. For this reason the value of maximum body mass is limited to 90 kg, which is 10 kg above the maximum body mass of those amputees (80 kg).

All examples of classification/designation illustrated in EXAMPLES 1 to 3 and commented in a) to c) require the manufacturer to specify, with justification, the conditions of use in his written instructions on the intended use of the prosthetic ankle-foot device or foot unit.

NOTE The above classifications/designations are also used in the examples of label layout (see 20.3 and Figure 14).

20 Labelling

20.1 General

Each prosthetic ankle-foot device or foot unit

a) for which compliance with the requirements of this International Standard is claimed (see 9.1 and 9.2) for a specific test loading level "P" (see 7.2) and

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 labelled in accordance with the classification/designation specified in 19.1. If appropriate, the label may include further information as shown in Figure 13 and addressed in 20.2.

The statements on the label 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.

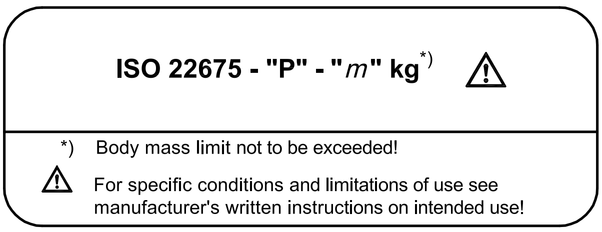


Figure 13 — General concept for the label layout

20.2 Use of mark "*)" and warning symbol

The **mark "*)"** behind "kg" shall allow reference to a brief statement on the label 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.

The **warning symbol** to be used in addition to the mark "*)" shall allow reference to a brief statement on the label regarding particular limitations of use, for example limitations concerning the activity of amputees. This is, for instance, the case if the stated body mass limit "m" exceeds the body mass limit of those amputees on whose locomotion data the stated test loading level "P" is based.

The use of mark "*)" and warning symbol is illustrated in the label models a) to c) of Figure 14, commented in 20.3.

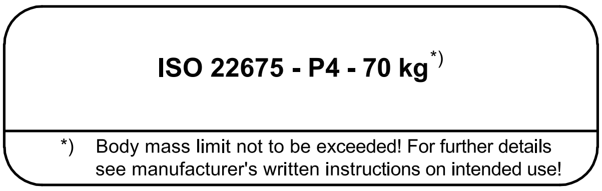
20.3 Examples of label layout

The layout of the label shall conform to any of the models a) to c) of Figure 14. The examples of classification/designation used in these models correspond to those used in EXAMPLES 1 to 3 of 19.2.

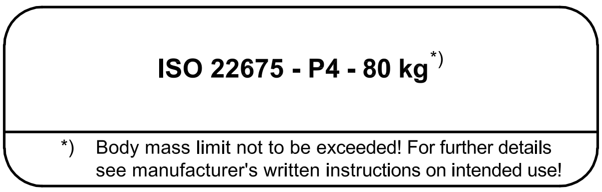
— The label according to model a) of Figure 14 shall apply to prosthetic ankle-foot devices and foot units corresponding to EXAMPLE 1 of 19.2, commented on in 19.2 a).

— The label according to model b) of Figure 14 shall apply to prosthetic ankle-foot devices and foot units corresponding to EXAMPLE 2 of 19.2, commented on in 19.2 b).

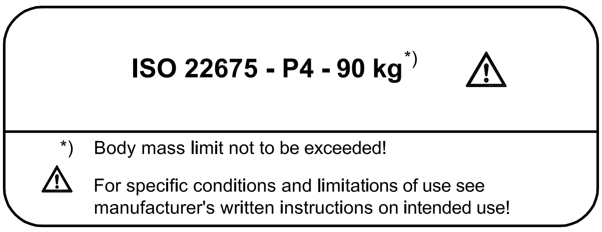
— The label according to model c) of Figure 14 shall apply to prosthetic ankle-foot devices and foot units corresponding to EXAMPLE 3 of 19.2, commented on in 19.2 c).



Model a)



Model b)



Model c)

Figure 14 — Models for the label layout

20.4 Label placement

The label shall be placed on the device and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the label 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 International Standard

A.1 Background statement

The test loading levels P5, P4 and P3 according to 7.2 of this International Standard correspond to the test loading levels P5, P4 and P3 according to 7.2 of ISO 10328:2006. These are based on data acquired at the time of development of ISO 10328:1996, 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 P4 and P3 are based on locomotion data from amputees whose body mass is less than 80 kg and 60 kg, respectively.

For the proposed additional test loading level P6 see Annex C.

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 International Standard 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 her/his 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 may 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 International Standard differs from that of the corresponding tests of ISO 10328, 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 International Standard are dealt with in detail in ISO/TR 22676 thus enabling the volume of this International Standard to be confined to only indispensible information. (For further information see Annex E and Bibliography.)

A.2.2 to A.2.4 present information on selected items, presented as extracts and summaries from ISO/TR 22676.

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

NOTE For the meaning of “reference” see also statements under “IMPORTANT” at the end of A.2.4.1 and A.2.4.2.

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).

a) According to Figure A.1 (p. 69), 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 α, β and γ.

The following equations apply:

$$\alpha + \beta = \gamma \quad \text{(A.1)}$$

$$\beta = \arctan (F_T/F_P) \quad \text{(A.2)}$$

b) The values of the tilting angles γ_1 and γ_2 of the foot platform for static and maximum cyclic heel and forefoot reference loading are consistent with those specified in ISO 10328 for the separate structural tests on ankle-foot devices and foot units. These values are γ_1 = – 15° for heel loading and γ_2 = 20° for forefoot loading (see Table 10, Figure 7 and subclause 17.2 of ISO 10328:2006 and Table 8 of this International Standard).

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 10328:2006 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 10328:2006).

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 equation (A.2) and the condition according to A.2.2.1 c) β = arctan (F_T/F_P) = arctan (± 0,15) = ± 8,5°.

— From equation (A.1) and the conditions according to A.2.2.1 b) $\alpha_1 = \gamma_1 - \beta_1$ = – 15° + 8,5° = – 6,5° and $\alpha_2 = \gamma_2 - \beta_2$ = 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 α_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 α_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 International Standard, 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 equation (A.3)

$$u(f) = f \tan (90 - \alpha) + u_0 \qquad \text{(A.3)}$$

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 α_1 and α_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 International Standard, this proportion shall 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 (p. 70).

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

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

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 International Standard 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 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 α_1 and α_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 F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} according to this International Standard (see Figure A.1) are consistent with the corresponding values F_{1x} and F_{2x} of the test forces F_1 and F_2 specified in ISO 10328:2006 for the separate tests on ankle-foot devices and foot units (see Tables 11 and D.3 of ISO 10328:2006). The specific values F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} are listed in Table A.1.

The specific values F_{1x} and F_{2x} of the test forces F_1 and F_2 related to the specific values F_{R1x} and F_{R2x} of the resultant reference forces F_{R1} and F_{R2} (see Figure A.1) are determined by the following equation, derived from the relationship described in A.2.2.1 a):

$$F_{1,\,2} = F_{R1,\,R2} \times \cos \alpha_{1,\,2} \qquad \text{(A.5)}$$

The specific values F_{1x} and F_{2x} of the test forces F_1 and F_2 calculated using equation (A.5) for α_1 = – 6,18° and α_2 = 11,14° (see A.2.2.2) are listed in Tables 9 and C.2.

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 10328:2006)								
	Symbol	Numerical values for heel and forefoot loading F_{1x} and F_{2x} at test loading level P_y							
		P6		P5		P4		P3	
		Heel	Forefoot	Heel	Forefoot	Heel	Forefoot	Heel	Forefoot
		N							
F_{R1sp}	F_{1sp},	2 800	—	2 240	—	2 065	—	1 610	—
F_{R2sp}	F_{2sp}	—	2 800	—	2 240	—	2 065	—	1 610
$F_{R1su,\ lower\ level}$	$F_{1su,\ lower\ level}$,	4 200	—	3 360	—	3 098	—	2 415	—
$F_{R2su,\ lower\ level}$	$F_{2su,\ lower\ level}$	—	4 200	—	3 360	—	3 098	—	2 415
$F_{R1su,\ upper\ level}$	$F_{1su,\ upper\ level}$,	5 600	—	4 480	—	4 130	—	3 220	—
$F_{R2su,\ upper\ level}$	$F_{2su,\ upper\ level}$	—	5 600	—	4 480	—	4 130	—	3 220
F_{R1cmax}	F_{1cr},	1 600	—	1 280	—	1 180	—	920	—
F_{R2cmax}	F_{2cr}	—	1 600	—	1 280	—	1 180	—	920
F_{R1fin}	F_{1fin},	2 800	—	2 240	—	2 065	—	1 610	—
F_{R2fin}	F_{2fin}	—	2 800	—	2 240	—	2 065	—	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 International Standard are determined by the parameters listed in a) to d). For the meaning of “reference” see “IMPORTANT”.

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 $\alpha_1 = -6{,}18°$ and $\alpha_2 = 11{,}14°$ (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 equation (A.5) for $\alpha_1 = -6{,}18°$ and $\alpha_2 = 11{,}14°$. These are specified in Table 9.

d) The tilting angles $\gamma_1 = -15°$ and $\gamma_2 = 20°$ of the foot platform for static (and maximum cyclic) heel and forefoot loading. These are specified in Table 8.

IMPORTANT — 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, since the concept of this International Standard 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 γ_1 or γ_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 γ_1 and γ_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 the statements of A.2.2 and A.2.3, the reference test loading conditions for cyclic loading according to this International Standard are determined by the parameters listed in a) and b). — [For the meaning of “reference” in a) see IMPORTANT of A.2.4.1 and for the meaning of “reference” in b) see IMPORTANT of this subclause.]

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 α (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 $F_c(\gamma)$ as illustrated in Figure 7. The instantaneous values of F_c are determined by equation (A.5) for the related instantaneous values of the resultant force F_R and the angle α (see Figure A.1).

   The description and specification of the profile of the test force $F_c(t)$ or $F_c(\gamma)$ 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 and Tables 10 and 11 and also by equation (4) of 13.4.2.9.

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

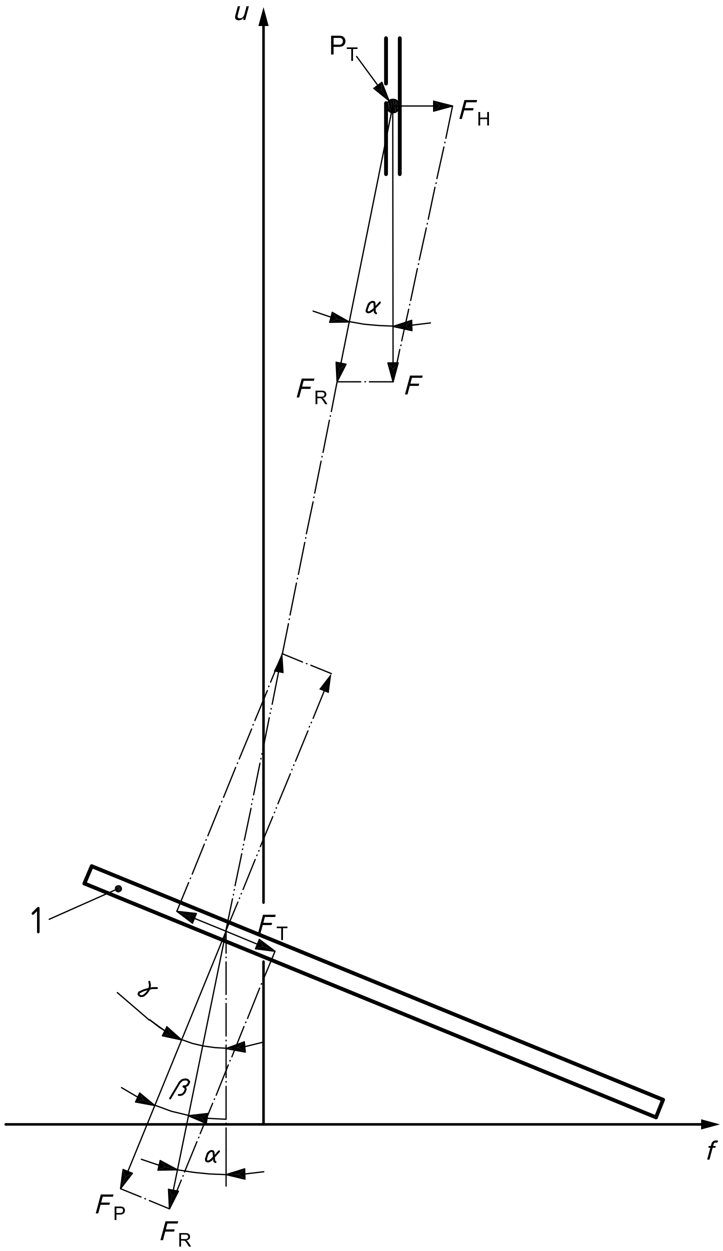
   The description and specification of the profile of the tilting angle $\gamma(t)$ of the foot platform is primarily based on the values $\gamma_1 = -15°$ (instant of 1st maximum F_{1cmax} of loading profile), $\gamma_{Fcmin} = 0°$ (instant of intermediate minimum F_{cmin} of loading profile) and $\gamma_2 = 20°$ (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 $\gamma(t)$ is given in Table 11 and also by equation (3) of 13.4.2.8.

IMPORTANT — 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 International Standard 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 $\gamma(t_x)$ 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 $\gamma = 0°$ 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

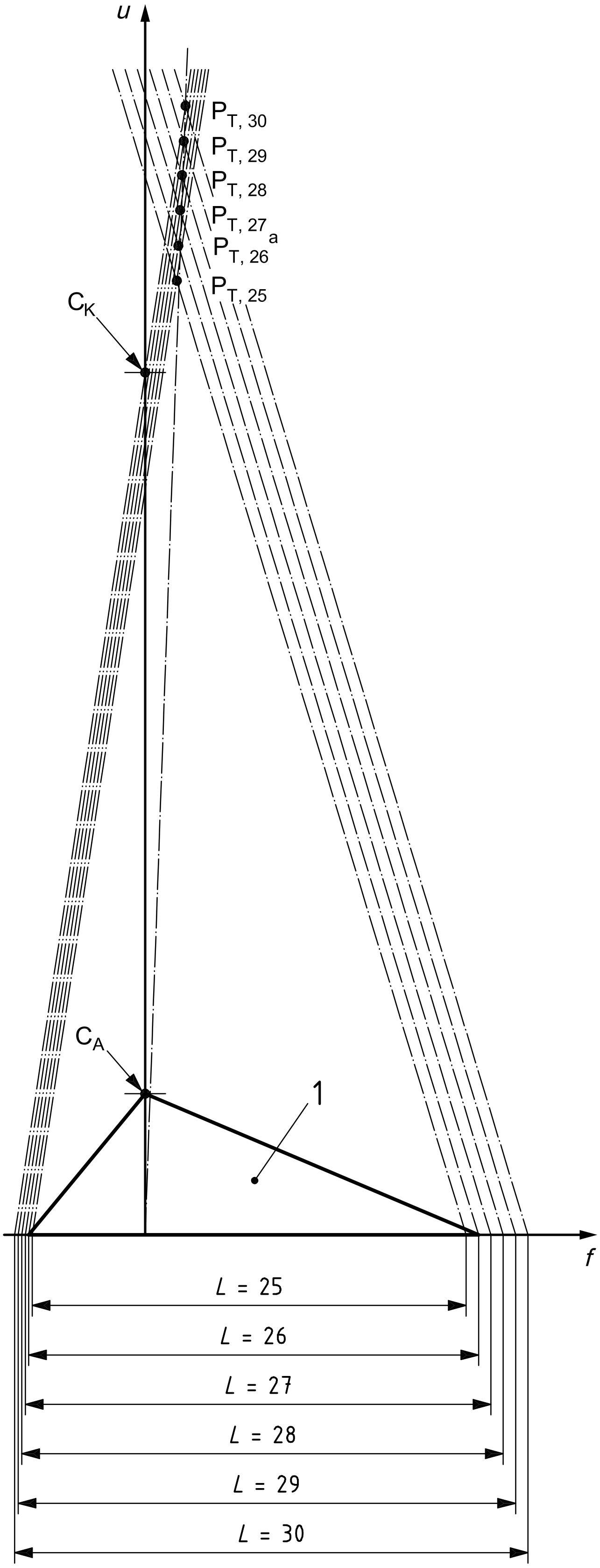
α inclination angle of line of action of resultant force F_R

β angle between resultant force F_R and force component F_P determining ratio F_T/F_P

γ tilting angle of foot platform

Figure A.1 — Illustration of different components of loading

Dimensions in millimetres



Key

1 symbolic view of foot

f, *u* axes of coordinate system

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).

Figure A.2 — Illustration of the dependence of the position of the top load application point P_T on the foot length L — (see A.2.2.3)

Annex B
(informative)

Guidance on the application of an alternative static ultimate strength test

B.1 Background statement

Due to the characteristics of most non-metallic materials used in lower limb prostheses, the rate of loading of between 100 N/s and 250 N/s, specified in 16.3.1.5 and 16.3.1.11 for the static ultimate strength test, may be too low.

To address this, an alternative static ultimate strength test is proposed in this annex, which applies higher rates of loading to be specified by the manufacturer/submitter of the sample under test. (Rates of between 1 kN/s and 5 kN/s are considered to be appropriate.)

This alternative static ultimate strength test is intended to be applied to samples with material properties and/or construction features which render them unable to sustain the required ultimate test force at a rate of loading specified for the standard static ultimate strength test previously referred to (e.g. structural members manufactured from materials subject to significant creep).

If the static ultimate strength test specified in 16.3.1 is conducted at a rate of loading higher than 250 N/s, the procedure includes the application of the static proof test specified in 16.2.1 and thus, if the required number of test samples from the prescribed batch complies with the performance requirements as specified in 16.3.2, additional static proof tests are unnecessary.

NOTE This alternative static ultimate strength test was first developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units of ISO 10328:2006. It has been adopted for the purposes of the static ultimate strength test of this International Standard.

B.2 Test procedure

a) Carry out steps 16.3.1.2 to 16.3.1.4 (16.3.1.8 to 16.3.1.10) of the static ultimate strength test.

b) Proceed with 16.3.1.5 (16.3.1.11) in the alternative way addressed therein and increase the test force F_1 (F_2) at the higher rate specified in the test submission document [see 12.3.4 b)] by the manufacturer/submitter of the test sample under test until the test sample fails, or the test force F_1 (F_2) attains the value of the ultimate test force $F_{1\text{su, upper level}}$ ($F_{2\text{su, upper level}}$) without failure of the test sample.

   Record the rate of loading and the highest value of the test force F_1 (F_2) reached during the test and whether failure has occurred.

c) If the test sample satisfies the performance requirements specified in 16.3.2, subject it to the static proof test specified in 16.2.1.1 and record the results.

d) To claim compliance with 16.3.3 and this annex B, the condition addressed in 16.3.3 b) shall be met. Record whether or not the test sample meets this condition.

Annex C
(informative)

Guidance on the application of an additional test loading level P6

C.1 Background statement

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, an additional test loading level, P6, is proposed in this annex. Additional test loading level P6 is derived from data acquired from measurements and testing of existing products in service. As an interim measure, pending validation, it is suggested that the test loading conditions specified in C.3 are appropriate.

NOTE Additional test loading level P6 was first developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units of ISO 10328:2006. It has been adopted for the purposes of the static and cyclic tests of this International Standard.

C.2 Test forces of the proof test of end attachments

The test forces of the proof test of end attachments shall be as specified in Table C.1

C.3 Test loading conditions

a) The test dimensions shall be as specified in Tables 6, 7 and 8.

b) The test forces and the prescribed number of cycles shall be as specified in Table C.2.

Table C.1 — Test forces of the proof test of end attachments for test loading level P6 (see 13.2.2.1)

End attachments for			Stabilizing test force, F_{stab}; (F_{Rstab}) [b] N	Settling test force, F_{set}; (F_{Rset}) [b] N	Proof test force, F_{pa}; (F_{Rpa}) [b] N
Test procedure	Test loading condition				
	Heel loading F_1 at $\gamma = -15°$	Forefoot loading F_2 at $\gamma = 20°$			
All tests [a]	•		50	1 273; (1 280)	6 681; (6 720)
		•		1 256; (1 280)	6 593; (6 720)

a End attachments that satisfy the stiffness requirements of the proof test of end attachments for proof test force $F_{pa} = 1{,}2\, F_{su,\ upper\ level}$ of test loading level P6 specified in this table are suitable for the static and cyclic tests of this International Standard carried out at test loading level P6 and at all lower levels.

For sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard and/or to the specific requirements of the ankle-foot devices or foot units submitted for test, particular conditions may apply (see the OPTION described in 13.2.2.1).

b The relationship between the values of F_x and F_{Rx} (placed in parentheses) is determined by equation (A.5), using the values of α_1 and α_2 specified in A.2.3. The values of F_{Rx} are calculated from the relevant values listed in Table A.1 (see A.2.3), using the factors specified in Table 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 C.2 — Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading level P6 (see 16.2, 16.3 and 16.4)

Test procedure and test force			Unit	Test loading condition	
				Heel loading, F_{1x}	**Heel loading**, F_{1x}
Static test procedure	Static proof test force	F_{1sp}	N	2 784	—
		F_{2sp}		—	2 747
	Static ultimate test force	$F_{1su, lower level}$	N	4 176	—
		$F_{2su, lower level}$		—	4 121
		$F_{1su, upper level}$	N	5 567	—
		$F_{2su, upper level}$		—	5 494
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax}	N	1 591	—
	Intermediate minimum value of pulsating test force	F_{cmin}	N	1 063	
	2nd maximum value of pulsating test force	F_{2cmax}	N	—	1 570
	Final static test force	F_{1fin} (= F_{1sp})	N	2 784	—
		F_{2fin} (= F_{2sp})		—	2 747
	Prescribed number of cycles		1	2×10^6	

NOTE The specific values of the different test forces are based on reference values, as described in A.2.2.2.

Annex D
(informative)

Summary of the records to be entered in the test laboratory/facility log

D.1 Log records required for equipment

D.1.1 Specific records of types of equipment

The specific types of equipment (end attachments, jigs, measuring devices, test equipment) used, together with a statement of essential features of the system, if appropriate, in accordance with 13.1 to 13.4.

D.1.2 Specific records of proof test of end attachments

a) The details of the assembly of end attachments, in accordance with 13.2.2.2.1;

b) the details of the adjustment of the top and bottom load application points P_T and P_B, in accordance with 13.2.2.2.2;

c) 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, in accordance with 13.2.2.2.3;

d) the values of the displacements δ_1 and δ_2 of the moving load application point from its reference position in the test equipment, in accordance with 13.2.2.2.5 and 13.2.2.2.6;

e) 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, in accordance with 13.2.2.2.6;

f) the value of the displacement δ_3 of the moving load application point from its reference position in the test equipment, in accordance with 13.2.2.2.7;

g) the values of the deflection D_1 and the permanent deformation D_2, in accordance with 13.2.2.2.8;

h) the results in accordance with 13.2.2.2.10.

D.1.3 Specific records of accuracy

a) Details of the methods used to measure accuracy and the calibration of the test equipment and any jig and measuring device in accordance with 14.1;

b) the accuracy of equipment, i.e. the 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, in accordance with 14.2;

c) the accuracy of procedure, i.e. the 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, in accordance with 14.3.

D.2 Log records required for test samples

a) a fully traceable identification for each sample tested and the date of submission – applied on submission. If the sample has no permanent identification mark, the test laboratory/facility shall affix one after the test/tests has/have been completed;

b) a certificate of sampling from the normal production line, if appropriate, in accordance with 10.1.1;

c) the type of sample in accordance with 10.2.1 or 10.2.2. In special cases refer to the test submission document;

d) the size of foot selected providing the worst-case loading in accordance with 10.1.2;

e) the type and identification of that part of the remainder of the test sample, to which the ankle-foot device or foot unit is connected in accordance with 10.3.4;

f) the worst-case alignment position in accordance with 10.6, specified in the test submission document;

g) the combination of segment lengths selected for the end attachments to achieve the fixed total length, specified in Table 7, in accordance with 10.3.3;

h) the load application adaptor or lever used in accordance with 11.4; if this is attached by the manufacturer/submitter, a fully documented test certificate shall be supplied by the manufacturer/submitter;

i) the alignment in accordance with 10.5 and 11.7;

j) the test loading condition and/or loading level with which compliance or non-compliance shall be demonstrated in accordance with 16.2.1.2, 16.3.1.2 and/or 16.4.1.3.

D.3 Log records required for tests

D.3.1 General records of all tests

a) The particular tests carried out in accordance with the relevant clauses of this International Standard; in special cases reference to the test submission document will be necessary;

b) the particular dimensions set and loads applied during the tests in accordance with the relevant clauses of this International Standard; in special cases reference to the test submission document will be necessary;

c) the date(s) at which the test(s) has/(have) been carried out;

d) the test results, i.e. the statement that the ankle-foot device or foot unit submitted for test complies with the requirements of this International Standard, or the reason why it does not comply with these requirements.

D.3.2 Specific records of static proof tests

D.3.2.1 For each test sample of the ankle-foot device or foot unit submitted for test, taken from the prescribed batch according to 16.2.3, records of

a) the application of the static proof test as part of the alternative static ultimate strength test of Annex B in accordance with 16.2.1.1, Clause B.1 and B.2 c) [see also D.4.1 b)];

b) the realignment and re-use of a test sample that has completed the cyclic test procedure (including the final static test) without failing, in accordance with 16.2.1.2;

c) the test loading level to be applied, together with the corresponding values of tilting angles of the foot platform and test forces, making specific reference to the application of the additional test loading level P6, specified in Annex C, if appropriate, in accordance with 16.2.1.2;

d) the use of a special jig in accordance with 16.2.1.2;

e) 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, in accordance with 16.2.1.3;

f) the finding whether or not the test sample sustains heel loading by the proof test force F_{1sp} and, if it does not, 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 in accordance with 16.2.1.5;

g) the decision on the application of the test procedure in forefoot loading in accordance with 12.3.3 and 16.2.1.5;

h) upon inspection of the test sample, the nature and, if possible, the location of any damage in accordance with 16.2.1.6;

i) the individual settings for the arrangement of the foot platform for forefoot loading, including the positioning of the specific heel block, in accordance with 16.2.1.7;

j) the finding whether or not the test sample sustains forefoot loading by the proof test force F_{2sp} and, if it does not, 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 in accordance with 16.2.1.8;

k) upon inspection of the test sample, the nature and, if possible, the location of any damage in accordance with 16.2.1.9;

l) the decision on whether or not the test sample has passed the test procedure in heel loading and the test procedure in forefoot loading in accordance with 16.2.1.10;

m) the repetition of the test on a substitute test sample if a test sample, which has already passed the cyclic test for ankle-foot devices and foot units, fails to satisfy the performance requirement of 16.2.2 in heel loading or in forefoot loading, including all specific records called for [a) to l)], in accordance with 16.2.1.11.

D.3.2.2 For the ankle-foot device or foot unit submitted for test records of the decision on the compliance with the static proof test for ankle-foot devices and foot units of this International Standard in accordance with 16.2.3, resulting in

a) a statement of compliance or

b) a record of the reason or reasons why compliance cannot be claimed.

D.3.3 Specific records of static ultimate strength tests

D.3.3.1 For each test sample of the ankle-foot device or foot unit submitted for test, taken from the prescribed batch according to 16.3.3, records of

a) the application of the alternative static ultimate strength test of Annex B in accordance with 16.3.1.1, 16.3.1.5 and 16.3.1.11 [see f) and p)] [and also 16.3.1.17 as an option – see x)]. [For details of the application see D.4.1 a)];

b) the realignment and re-use of a test sample that has completed the static proof test and/or the cyclic test procedure (including the final static test) without failing, in accordance with 16.3.1.2;

c) the test loading level to be applied, together with the corresponding values of the tilting angle γ_1 of the foot platform and the test force F_1, making specific reference to the application of the additional test loading level P6 specified in Annex C, if appropriate, in accordance with 16.3.1.2;

d) the use of a special jig in accordance with 16.3.1.2;

e) 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, in accordance with 16.3.1.3;

f) the highest value of the test force F_1 reached during the test in heel loading, the rate of loading and whether failure has occurred, making specific reference to the application of test force F_1 at a higher rate of loading [see a)], if appropriate, in accordance with 16.3.1.5;

g) at the request of the manufacturer/submitter, the results of the continuation of the test in heel loading until failure actually occurs in accordance with 12.3.4 and 16.3.1.5;

h) the decision on whether the test sample passes or fails the test in heel loading in accordance with 16.3.1.6;

i) the results of the static proof test specified in 16.2.1.1, to which a test sample has to be subjected after having passed the test in heel loading at test force F_1 at a higher rate of loading [see a) and f)], in accordance with 16.3.1.6;

j) the decision on the application of the test procedure in forefoot loading in accordance with 12.3.3 and 16.3.1.6;

k) upon inspection of the test sample, the nature and, if possible, the location of any damage in accordance with 16.3.1.7;

l) the realignment and re-use of a test sample that has completed the static proof test and/or the cyclic test procedure (including the final static test) without failing, in accordance with 16.3.1.8;

m) the test loading level to be applied, together with the corresponding values of the tilting angle γ_2 of the foot platform and the test force F_2, making specific reference to the application of the additional test loading level P6 specified in Annex C, if appropriate, in accordance with 16.3.1.8;

n) the use of a special jig in accordance with 16.3.1.8;

o) the individual settings for the arrangement of the foot platform for forefoot loading, including the positioning of the specific heel block, in accordance with 16.3.1.9;

p) the highest value of the test force F_2 reached during the test in forefoot loading, the rate of loading and whether failure has occurred, making specific reference to the application of test force F_2 at a higher rate of loading [see a)], if appropriate, in accordance with 16.3.1.11;

q) at the request of the manufacturer/submitter, the results of the continuation of the test in forefoot loading until failure actually occurs in accordance with 12.3.4 and 16.3.1.11;

r) the decision on whether the test sample passes or fails the test in forefoot loading in accordance with 16.3.1.12;

s) the results of the static proof test specified in 16.2.1, to which a test sample shall be subjected after having passed the test in forefoot loading by the test force F_2 at a higher rate of loading [see a) and p)], in accordance with 16.3.1.12;

t) upon inspection of the test sample, the nature and, if possible, the location of any damage in accordance with 16.3.1.13;

u) the decision on whether or not the test sample referred to in 16.3.1.2 has passed the test procedure in heel loading (16.3.1.2 to 16.3.1.5) and the test sample referred to in 16.3.1.8 has passed the test procedure in forefoot loading (16.3.1.8 to 16.3.1.11) in accordance with 16.3.1.14;

v) the repetition of the test on a substitute test sample in the failed direction of loading if a test sample that has already passed the static proof test and/or the cyclic test, fails to satisfy either of the performance requirements of 16.3.2 in heel loading or in forefoot loading, including all specific records called for [a) to u)], in accordance with 16.3.1.15;

w) the repetition of the test on a substitute test sample in the failed direction of loading if a test sample that has already passed the static ultimate strength test in one direction of loading, fails this test in the other direction of loading, including all specific records called for [a) to u)], in accordance with 16.3.1.16;

x) (as an option) the repetition of the test on a substitute test sample in the failed direction of loading at an increased rate of loading [see a)] if a test sample fails this test in one direction of loading at a rate of loading of between 100 N/s and 250 N/s, including all specific records called for [a) to u)], in accordance with 16.3.1.17.

D.3.3.2 For the ankle-foot device or foot unit submitted for test records of the decision on the compliance with the static ultimate strength test for ankle-foot devices and foot units of this International Standard in accordance with 16.3.3, resulting in

a) a statement of compliance or

b) a record of the reason or reasons why compliance cannot be claimed.

D.3.4 Specific records of cyclic tests

D.3.4.1 For each test sample of the ankle-foot device or foot unit submitted for test, taken from the prescribed batch according to 16.4.3, records of

a) the test loading level to be applied, together with the corresponding profiles of the tilting angle $\gamma(t)$ of the oscillating foot platform and the pulsating test force $F_{c}(t)$ or $F_{c}(\gamma)$, making specific reference to the application of the additional test loading level P6 specified in Annex C, if appropriate, in accordance with 16.4.1.3;

b) the use of a special jig in accordance with 16.4.1.3;

c) 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, in accordance with 16.4.1.4;

d) the individual settings of the means of resistance to dislocation of the test sample during its lift-off phase in accordance with 16.4.1.5;

e) the finding whether or not the test sample sustains heel loading by the maximum test force F_{1cmax} and forefoot loading by the maximum test force F_{2cmax} and, if it does not, the highest value of test force reached in each direction of loading in accordance with 16.4.1.6;

f) the decision on the termination of the test in accordance with 16.4.1.6;

g) the frequency called for in accordance with 12.3.5 a), together with the number of cycles required to settle down, in accordance with 16.4.1.7;

h) a statement whether the profiles of the test force $F_{c}(t)$ or $F_{c}(\gamma)$ and the tilting angle $\gamma(t)$ of the oscillating foot platform are applied in accordance with 13.4.2.10, 14.3 f), g) and h), in accordance with 16.4.1.7;

i) the agreement on a frequency differing from the prescribed value in accordance with 16.4.1.7;

j) the termination of the test, if the pulsating test force $F_c(t)$ or $F_c(\gamma)$ and/or the tilting angle $\gamma(t)$ of the oscillating foot platform cannot be applied at any frequency agreed upon between the test laboratory/facility and the manufacturer/submitter, in accordance with 16.4.1.7;

k) the frequency applied, i.e. the frequency called for or agreed upon [see g) and i)], together with the results of the inspection of the waveform and the decision on the continuation of the test in accordance with 16.4.1.8;

l) the details of the exchange/replacement of specified parts, including the number of cycles at shutdown and the conditions of the restart of the test in accordance with 12.3.5 b), 16.4.1.2 a) and 16.3.1.9;

m) the number of cycles at shutdown and whether failure has occurred, in accordance with 16.4.1.10;

n) the finding whether or not the test sample that has passed the cyclic test sustains the final static loading successively applied by the test force F_{1fin} to the heel and by the test force F_{2fin} to the forefoot and, if it does not, 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 in accordance with 16.4.1.11;

o) the decision on whether the test sample has passed or failed the cyclic test procedure in accordance with 16.4.1.12;

p) upon inspection of the test sample, the nature and, if possible, the location of any damage in accordance with 16.4.1.13;

q) upon visual examination of the test sample at the request of the manufacturer/submitter, the presence, location and nature of any fractures and/or cracks, together with the magnification used, in accordance with 12.3.4 c), 16.4.1.2 c) and 16.4.1.14.

D.3.4.2 For the ankle-foot device or foot unit submitted for test records of the decision on the compliance with the cyclic test for ankle-foot devices and foot units of this International Standard in accordance with 16.4.3.1, resulting in

a) a statement of compliance or

b) a record of the reason or reasons why compliance cannot be claimed.

D.4 Log records required for the alternative static ultimate strength tests according to Annex B

D.4.1 For each test sample of the ankle-foot device or foot unit submitted for test, taken from the prescribed batch according to 16.3.3, records of

a) the rate of loading and the highest value of test force and whether failure has occurred in accordance with B.2 b) [see also D.3.3.1 a)];

b) the results of the subsequent static proof test in accordance with B.2 c) [see also D.3.2.1 a)].

D.4.2 For the ankle-foot device or foot unit submitted for test records of the decision on the compliance with the alternative static ultimate strength test for ankle-foot devices and foot units of this International Standard in accordance with B.2 d), resulting in

a) a statement of compliance or

b) a record of the reason or reasons why compliance cannot be claimed.

Annex E
(informative)

Information on Technical Report ISO/TR 22676 [1]

E.1 Background statement

The guidance offered in ISO/TR 22676 has required extensive analytical work which would have enlarged this International Standard without directly supporting its application.

Most of the results from this work support, however, the understanding of the theoretical and technical background and provide valuable findings concerning the design of appropriate test equipment.

The guidance offered can also serve as a basis for deliberations and decisions on a uniform design concept for the test equipment required, in order to optimize the conditions of comparability of test results achieved at different places.

ISO/TR 22676 is, therefore, considered to be an appropriate means to make this information accessible to all interested parties.

E.2 Contents of ISO/TR 22676

For ease in handling, Table E.1 lists the contents of ISO/TR 22676:2006 and also indicates, which of the items covered are also dealt with in this International Standard.

Table E.1 — Contents of ISO/TR 22676 and list of corresponding clauses/subclauses of this International Standard, in which selected items are dealt with

Clauses and subclauses of ISO/TR 22676:2006			Corresponding clauses/subclauses of this standard	
No.	**Heading**	**Page**	**No.**	**Page**
2	Guidance on the specification of the test loading conditions of ISO 22675	1	A.2	63
2.1*	General	1	A.2.1	63
2.2	Directions of static and maximum cyclic heel and forefoot reference loading	1	A.2.2	64
2.2.1**	Basic relationships and conditions	1	A.2.2.1	64
2.2.2*	Lines of action of the resultant reference forces F_{R1} and F_{R2}	2	A.2.2.2	64
2.2.3*	Position of the top load application point P_T	3	A.2.2.3	65
2.3**	Magnitudes of static and maximum cyclic heel and forefoot reference loading	6	A.2.3	66
2.4	Reference test loading conditions of static and cyclic tests	7	A.2.4	67
2.4.1**	Static tests	7	A.2.4.1	67
2.4.2**	Cyclic test	8	A.2.4.2	67
3	Guidance on the design of appropriate test equipment for the application of ISO 22675	20	—	—
3.1	Background statement	20	—	—
3.2	Basic design for test equipment	20	—	—
3.3	Design variants for load application	24	—	—
3.3.1	General	24	—	—
3.3.2	Design variant A	24	—	—
3.3.3	Design variant B	24	—	—
3.3.4	Main differences between design variants A and B	25	—	—
3.4	Examples of crank gear designs	25	—	—
3.4.1	General	25	—	—
3.4.2	Asymmetrical (60:40) crank gear	25	—	—
3.4.3	Symmetrical (50:50) crank gear	26	—	—
3.5	Effect of deviations of the tilting angle $\gamma(t)$ from the specified profile (curve), addressed in 3.4, on the test loading conditions of ISO 22675	30	—	—
3.6	Effect of the position of the tilting axis TA of the foot platform on the elevation E and A-P displacement Δf of the test sample at the foot	35	E.3.2	82
3.6.1*	General	35	E.3.2.1	82
3.6.2	Position of the tilting axis TA of the foot platform	36	—	—
3.6.3	Values of elevation E	36	—	—
3.6.4	Values of A-P displacement Δf	37	—	—
3.6.5**	Conclusions	39	E.3.2.2	82
3.7*	Effect of the elevation E and A-P displacement Δf of the test sample, caused by the tilting of the foot platform, on the test loading conditions of ISO 22675	43	E.3.3	83
3.8	Transposition of the top load application point P_T for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L	49	E.3.4	86
3.8.1**	General	49	E.3.4.1	86
3.8.2**	Possibilities of transposing the top load application point P_T	49	E.3.4.2	86
3.8.3**	Practicality	50	E.3.4.3	87
3.9	Effect of the position of the tilting axis TA of the foot platform on the tilting moment and the driving torque	53	—	—
3.10	Alternative design of foot platform	58	—	—

NOTE Items of subclauses marked ** are fully included in Annexes A and E; items of subclauses marked * are only covered in part.

E.3 Selected items of ISO/TR 22676

E.3.1 General

In addition to the information on ISO/TR 22676 given in E.2, selected items of the technical report directly related to specific normative elements of the main body of this International Standard are addressed in A.2 and E.3.

E.3.2 Effect of the position of the tilting axis TA of the foot platform on the elevation E and the A-P displacement Δf of the test sample at the foot

E.3.2.1 General

The tilting of the foot platform during the cyclic test up to the values occurring at the instant of heel contact ($\gamma_{HC} = -20°$) and at the instant of toe-off ($\gamma_{TO} = 40°$), specified in Table 11, can move the ankle-foot device or foot unit by considerable amounts of both elevation E, illustrated in Figure E.1, and A-P displacement Δf, illustrated in Figure E.2.

This is not desirable, particularly because any A-P displacement Δf of a test sample at the foot will result in an angular movement $\Delta\varphi$ of the test sample about the top load application point P_T, as addressed in E.3.3. The higher the maximum value of A-P displacement Δf, the greater the angular movement $\Delta\varphi$ and hence, the greater the deviations from the specified test loading conditions will be.

As a general rule, the maximum value of angular movement $\Delta\varphi$ about the top load application point P_T at the instants of F_{1cmax} (1st maximum of the loading profile) and F_{2cmax} (2nd maximum of the loading profile) should not exceed 1°.

As is demonstrated in 4.6 of ISO/TR 22676:2006, this can be achieved by an appropriate positioning of the tilting axis TA of the foot platform.

E.3.2.2 Conclusions

The analysis in 4.6 of ISO/TR 22676:2006 indicates the position of the tilting axis TA, which minimizes the values of the elevation E and the A/P displacement Δf, at

$$f_{TA,\ L} = 0{,}365\ L \text{ and } u_{TA,\ L} = 0{,}1\ L$$

where L is the foot length in centimetres.

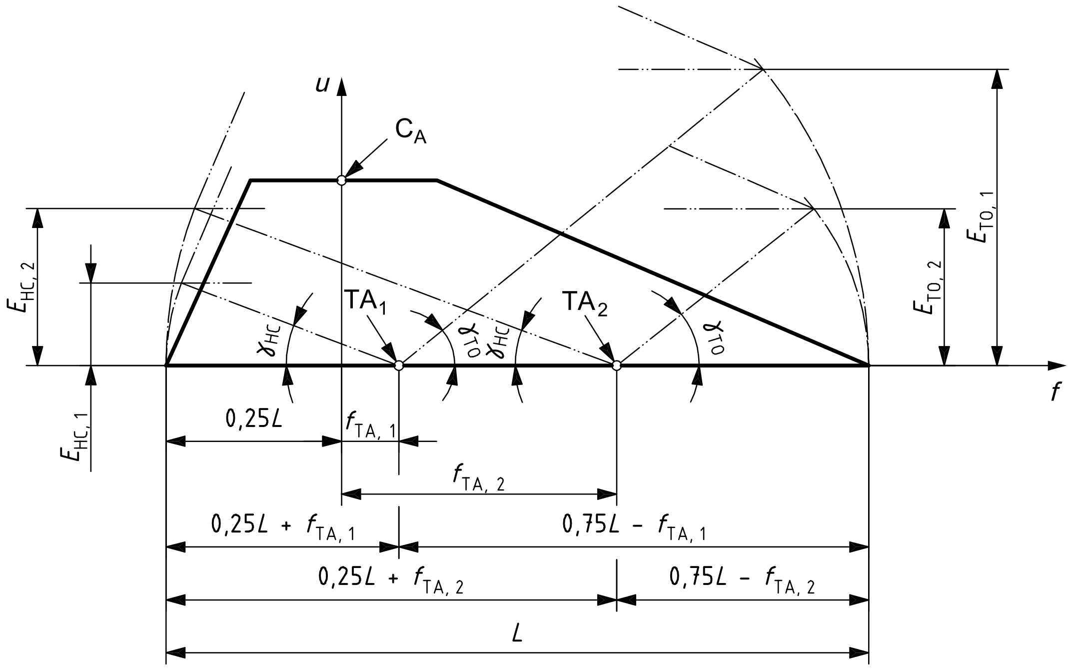
The coordinates clearly indicate a dependence of the position of the tilting axis TA on the foot length L.

The coordinates $f_{TA,\ L}$ and $u_{TA,\ L}$ are specified in Table 7 for a wide range of foot lengths, L. In addition, Table 7 includes the above equations that determine these coordinates for any other foot length.

NOTE The position of the tilting axis TA specified above is also illustrated in Figure E.5.

In order to limit the complexity of the design of the foot platform, it is possible to regard the dependence of the position of its tilting axis TA on the foot length, L by a corresponding transposition of the related top load application point P_T, which needs to be adjusted anyway, since it is also dependent on the foot length L.

This can be carried out in several ways, described in E.3.4.



Key

f, u	axes of coordinate system
C_A	effective ankle-joint centre
$TA_{1, 2}$	specific positions of tilting axis of foot platform on f-axis
L	foot length
γ_{HC}	tilting angle of foot platform at instant of heel contact ($\gamma_{HC} = -20°$)
γ_{TO}	tilting angle of foot platform at instant of toe-off ($\gamma_{TO} = 40°$)
$E_{HC, 1, 2}$	specific values of elevation at instant of heel contact, related to specific positions of tilting axis TA of foot platform
$E_{TO, 1, 2}$	specific values of elevation at instant of toe-off, related to specific positions of tilting axis TA of foot platform

Figure E.1 — Effect of f-position of tilting axis TA of foot platform on the elevation E of the foot at the instants of heel contact and toe-off

E.3.3 Effect of the elevation E and A-P displacement Δf of the test sample, caused by the tilting of the foot platform, on the test loading conditions of this International Standard

The elevation E and the A-P displacement Δf of the test sample at the foot, caused by the tilting of the foot platform during the cyclic test up to the values of γ_{HC} and γ_{TO} occurring at the instants of heel contact and toe-off at magnitudes depending on the position of the tilting axis TA of the foot platform, is described in detail in E.3.2 and illustrated in Figures E.1 and E.2.

One example of the effect of elevation E and A-P displacement Δf of the test sample at the foot on the test loading conditions of this International Standard is illustrated in Figure E.3.

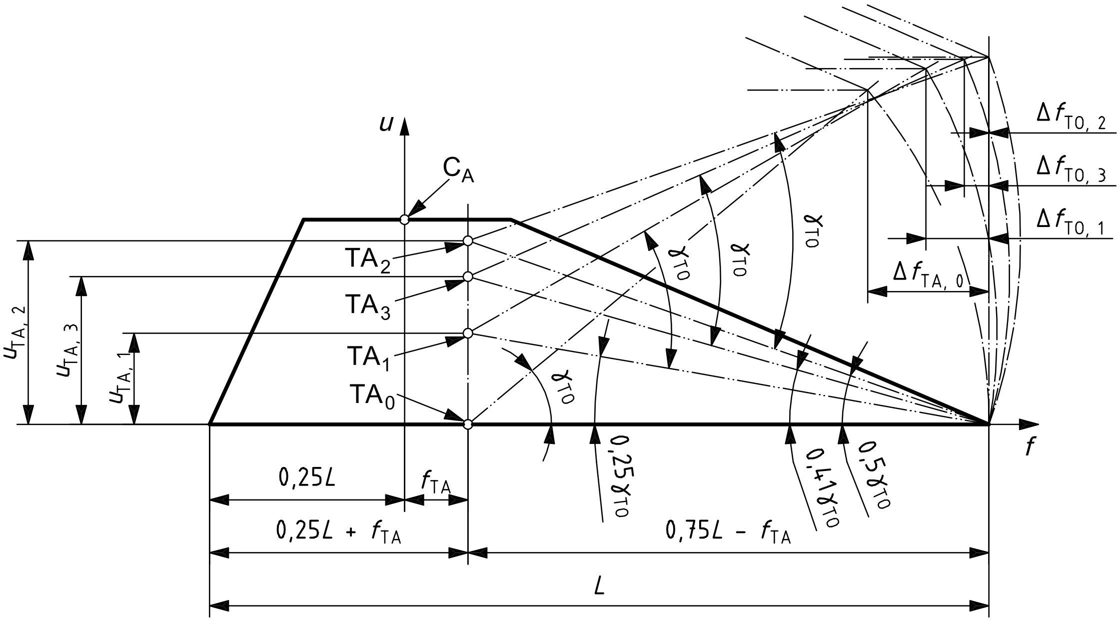
The situation illustrated in Figure E.3 is determined by

— a specific position of the top load application point P_T at $f_{T, L}$ and $u_{T, L}$ relevant to a specific foot length L;

— a position of the tilting axis TA of the foot platform on a straight line passing through the top load application point P_T parallel to the u-axis;

— a (fictitious) design of ankle-foot device or foot unit with a plane foot sole, illustrated by a symbolic view of foot;

— the instant of toe-off at a tilting angle of the foot platform of $\gamma_{TO} = 40°$, specified in Table 11.



Key

f, u	axes of coordinate system
C_A	effective ankle-joint centre
$TA_{0...3}$	specific positions of tilting axis of foot platform on a straight line parallel to u-axis
L	foot length
γ_{TO}	tilting angle of foot platform at instant of toe-off (γ_{TO} = 40°)
$\Delta f_{TO,\ 0...3}$	specific values of A-P displacement at instant of toe-off, related to specific positions of tilting axis TA of foot platform

Figure E.2 — Effect of u-position of tilting axis TA of foot platform on the A/P displacement Δf of the foot at the instant of toe-off

From the illustrations of Figure E.3 the following can be concluded.

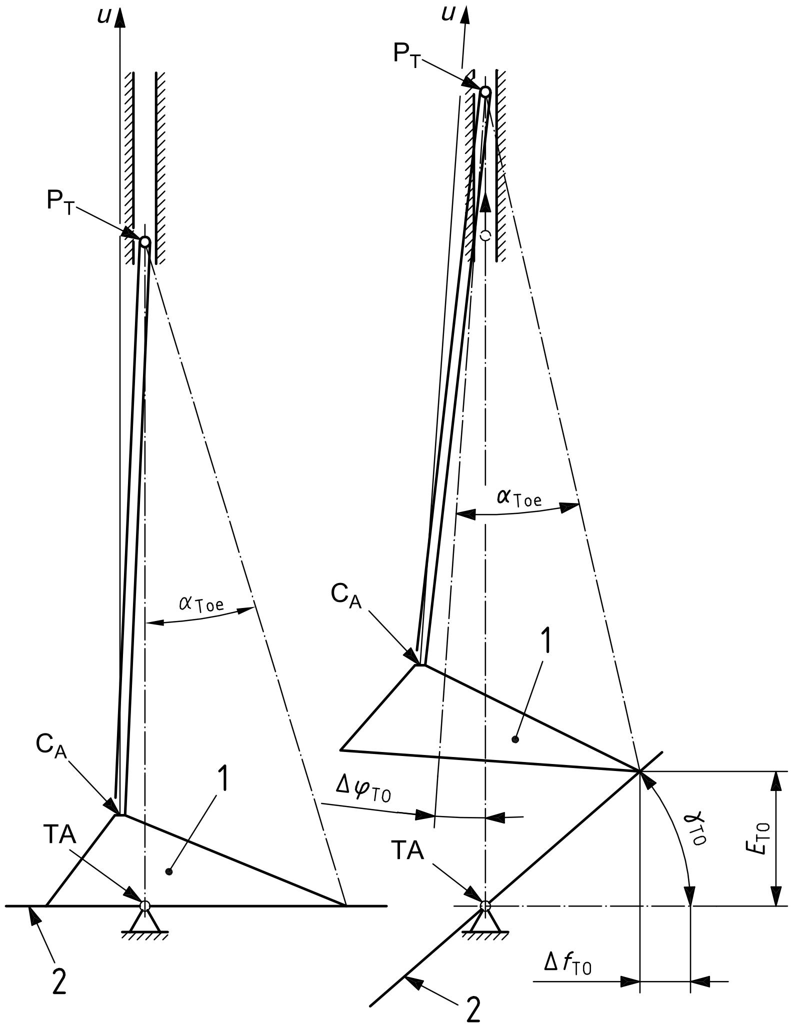
a) The elevation E_{TO} and the A-P displacement Δf_{TO} of the test sample at the point of the foot, caused by the tilting of the foot platform at an angle of γ_{TO}, results in an angular movement of the test sample about the top load application point P_T by $\Delta\varphi_{TO}$.

b) The angular movement of the test sample about the top load application point P_T increases the angle between the foot (sole) and (the contact surface of) the foot platform at a total of $\gamma_{TO,\ total} = \gamma_{TO} + \Delta\varphi_{TO}$.

c) Apparently, a deviation of the tilting angle, γ of the foot platform from the specified profile (curve) will affect the values of the angles α and β, related to the tilting angle γ by the equation $\alpha + \beta = \gamma$ [see equation (A.1) and Figure A.1].

As is demonstrated in 4.7 of ISO/TR 22676:2005 for a test sample set-up with an ankle-foot device or foot unit of foot length L = 30 cm and a position of the top load application point P_T at $f_{T,\ 30}$ = 25 mm and $u_{T,\ 30}$ = 667 mm according to A.2.2.3 and Table 7 in an arrangement according to 13.4.2 and Figure 5, a position of the tilting axis TA of the foot platform at $f_{TA,\ 30}$ = 0,365 × 30 cm = 110 mm and $u_{TA,\ 30}$ = 0,10 × 30 cm = 30 mm according to E.3.2.2 will keep the angular movement $\Delta\varphi$ of this test sample within a range of 0,7° anterior $\leqslant \Delta\varphi \leqslant$ 0,7° posterior.

NOTE Only for orientation it is mentioned here, that a position of the tilting axis TA of the foot platform at f_{TA} = 25 mm and u_{TA} = 0 mm, as illustrated in Figure E.1, will result in a range of angular movement $\Delta\varphi$ of the same test sample of 0,5° anterior $\leqslant \Delta\varphi \leqslant$ 4° posterior.



Key

1 symbolic view of foot

2 foot platform

C_A ankle reference centre

P_T top load application point

TA tilting axis of foot platform

Figure E.3 — Illustration of the effect of A-P displacement Δf on the angular movement $\Delta \varphi$ of the test sample about the top load application point P_T

E.3.4 Transposition of the top load application point P_T for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L

E.3.4.1 General

As already indicated in E.3.2.2, it is possible to take account of the dependence of the position of the tilting axis TA of the foot platform on the foot length L by a corresponding transposition of the related top load application point P_T, which needs to be adjusted anyway, since it is also dependent on the foot length L.

This procedure has two advantages:

— It simplifies the setting-up of the test sample in the test equipment, since it reduces the amount of adjustment work and

— it does not necessarily require a design of the foot platform that allows the position of its tilting axis TA to be adjusted (but see NOTES to E.3.4.2).

E.3.4.2 Possibilities of transposing the top load application point P_T

According to Figure E.4, the procedure addressed in E.3.4.1 can be carried out in principle by

a) specifying a fixed standard or compromise position of the tilting axis TA of the foot platform, determined by the offsets $f_{TA, 20}$ and $u_{TA, 32}$ (see NOTE 1) or $u_{TA, C}$, respectively (see NOTE 2),

b) transposing the top load application point $P_{T, L}$ relevant to a specific foot length L of the test sample parallel to the f-axis by $\Delta f_{TA, L}$, the value of $\Delta f_{TA, L} = (f_{TA, 20} - f_{TA, L})$ representing the difference between the offset $f_{TA, 20}$ of the fixed position of the tilting axis TA [see a)] and its offset $f_{TA, L}$ relevant to a specific foot length L (see Table E.2),

c) transposing the top load application point $P_{T, L}$ relevant to a specific foot length L of the test sample parallel to the u-axis by $\Delta u_{TA, L}$ [see 1)] or $\Delta u_{TA, C}$ [see 2)], where

1) the value of $\Delta u_{TA, L} = (u_{TA, 32} - u_{TA, L})$ represents the difference between the offset $u_{TA, 32}$ of the fixed position of the tilting axis TA [see a)] and its offset $u_{TA, L}$ relevant to a specific foot length L, and

2) the value of $\Delta u_{TA, C} = (u_{TA, 32} - u_{TA, C})$ represents the difference between the offset $u_{TA, 32}$ of the fixed position of the tilting axis TA [see a)] and a specified compromise offset $u_{TA, C}$ of the tilting axis TA of the foot platform, uniformly applied to test samples of any foot length L,

the values of $\Delta u_{TA, L}$ and $\Delta u_{TA, C}$ corresponding to the thickness of the compensation plates used for the elevation of the contact surface of the foot platform required to adapt it to the value of $u_{TA, L}$ or $u_{TA, C}$, respectively (but see NOTE 3).

The results of c) 1) and c) 2) are also listed in Table E.2.

NOTE 1 The possibilities of transposing the top load application point P_T shown in E.3.4.2, Figure E.4 and Table E.2 require the fixed standard position of the tilting axis TA to be determined by a value of $f_{TA, L}$ relevant to the smallest size and a value of $u_{TA, L}$ relevant to the largest size of foot covered by the range of foot lengths 20 cm $\leqslant L \leqslant$ 32 cm, which is considered to cover the vast majority of sizes expected to be submitted for test. If appropriate, this range can easily be extended to smaller or larger sizes with subsequent changes of the values of $\Delta f_{TA, L}$, $\Delta u_{TA, L}$ and $\Delta u_{TA, C}$.

NOTE 2 As is demonstrated in 3.8 of ISO/TR 22676:2006, the most appropriate <u>uniform</u> compromise offset $u_{TA, C}$ of the tilting axis TA of the foot platform addressed in c) 2) is $u_{TA, C}$ = 26 mm (0,1 L according to E.3.2.2 for a foot of the length L = 26 cm) applicable to all foot lengths L, applied together with the <u>individual</u> offset f_{TA} = 0,365 L according to E.3.2.2 relevant to each individual foot length L (see Figure E.5). The resulting displacements Δf will cause angular movements $\Delta\varphi$ about the top load application point P_T in an arrangement according to 13.4.2 and Figure 5 keeping just below 1° (0,99°).

NOTE 3 A compromise in the design of the foot platform may be the limited adjustability of the position of its tilting axis TA only in the u-direction. Its technical realization is considered to be rather simple, since the fixed distance between two successive u-positions of the tilting axis TA, the value of which is 1 mm (see Figure E.5 and Table E.2), can be provided, for example, by a grid of keyways cut into the contact surfaces of the adjustable bearing blocks of the tilting axis TA and the foot platform, to which these are attached by screws. In this case the compensation plates addressed in c) are, of course, not needed.

E.3.4.3 Practicality

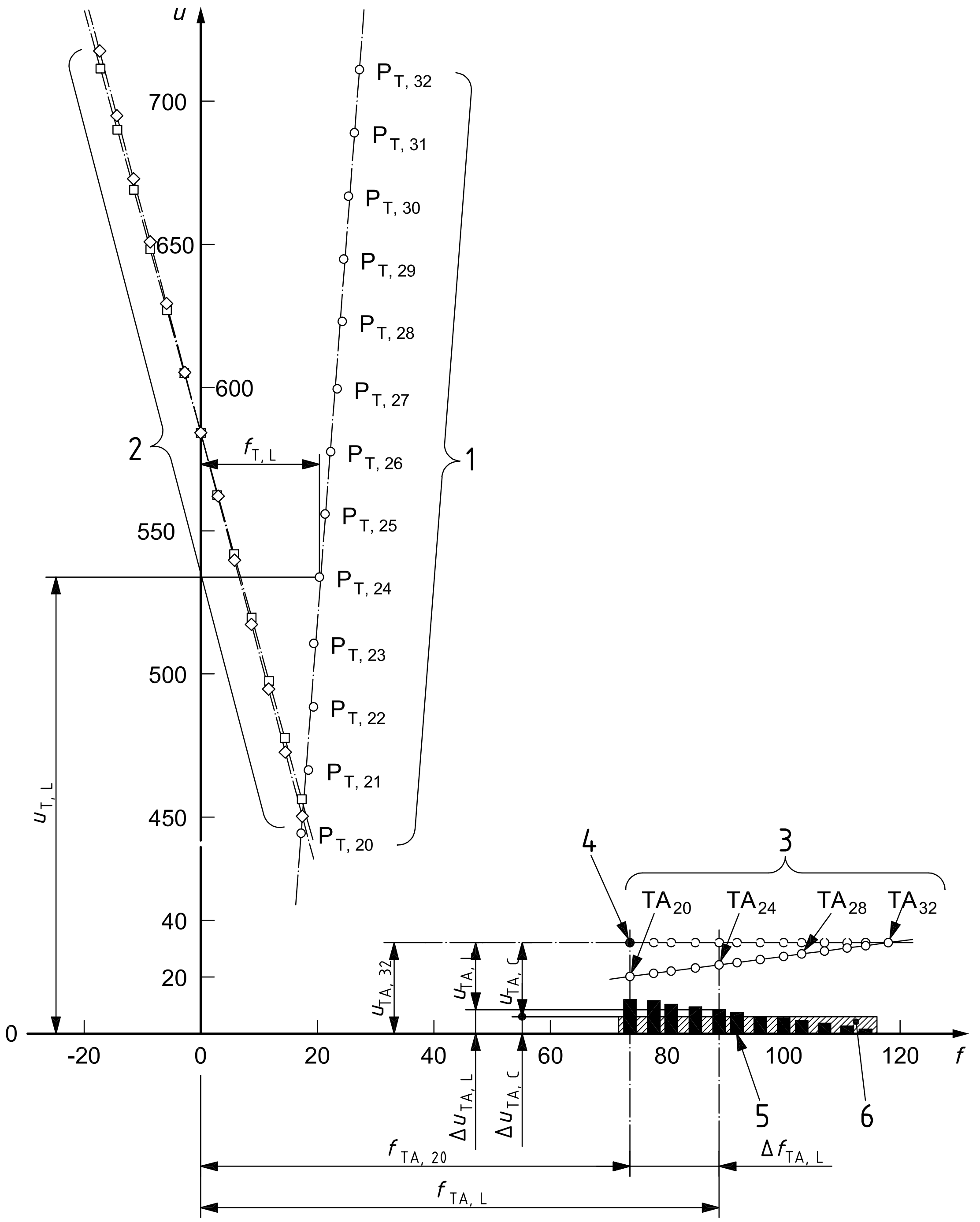
The procedure described in E.3.4.1 and E.3.4.2 is considered to be both appropriate and practicable.

— It provides appropriate means of diminishing the elevation E and A-P displacement Δf of the test sample at the foot, caused by the tilting of the foot platform up to the values occurring at the instants of heel contact and toe-off (see E.3.2).

— It simplifies the setting-up of the test sample in the test equipment, since it reduces the amount of adjustment work (see E.3.4.1).

— It does not increase the complexity of the design of the foot platform to an intolerable extent (see E.3.4.2).

The only difference to be regarded is, that the u-axis of the coordinate system (see 6.2 and Figure 1) and the effective ankle-joint centre (see 6.7.3) located on it, which are used as reference for the alignment of the test sample and its setting-up in the test equipment, no longer have a fixed position relative to the base frame of the test equipment. Moreover, they keep their fixed position relative to the top load application point P_T and, hence, are transposed together with it.



Key

1 individual position of top load application point $P_{T, L}$ for different foot lengths L

2 transposed positions of top load application point $P_{T, L}$ for different foot lengths L; positions marked square transposed by $\Delta f_{TA, L}$ and $\Delta u_{TA, L}$ and positions marked rhombic transposed by $\Delta f_{TA, L}$ and $\Delta u_{TA, C}$

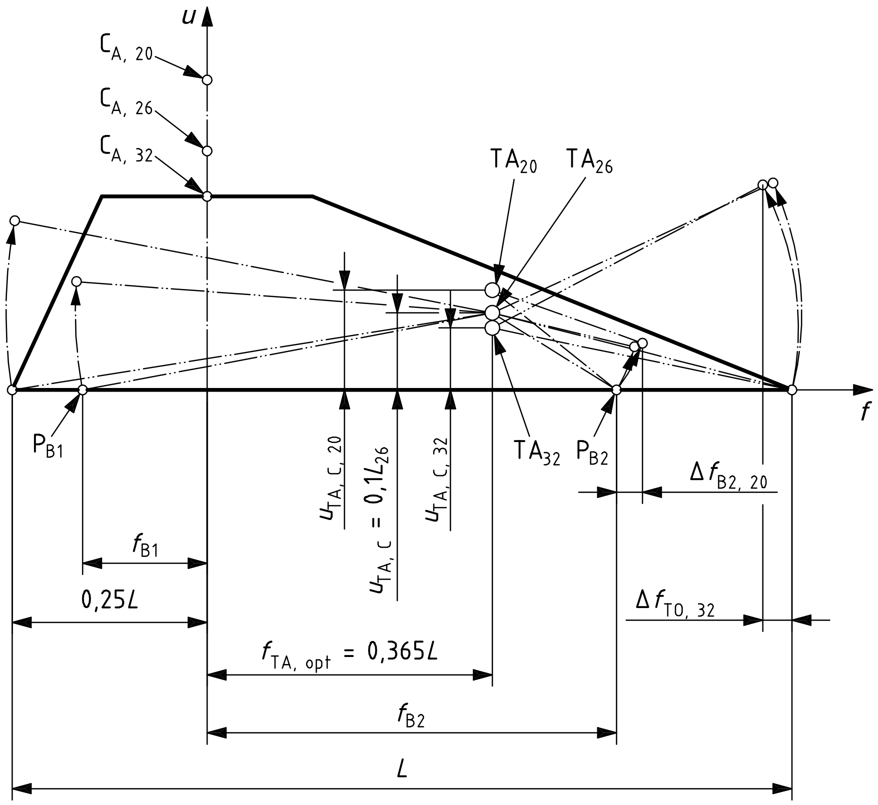
3 individual position of tilting axis TA_L of foot platform for different foot lengths L

4 fixed standard or compromise position of tilting axis TA of foot platform at $f_{TA, 20}$ and $u_{TA, 32}$ or $u_{TA, C}$, respectively

5 individual elevation of contact surface of foot platform by compensation plates of different thickness $\Delta u_{TA, L}$ (or by corresponding adjustment) for adaptation to individual foot length L

6 uniform elevation of contact surface of foot platform by $\Delta u_{TA, C}$ for adaptation to compromise offset $u_{TA, C}$ applicable to all foot lengths L

Figure E.4 — Illustration of possibilities of transposing the top load application point P_T for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L



Key

f, u	axes of coordinate system
$C_{A, 20, 26, 32}$	specific positions of effective ankle-joint centre C_A related to feet of specific lengths L = 20 cm, L = 26 cm and L = 32 cm
$TA_{20, 26, 32}$	specific positions of tilting axis TA of foot platform related to feet of specific lengths L = 20 cm, L = 26 cm and L = 32 cm
$u_{TA, C, 20, 26, 32}$	dimension of uniform compromise offset $u_{TA, C}$ = $u_{TA, 26}$ = 26 mm (0,1 × foot length L = 26 cm) related to feet of specific lengths L = 20 cm, L = 26 cm and L = 32 cm
P_{B1}	position of bottom load application point on heel
P_{B2}	position of bottom load application point on forefoot
$\Delta f_{B2, 20}$	anterior displacement of bottom load application point P_{B2} at the instant of maximum forefoot reference loading (test force F = F_{2cmax}) related to foot of specific length, L = 20 cm
$\Delta f_{TO, 32}$	posterior displacement of point of foot at instant of toe-off (test force F = 0) related to foot of specific length, L = 32 cm
L	foot length

Figure E.5 — Illustration of the effect of a fixed compromise offset $u_{TA, C}$ of the tilting axis TA of the foot platform on the A-P displacement Δf at the foot [see E.3.4.2 c) 2)]

Table E.2 — Possibilities of transposing the top load application point P_T for compensation of the dependence of the position of the tilting axis TA of the foot platform on the foot length L

Foot length L [a]	Coordinates of "regular" position of top load application point $P_{T, L}$		Coordinates of "regular" position of tilting axis TA of foot platform		Procedure according to E.3.4.2 b) and E.3.4.2 c) 1) for compensation of fixed position of tilting axis TA of foot platform at $f_{TA, 20} = 73$ [b] and $u_{TA, 32} = 32$ [b]			Transposition of $P_{T, L}$ according to E.3.4.2 b) and E.3.4.2 c) 2) for compensation of fixed compromise position of tilting axis TA of foot platform at $f_{TA, 20} = 73$ [b] and $u_{TA, C} = 26$ [c]	
	$f_{T, L}$	$u_{T, L}$	$f_{TA, L}$	$u_{TA, L}$	Transposition of $P_{T, L}$		Use of compen-sation plates of thickness	$\Delta f_{TA, L}$	$\Delta u_{TA, C}$ [c]
					$\Delta f_{TA, L}$	$\Delta u_{TA, L}$			
cm	mm	mm	mm	mm	mm	mm	mm	mm	mm
20	17	445	73	20	0	12	12	0	6
21	18	467	77	21	− 4	11	11	− 4	6
22	19	489	80	22	− 7	10	10	− 7	6
23	19	511	84	23	− 11	9	9	− 11	6
24	20	534	88	24	− 15	8	8	− 15	6
25	21	556	91	25	− 18	7	7	− 18	6
26	22	578	95	26	− 22	6	6	− 22	6
27	23	600	99	27	− 26	5	5	− 26	6
28	24	623	102	28	− 29	4	4	− 29	6
29	24	645	106	29	− 33	3	3	− 33	6
30	25	667	110	30	− 37	2	2	− 37	6
31	26	689	113	31	− 40	1	1	− 40	6
32	27	711	117	32	− 44	0	0	− 44	6

[a] The range of foot lengths $20 \leqslant L \leqslant 32$ is considered to cover the vast majority of sizes expected to be submitted for test. This range can easily be extended to smaller or larger sizes with subsequent changes of the values of $\Delta f_{TA, L}$, $\Delta u_{TA, L}$ and $\Delta u_{TA, C}$.

[b] The possibilities of transposing the top load application point P_T shown require the fixed standard position of the tilting axis TA to be determined by a value of $f_{TA, L}$ relevant to the smallest size and a value of $u_{TA, L}$ relevant to the largest size of foot covered by the range of foot lengths $20 \leqslant L \leqslant 32$.

[c] For a real arrangement of foot platform with the tilting axis TA located at a uniform compromise offset $u_{TA, C}$ above the platform surface, the value of $\Delta u_{TA, C}$ would be zero. The value of $\Delta u_{TA, C} = 6$ only applies to the specific arrangement shown in E.3.4.2, Figure E.4 and this table. It regards the difference between the offset $u_{TA, 32} = 32$ relevant to the maximum foot length $L = 32$ and the most appropriate fixed compromise offset $u_{TA, C} = 26$ relevant to a foot length $L = 26$ (see NOTE 2 of E.3.4.2) and allows the effects of the two different examples of transposition to be illustrated in a comparable manner.

Annex F
(informative)

Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142

This International Standard has been prepared to support the essential principles of safety and performance of prosthetic ankle-foot devices and foot units as medical devices according to ISO/TR 16142. This International Standard is suitable for conformity assessment purposes.

Compliance with this International Standard provides one means of demonstrating conformity with specific essential principles of ISO/TR 16142. Other means are possible.

NOTE 1 The ***essential principles of safety and performance*** according to ISO/TR 16142 conform, in both structure and contents, to the ***essential requirements*** according to Annex I of the European Directive 93/42/EEC concerning medical devices with a few exceptions.

NOTE 2 This annex has been enclosed to provide the same information as original Annex ZA, which has been removed from this International Standard for formal reasons. Table F.1 conforms to Table ZA.1 of original Annex ZA in both structure and contents, with the exception of the column headings.

Table F.1 — Correspondence between this International Standard and the essential principles of ISO/TR 16142

Clauses/subclauses of this International Standard	Corresponding essential principle of ISO/TR 16142:1999	Qualifying remarks/notes
5; 6; 7; 8; 9; 10; 15; 16	A.2, A.4, A.12.7.1	
5, 19, 20	A.9.1	
5; 19; 20	A.13	
20	A.13	

Bibliography

[1] ISO/TR 22676:2006, *Prosthetics — Testing of ankle-foot devices and foot units — Guidance on the application of the test loading conditions of EN ISO 22675 and on the design of appropriate test equipment*

[2] ISO/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

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