FINAL
DRAFT

INTERNATIONAL
STANDARD

**ISO/FDIS
22675**

ISO/TC **168**

Secretariat: DIN

Voting begins on:
2016-02-11

Voting terminates on:
2016-04-11

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

Please see the administrative notes on page iii

Reference number
ISO/FDIS 22675:2016(E)

ISO/CEN PARALLEL PROCESSING

This final draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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Foreword

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

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

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

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

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics*.

a) Test loading levels P7 and P8 have been introduced in Table 10, Table A.1, Table C.1, Table C.2 and the clauses pointing at these tables have been updated. Additional information on P7 and P8 is given in Annex A.1;

b) Table 9 has been revised

c) Annex C has changed from informative to normative

European Foreword

By agreement between ISO and CEN, this European Foreword is included in the FDIS but will not appear in the published ISO document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard 'within the meaning of Annex ZA', the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE 1 The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 8549-1:1989	—	ISO 8549-1:1989
ISO/TR 16142:1999	—	ISO/TR 16142:1999
ISO 22523:2006	ISO 22523:2006	ISO 22523:2006

Introduction

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

a) the inconsistency of the lines of application of the heel and forefoot test forces with those of the test forces of test loading conditions I and II for the principal structural tests specified in 16.2 (static tests) and 16.3 (cyclic test) of ISO 10328:2016;

b) the unrealistic course and magnitude of loading in the phase between the instants of maximum heel and forefoot loading during the cyclic test;

c) the effect of periodical “stepping in a hollow” during the cyclic test, resulting from simultaneous heel and forefoot loading at different angles.

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

Finally, it has to be noted that the potential of the general concept applied to the test procedures specified in this 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.

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 ISO 22523:2006 through submission to the relevant tests of ISO 10328:2006, 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 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 10328:2016, without changing the values of the angles of the heel and forefoot platform(s) for the structural tests on ankle-foot devices and foot units specified in ISO 10328:2016.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 10328:2016, *Prosthetics — Structural testing of lower limb prostheses — Requirements and test methods*

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

3 Terms and definitions

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

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

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

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

3.4
batch
set of test samples of an ankle-foot device or foot unit submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this 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	F_{set}
Stabilizing test force	F_{stab}
Proof test force of end attachments	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	$F_c(t)$; $F_c(\gamma)$
1st and 2nd maximum value of pulsating test force	F_{1cmax}, F_{2cmax}
Intermediate minimum value of pulsating test force	F_{cmin}
Final static test force on heel/forefoot	F_{1fin}, F_{2fin}
NOTE Further details of the test forces listed are given in Table 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 10328:2016.

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

Each test configuration specifies reference parameters both for the position of the line of application of the test force and for the alignment of test samples within the coordinate system.

6.2 Origin and axes of the coordinate system

The origin and the axes of the coordinate system are specified in a) to 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.

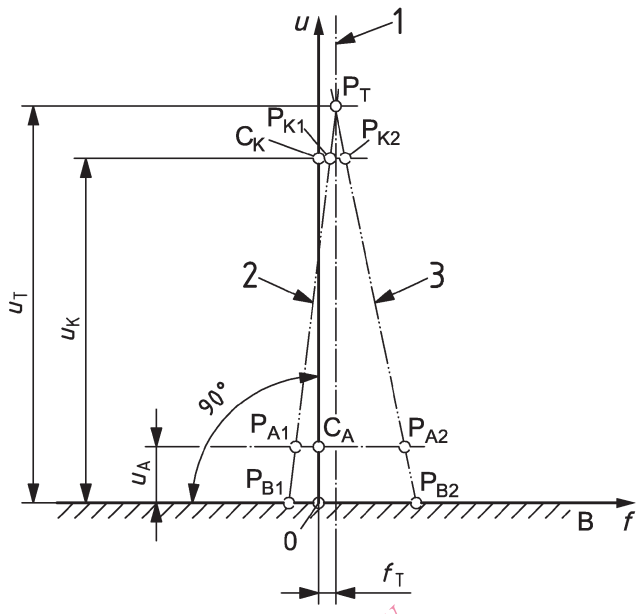
If a test sample is not in the vertical position, the axes of the coordinate system shall be rotated to correspond.

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).