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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.

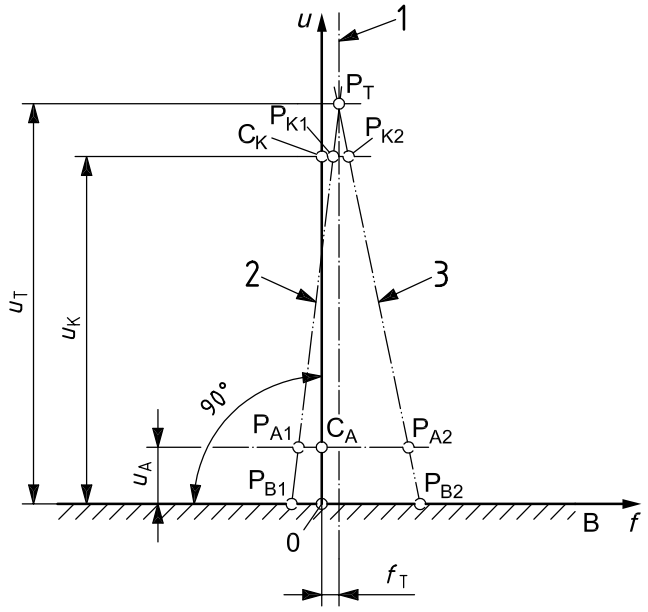
If a test sample is not in the vertical position, the axes of the coordinate system shall be rotated to correspond.

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).

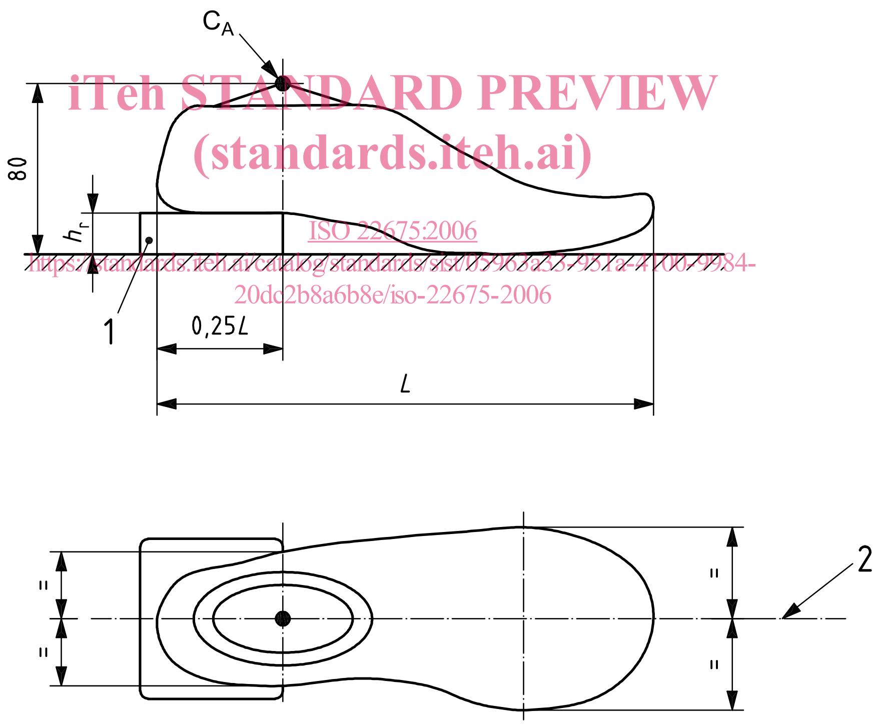
6.7.3.4 The effective ankle-joint centre C_A lies

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)