ISO 22675:2023(E)

Date: 2023-~~07-10~~08-22

ISO/TC 168/WG 3

Secretariat: DIN

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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Contents

Page

Foreword

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This document was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 22675:2016), which has been technically revised.

The main changes are as follows:

— test Ranges (R) have been introduced;

— test loading levels P7 and P8 have been introduced in Table 5, 8, 9, 10, 11 and A.1 and the clauses pointing at these tables have been updated;

— Former Annex C has been deleted and integrated in main text;

— Subclause 15.2 has been updated;

— Subclause 16.5 has been added.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

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

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

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

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

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

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

NOTE Further guidance on the specification of the test loading conditions and test loading levels and on the design of appropriate test equipment is given in ISO/TR 22676.

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

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

1 Scope

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

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

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

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

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

This document specifies Test Ranges (R) by specifying locomotion profiles for the cyclic test in relation to the intended use. According to the concept of the tests of this document, each sample of ankle-foot device or foot unit submitted for test is, nevertheless, free to develop its individual performance under load.

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

NOTE The lines of action of the heel and forefoot forces generated by the static test procedure for Test Range 4 (R4) specified in this document approach those determining the sagittal plane loading of the test loading conditions I and II for the principal structural tests referring to ISO 10328:2016, without changing the values of the angles of the heel and forefoot platform(s) for the structural tests on ankle-foot devices and foot units specified in ISO 10328:2016.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7000, *Graphical symbols for use on equipment — Registered symbols*

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

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

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

IEC 60417, *Graphical symbols for use on equipment*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

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

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

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

3.4
batch
set of test samples of an ankle-foot device or foot unit submitted together to a test laboratory/facility to undertake tests to demonstrate conformity with requirements

3.5
shock absorption capacity
capacity of a specimen to absorb energy by deflection without a proportional increase of force

3.6
test force
force applied to a sample under test

Note 1 to entry: Test equipment, build to test to previous versions of this document (using compression force with a positive sign) do not need to be reprogrammed.

3.7
accuracy of equipment
accuracy to which the test equipment and any jig and measuring device measures linear and angular dimensions, test forces and the frequency of cyclic tests

3.8
accuracy of procedure
tolerances with which linear and angular dimensions are set and finally adjusted, test forces and tilting angles are applied and the frequency of cyclic tests is controlled

4 Symbols

F, F_1, F_2	Test forces 1, 2 and 3
F_{set}	Settling test force
F_{stab}	Stabilizing test force
F_{pa}	Proof test force of end attachments
F_{1sp}, F_{2sp}	Static proof test force on heel/forefoot
F_{1su}, F_{2su}	Static ultimate test force on heel/forefoot
$F_c(t)$; $F_c(\beta)$	Pulsating test force
F_{1cmax}, F_{2cmax}	1st and 2nd maximum value of pulsating test force
F_{cmin}	Intermediate minimum value of pulsating test force
F_{1fin}, F_{2fin}	Final static test force on heel/forefoot

5 Strength and related performance requirements and conditions of use

5.1 A prosthetic ankle-foot device or foot unit shall have the strength to sustain the loads occurring during use by amputees in the manner intended by the manufacturer for that device according to their written instructions on its intended use in accordance with ISO 22523:2006, 4.4.1. Based on the written instructions, the manufacturer assigns a Test Range (R) that is appropriate to test the strength for the intended use. The manufacturer/supplier is responsible for the instructions for use and the related assignment. National or international classification schemes are independent to the instructions and the related assignment. For the assessment of the strength to sustain loads occurring during use, this document provides means of determining different categories of strength. These are listed in Table 1, together with the related performance requirements and the test methods for their verification.

5.2 In order to demonstrate the strength to sustain the loads occurring during use by amputees of a specific ankle-foot device or foot unit, the following safety concept shall apply:

The device shall

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

b) be used in accordance with the body mass limit specified by the manufacturer in consideration of the intended use of that device, and

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

c) be used solely for the intended use as described in the IFU.

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

Table 1 — Categories of strength addressed in this document, together with the related performance requirements and test methods for their verification

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

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

6 Coordinate system and test configurations

6.1 General

The test configurations of this document are defined in a manner similar to that applied in ISO 10328:2016.

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

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

6.2 Origin and axes of the coordinate system

The origin and the axes of the coordinate system are specified in a) to d) in relation to a prosthesis which is standing on the ground in an upright position. In Figure 1 the ground is represented by the bottom plane B.

NOTE 1 ISO 9787 defines coordinate systems for robots. ISO 8855 defines the same coordinate system for vehicles in a right-hand system: Upward (u), thumb: z; Forward (f), pointer finger: x; Outward (o) (to the left), middle finger: y.

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

a) The origin 0 of the coordinate system is located in the bottom plane B.

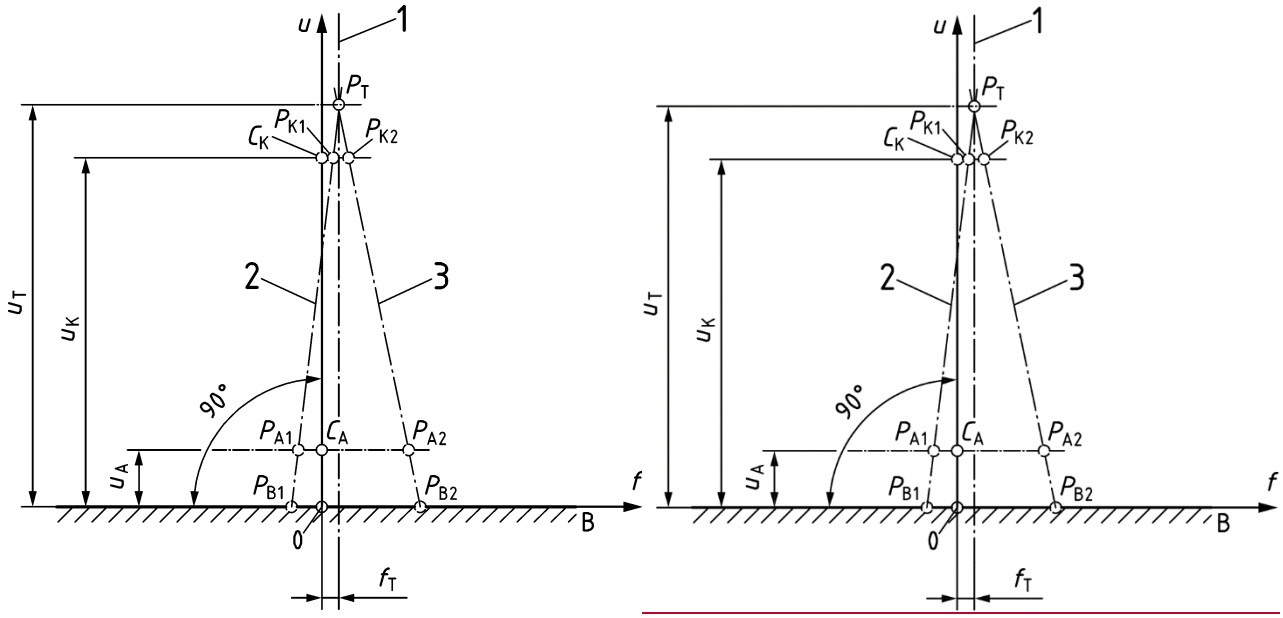
b) The *u*-axis extends from the origin 0 perpendicular to the bottom plane B and passes through the effective ankle-joint centre C_A, specified in 6.7.3 (see Figure 1). Its positive direction is upwards (in the proximal direction).

NOTE 2 The location of the effective ankle-joint centre C_A (see Figure 1) is defined in 6.7.3.4. Connectors or ankle-joint units, connecting the ankle-foot unit to proximal elements, can be located in positions different to C_A.

NOTE 3 The *u*-axis also passes through the effective knee-joint centre C_K (see Figure 1). This can be relevant to the setting-up of test samples of specific designs of ankle-foot devices or foot units which extend towards the knee unit of a lower limb prosthesis and which, therefore, also require the knowledge of the position of the effective knee joint centre.

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

d) The *o*-axis extends from the origin 0 perpendicular to both, the *u*-axis and to the *f*-axis (see Figure 1). Its positive direction points medial for right sided foot.



Key

B bottom plane (see 6.2)

0	origin of coordinate system [see 6.2 a)]
u	(upward) axis of coordinate system [see 6.2 b)]
f	(forward) axis of coordinate system [see 6.2 c)]
C_A	effective ankle-joint centre [see 6.2 b) and 6.7.3]
C_K	effective knee-joint centre [see NOTE of 6.2 b)]
P_T	top load application point (see 6.3)
P_{K1}, P_{K2}	knee load reference points (see 6.3)
P_{A1}, P_{A2}	ankle load reference points (see 6.3)
P_{B1}, P_{B2}	bottom load application points (see 6.3)
1	line of application of test force F (see 6.5)
2	line of action of resultant reference force F_{R1} (heel loading) (see 6.6)
3	line of action of resultant reference force F_{R2} (forefoot loading) (see 6.6)

Figure 1 — Coordinate system with reference parameters

6.3 Reference points

The reference points determine the position of the line of application of the test force F (see 6.5) and the lines of action of the resultant reference forces F_{R1} (heel loading) and F_{R2} (forefoot loading) (see 6.6 and Figure A.1) within the f-u-plane of the coordinate system (see 6.2 and Figure 1). The coordinates of the reference points are as follows:

— top load application point (see NOTE 1), P_T (f_T, u_T);

— knee load reference point, P_K (f_K, u_K);

— ankle load reference point (see NOTE 2), P_A (f_A, u_A);

— bottom load application point, P_B (f_B, 0).

The only reference point to be defined and specified for the application of the test principles outlined in 15.1 is the top load application point P_T, at which the test force F (see 6.4) is applied to the test sample (see Figure 1).

The reference points at knee, ankle and bottom level are required to specify the lines of action of the resultant reference forces F_{R1} and F_{R2}.

In the subsequent clauses of this document, the f-coordinates are also referred to as "offsets".

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

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