

**PROTEESIMINE. HÜPPELIIGESE JA PÖIA PROTEESIDE
KATSETAMINE. NÕUDED JA KATSEMEETODID**

**Prosthetics - Testing of ankle-foot devices and foot
units - Requirements and test methods
(ISO 22675:2024)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 22675:2025 sisaldab Euroopa standardi EN ISO 22675:2025 ingliskeelset teksti. Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 21.05.2025. Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	This Estonian standard EVS-EN ISO 22675:2025 consists of the English text of the European standard EN ISO 22675:2025. This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 21.05.2025. The standard is available from the Estonian Centre for Standardisation and Accreditation.
---	---

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 31.220.10

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele. Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation. No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation and Accreditation: Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2024)

Prothèses - Essais d'articulations cheville-pied et
unités de pied - Exigences et méthodes d'essai (ISO
22675:2024)

Prothetik - Prüfung von Knöchel-Fuß-Passteilen und
Fußeinheiten - Anforderungen und Prüfverfahren (ISO
22675:2024)

This European Standard was approved by CEN on 19 November 2024.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 22675:2025) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products and accessibility" the secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2025, and conflicting national standards shall be withdrawn at the latest by November 2025.

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

This document supersedes EN ISO 22675:2016.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 22675:2024 has been approved by CEN as EN ISO 22675:2025 without any modification.

Contents

Page

Foreword	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Symbols	3
5 Strength and related performance requirements and conditions of use	3
6 Coordinate system and test configurations	4
6.1 General	4
6.2 Origin and axes of the coordinate system	4
6.3 Reference points	5
6.4 Test force F	6
6.5 Line of application of test force F	6
6.6 Lines of action of resultant reference forces F_{R1} and F_{R2}	6
6.7 Longitudinal axis of the foot and effective ankle joint centre	6
6.7.1 General	6
6.7.2 Longitudinal axis of the foot	6
6.7.3 Effective ankle-joint centre C_A	6
7 Test loading conditions and test loading levels	8
7.1 Test loading conditions	8
7.2 Test loading levels and Test Ranges (R)	8
8 Values of test forces, dimensions and cycles	9
9 Compliance	17
9.1 General	17
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	18
9.2.1 Arrangements for testing	18
9.2.2 Requirements for claiming compliance	18
9.3 Number of tests and test samples required to claim compliance with this document	18
9.4 Multiple use of test samples	18
9.4.1 General	18
9.4.2 Restriction	19
9.5 Testing at particular test loading levels not specified in this document	19
10 Test samples	20
10.1 Selection of test samples	20
10.1.1 General	20
10.1.2 Selection of ankle-foot devices and foot units of appropriate size of foot	20
10.2 Types of test sample	21
10.2.1 Complete structure	21
10.2.2 Partial structure	21
10.3 Preparation of test samples	21
10.4 Identification of test samples	21
10.5 Alignment of test samples	22
10.6 Worst-case alignment position of test samples	22
11 Responsibility for test preparation	24
12 Test submission document	25
12.1 General requirements	25
12.2 Information required for test samples	25
12.3 Information required for tests	26
12.3.1 General	26

	12.3.2	For all tests.....	26
	12.3.3	For the static proof test and the static ultimate strength test.....	26
	12.3.4	For the static ultimate strength test.....	26
	12.3.5	For the cyclic test.....	26
13	Equipment.....		27
	13.1	General.....	27
	13.2	End attachments.....	27
	13.2.1	General.....	27
	13.2.2	Proof test of end attachments.....	27
	13.3	Jig.....	29
	13.4	Test equipment.....	30
	13.4.1	Test equipment to perform static heel and forefoot loading.....	30
	13.4.2	Test equipment to perform cyclic loading.....	31
14	Accuracy.....		37
	14.1	General.....	37
	14.2	Accuracy of equipment.....	38
	14.3	Accuracy of procedure.....	38
15	Test principles.....		38
	15.1	General.....	38
	15.2	Static test procedure.....	39
	15.3	Cyclic test procedure.....	42
16	Test procedures.....		42
	16.1	Test loading requirements.....	42
	16.1.1	Preparation for test loading.....	42
	16.1.2	Test loading conditions.....	45
	16.2	Static proof test.....	46
	16.2.1	Test method.....	46
	16.2.2	Performance requirement.....	48
	16.2.3	Compliance conditions.....	48
	16.3	Static ultimate strength test.....	50
	16.3.1	Test method.....	50
	16.3.2	Performance requirements.....	52
	16.3.3	Compliance conditions.....	52
	16.4	Cyclic test.....	53
	16.4.1	Test method.....	53
	16.4.2	Performance requirements.....	56
	16.4.3	Compliance conditions.....	56
	16.5	Separate static test in torsion.....	59
	16.5.1	General.....	59
	16.5.2	Purpose of test.....	59
	16.5.3	Test method.....	59
	16.5.4	Performance requirements.....	60
	16.5.5	Compliance conditions.....	60
17	Test laboratory/facility log.....		61
	17.1	General requirements.....	61
	17.2	Specific requirements.....	61
18	Test report.....		61
	18.1	General requirements.....	61
	18.2	Specific requirements.....	62
	18.3	Options.....	62
19	Classification and designation.....		62
	19.1	General.....	62
	19.2	Example of classification and designation.....	62
20	Identifier.....		63
	20.1	General.....	63

20.2	Identifier layout.....	63
20.3	Identifier placement.....	63
Annex A (informative) Reference data for the specification of the test loading conditions and test loading levels of this document.....		64
Annex B (informative) Guidance on the application of an alternative static ultimate strength test.....		73
Annex C (informative) Summary of the records entered in the test laboratory/facility log.....		74
Annex D (informative) Information on ISO/TR 22676.....		79
Annex E (informative) Background data (reduced) of the six-minute walk test for adults		90
Bibliography		91

Foreword

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

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

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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

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

The main changes are as follows:

- test Ranges (R) have been introduced;
- test loading levels P7 and P8 have been introduced in [Table 5](#), [8](#), [9](#), [10](#), [11](#) and [A.1](#) and the clauses pointing at these tables have been updated;
- Former [Annex C](#) has been deleted and integrated in main text;
- [Subclause 15.2](#) has been updated;
- [Subclause 16.5](#) has been added.

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

Introduction

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

- a) the inconsistency of the lines of application of the heel and forefoot test forces with those of the test forces of test loading conditions I and II for the principal structural tests specified in 16.2 (static tests) and 16.3 (cyclic test) of ISO 10328:2016;
- b) the unrealistic course and magnitude of loading in the phase between the instants of maximum heel and forefoot loading during the cyclic test;
- c) the effect of periodical “stepping in a hollow” during the cyclic test, resulting from simultaneous heel and forefoot loading at different angles.

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

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

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

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

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

1 Scope

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

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

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

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

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

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

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

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

2 Normative references

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

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

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

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

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

IEC 60417, *Graphical symbols for use on equipment*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

3.1

proof strength

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

3.2

ultimate strength

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

3.3

fatigue strength

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

3.4

batch

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

3.5

shock absorption capacity

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

3.6

test force

force applied to a sample under test

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

3.7

accuracy of equipment

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

3.8

accuracy of procedure

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