

PROTEESIMINE. ALAJÄSEME PROTEESIDE
KONSTRUKTSIOONI KATSETAMINE. NÕUDED JA
KATSEMEETODID

Prosthetics - Structural testing of lower-limb prostheses
- Requirements and test methods (ISO 10328:2016)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10328:2016 sisaldab Euroopa standardi EN ISO 10328:2016 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10328:2016 consists of the English text of the European standard EN ISO 10328:2016.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.06.2016.	Date of Availability of the European standard is 22.06.2016.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

ICS 11.040.40

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:

Aru 10, 10317 Tallinn, Eesti; 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

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.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:

Aru 10, 10317 Tallinn, Estonia; homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Prosthetics - Structural testing of lower-limb prostheses -
Requirements and test methods (ISO 10328:2016)

Prothèses - Essais portant sur la structure des
prothèses de membres inférieurs - Exigences et
méthodes d'essai (ISO 10328:2016)

Prothetik - Prüfung der Struktur von Prothesen der
unteren Gliedmaßen - Anforderungen und
Prüfverfahren (ISO 10328:2016)

This European Standard was approved by CEN on 12 May 2016.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 10328:2016) has been prepared by Technical Committee ISO/TC 168 "Prosthetics and orthotics" in collaboration with Technical Committee CEN/TC 293 "Assistive products for persons with disability" 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 December 2016, and conflicting national standards shall be withdrawn at the latest by December 2016.

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

This document supersedes EN ISO 10328:2006.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10328:2016 has been approved by CEN as EN ISO 10328:2016 without any modification.

Annex ZA
(informative)
Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] aimed to be covered

This European standard has been prepared under a Commission's standardisation request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk has to be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
9.1	5	With respect to use in combination with other devices or equipment.
9.1	20 and 21	With respect to any restrictions on use which shall be indicated on the label or in the instructions for use.
12.7.1	5, 7, 8, 9, 10, 15, 16, 17 and 18	Only covered for mechanical strength.
13.1	5, 20, and 21.4	Essential requirement 13.1 is not fully covered here; only the aspects of classification are addressed.

Essential Requirements of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
13.3 b)	21	Only covered for classification of the use of the device.
13.3 k)	21.2	Only covered for limitations due to body mass limit and specific activities undertaken by the user.

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

Contents

Page

Foreword	vii
Introduction	viii
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Designations and symbols of test forces and moments	2
5 Strength and related performance requirements and conditions of use	3
6 Coordinate systems and test configurations	5
6.1 General	5
6.2 Axes of coordinate systems	5
6.3 Reference planes	5
6.3.1 General	5
6.3.2 Top reference plane, T	5
6.3.3 Knee reference plane, K	5
6.3.4 Ankle reference plane, A	6
6.3.5 Bottom reference plane, B	6
6.4 Reference points	7
6.5 Test force	8
6.6 Load line	8
6.7 Longitudinal axis of the foot and effective joint centres and centrelines	8
6.7.1 General	8
6.7.2 Longitudinal axis of the foot	8
6.7.3 Effective ankle-joint centre	8
6.7.4 Effective ankle-joint centreline	10
6.7.5 Effective knee-joint centreline	10
6.7.6 Effective knee-joint centre	11
6.8 Reference distances	11
6.8.1 Offsets	11
6.8.2 Combined offsets	11
6.8.3 Effective lever arms L_A and L_K	11
6.8.4 Distance L_{BT}	11
7 Test loading conditions and test loading levels	11
7.1 Test loading conditions	11
7.1.1 General	11
7.1.2 Test loading conditions of principal structural tests	12
7.1.3 Test loading conditions of separate structural tests	12
7.2 Test loading levels	12
8 Values of test loads, dimensions and cycles	13
9 Compliance	20
9.1 General	20
9.2 Selection of tests required to claim compliance with this International Standard	21
9.3 Arrangements for tests on samples of prosthetic structures including ankle-foot devices or foot units, required to claim compliance with this International Standard	21
9.3.1 General	21
9.3.2 Particular arrangements concerning the ankle-foot device or foot unit	21
9.3.3 Particular arrangements and requirements concerning the part required to connect the ankle-foot device or foot unit to the remainder of the prosthetic structure	21
9.4 Number of tests and test samples required to claim compliance with this International Standard	22
9.5 Multiple use of test samples	22

9.5.1	General	22
9.5.2	Restriction	22
9.6	Testing at particular test loading levels not specified in this International Standard	23
10	Test samples	25
10.1	Selection of test samples	25
10.1.1	General	25
10.1.2	Selection of ankle-foot devices and foot units of appropriate size of foot	26
10.2	Types of test samples	27
10.2.1	Complete structure	27
10.2.2	Partial structure	29
10.2.3	Any other structure	29
10.3	Preparation of test samples	29
10.4	Identification of test samples	30
10.5	Alignment of test samples	31
10.5.1	Test samples for principal tests and separate tests on knee locks	31
10.5.2	Test samples for separate tests on ankle-foot devices and foot units	31
10.5.3	Test samples for separate static ultimate strength tests in maximum knee flexion for knee joints and associated parts	31
10.5.4	Test samples for separate tests on knee locks	32
10.6	Worst-case alignment position of test samples	32
11	Responsibility for test preparation	33
12	Test submission document	34
12.1	General requirements	34
12.2	Information required for test samples	35
12.2.1	All test samples	35
12.2.2	Test samples for tests on ankle-foot devices and foot units	35
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts	35
12.3	Information required for tests	35
12.3.1	General	35
12.3.2	For all tests	35
12.3.3	For static tests in torsion and on ankle-foot devices and foot units	36
12.3.4	For static ultimate strength tests	36
12.3.5	For cyclic tests	36
12.3.6	For tests in torsion	36
12.3.7	For tests on ankle-foot devices and foot units	36
13	Equipment	37
13.1	General	37
13.2	Equipment for the principal tests specified in 16.2 and 16.3	37
13.2.1	End attachments	37
13.2.2	Jig (optional)	39
13.2.3	Test equipment	40
13.3	Equipment for the separate static test in torsion specified in 17.1	42
13.3.1	Test equipment	42
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2	42
13.4.1	Test equipment	42
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3	46
13.5.1	Extension pieces	46
13.5.2	Test equipment to perform static compression loading – (Compression testing machine or other equipment)	46
13.6	Equipment for the separate tests on knee locks specified in 17.4	46
13.6.1	End attachments	46
13.6.2	Jig (optional)	46
13.6.3	Test equipment	46
14	Accuracy	47

14.1	General	47
14.2	Accuracy of equipment	47
14.3	Accuracy of procedure	47
15	Test principles	48
15.1	General	48
15.2	Static test procedure	48
15.3	Cyclic test procedure	48
16	Test procedures – Principal structural tests	48
16.1	Test loading requirements	48
16.1.1	Preparation for test loading	48
16.1.2	Application of test loading	48
16.2	Principal static test procedure	50
16.2.1	Principal static proof test	50
16.2.2	Principal static ultimate strength test	55
16.3	Principal cyclic test procedure	59
16.3.1	General requirements	59
16.3.2	Test method	59
16.3.3	Performance requirements	63
16.3.4	Compliance conditions	64
17	Test procedures — Separate structural tests	68
17.1	Separate static test in torsion	68
17.1.1	General	68
17.1.2	Purpose of test	68
17.1.3	Test method	68
17.1.4	Performance requirements	70
17.1.5	Compliance conditions	70
17.2	Separate tests on ankle-foot devices and foot units	72
17.2.1	General	72
17.2.2	Purpose of tests	72
17.2.3	Separate static proof test for ankle-foot devices and foot units	72
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units	76
17.2.5	Separate cyclic test for ankle-foot devices and foot units	81
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts	86
17.3.1	General	86
17.3.2	Purpose of test	86
17.3.3	Applicability of the test to specific test samples	86
17.3.4	Test method	87
17.3.5	Performance requirement	88
17.3.6	Compliance conditions	88
17.4	Separate tests on knee locks	89
17.4.1	General	89
17.4.2	Purpose of tests	90
17.4.3	Separate static proof test for knee locks	90
17.4.4	Separate static ultimate strength test for knee locks	94
17.4.5	Separate cyclic test for knee locks	96
18	Test laboratory/facility log	105
18.1	General requirements	105
18.2	Specific requirements	105
19	Test report	105
19.1	General requirements	105
19.2	Specific requirements	106
19.3	Options	106
20	Classification and designation	106
20.1	General	106

20.2	Examples of classification and designation.....	106
21	Labelling.....	107
21.1	General.....	107
21.2	Use of mark “*”) and warning symbol.....	108
21.3	Examples of label layout.....	108
21.4	Label placement.....	108
Annex A	(informative) Description of internal loads and their effects	110
Annex B	(informative) Reference data for the specification of test loading conditions and test loading levels of principal cyclic tests.....	114
Annex C	(informative) Guidance on the application of an alternative static ultimate strength test	118
Annex D	(normative) Guidance on the application of an additional test loading levels P6, P7 and P8	119
Annex E	(informative) Summary of the records to be entered in the test laboratory/facility log	122
Annex F	(informative) Background information on the loading profiles generated by test equipment according to 13.4.1.2 for separate cyclic tests for ankle-foot devices and foot units according to 17.2.5.1.....	137
Annex G	(informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142	139
Bibliography	140

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*.

This second edition cancels and replaces the first edition ISO 10328:2006 which has been technically revised with the following changes:

- a) Test loading levels P7 and P8 have been introduced in [Table B.1](#), [Table B.2](#), [Table B.3](#), Table 4.1, [Table D.1](#), [Table D.2](#), [Table D.3](#) and the clauses pointing at these tables have been updated. Additional information on P7 and P8 is given in Annex B.1;
- b) [Table 9](#) has been revised;
- c) [Annex D](#) has changed from informative to normative.

Introduction

Throughout this International Standard, the term prosthesis means an externally applied device used to replace wholly, or in part, an absent or deficient limb segment.

As a result of concern in the international community about the need to provide prostheses that are safe in use, and also because of an awareness that test standards would assist the development of better prostheses, a series of meetings was held under the aegis of the International Society for Prosthetics and Orthotics (ISPO). The final one was held in Philadelphia, PA, USA in 1977 at which a preliminary consensus was reached on methods of testing and the required load values. From 1979 onwards this work was continued by ISO Technical Committee 168 leading to the development of ISO 10328:1996. The test procedures may not be applicable to prostheses of mechanical characteristics different from those used in the consensus.

During use, a prosthesis is subjected to a series of load actions, each varying individually with time. The test methods specified in this International Standard use static and cyclic strength tests which typically produce compound loadings by the application of a single test force.

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. This International Standard specifies fatigue testing of structural components. The tests specified do not provide sufficient data to predict actual service life.

The evaluation of lower-limb prostheses and their components requires controlled field trials in addition to the laboratory tests specified in this International Standard.

The laboratory tests and field trials should be repeated when significant design changes are made to a load-bearing part of a prosthesis.

Ideally, additional laboratory tests should be carried out to deal with function, wear and tear, new material developments, environmental influences and user activities as part of the evaluation procedure. There are no standards for such tests, so appropriate procedures will need to be determined.