

Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods

Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN ISO 10328:2006 sisaldab Euroopa standardi EN ISO 10328:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 24.11.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN ISO 10328:2006 consists of the English text of the European standard EN ISO 10328:2006.</p> <p>This document is endorsed on 24.11.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
--	---

<p>Käsitlusala: This International Standard specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 1) where, with one exception, compound loadings are produced by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.</p>	<p>Scope: This International Standard specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 1) where, with one exception, compound loadings are produced by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.</p>
---	---

ICS 11.040.40

Võtmesõnad:

ICS 11.040.40

English Version

Prosthetics - Structural testing of lower-limb prostheses -
Requirements and test methods (ISO 10328:2006)

Prothèses - Essais portant sur la structure des prothèses
de membres inférieurs - Exigences et méthodes d'essai
(ISO 10328:2006)

Prothetik - Prüfung der Struktur von Prothesen der unteren
Gliedmaßen - Anforderungen und Prüfverfahren (ISO
10328:2006)

This European Standard was approved by CEN on 13 April 2006.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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



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

Management Centre: rue de Stassart, 36 B-1050 Brussels

Foreword

This document (EN ISO 10328:2006) 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 April 2007, and conflicting national standards shall be withdrawn at the latest by April 2007.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 10328:2006 has been approved by CEN as EN ISO 10328:2006 without any modifications.

ANNEX ZA

(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports corresponding essential requirements of EU Directive 93/42/EEC concerning medical devices.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC concerning medical devices: 5, 6, 7, 8, 9, 10, 15, 16, 17, 20 and 21 (see Table ZA.1).

Compliance with this standard provides one means of conforming with the essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and EU Directives

Clauses of this European Standard	Corresponding Essential Requirements of Directive 93/42/EEC	Comments
5; 6; 7; 8; 9; 10; 15; 16; 17	2, 4, 12.7.1	
5; 20; 21	9.1	
5; 20; 21	13.1	Essential requirement 13.1 is not fully covered here; only the aspects of classification are addressed.
21	13.3 k)	

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

Prothèses — Essais portant sur la structure des prothèses de membres inférieurs — Exigences et méthodes d'essai



PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

© ISO 2006

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword.....	ix
Introduction.....	x
1 Scope	1
2 Normative references	2
3 Terms and definitions	2
4 Designations and symbols of test forces and moments	3
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	5
6.3.5 Bottom reference plane, B	6
6.4 Reference points	8
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	21
9.1 General	21
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.....	23
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.....	25
10.2	Types of test samples.....	26
10.2.1	Complete structure	26
10.2.2	Partial structure.....	28
10.2.3	Any other structure	28
10.3	Preparation of test samples	28
10.4	Identification of test samples.....	29
10.5	Alignment of test samples	30
10.5.1	Test samples for principal tests and separate tests on knee locks	30
10.5.2	Test samples for separate tests on ankle-foot devices and foot units	30
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	31
10.6	Worst-case alignment position of test samples	32
11	Responsibility for test preparation	32
12	Test submission document.....	33
12.1	General requirements	33
12.2	Information required for test samples	34
12.2.1	All test samples.....	34
12.2.2	Test samples for tests on ankle-foot devices and foot units	34
12.2.3	Test samples for static ultimate strength tests in maximum knee flexion for knee joints and associated parts	34
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.....	35
12.3.4	For static ultimate strength tests	35
12.3.5	For cyclic tests	35
12.3.6	For tests in torsion.....	35
12.3.7	For tests on ankle-foot devices and foot units	36
13	Equipment.....	36
13.1	General.....	36
13.2	Equipment for the principal tests specified in 16.2 and 16.3	36
13.2.1	End attachments	36
13.2.2	Jig (optional).....	38
13.2.3	Test equipment.....	38
13.3	Equipment for the separate static test in torsion specified in 17.1	40
13.3.1	Test equipment.....	40
13.4	Equipment for the separate tests on ankle-foot devices and foot units specified in 17.2	40
13.4.1	Test equipment.....	40
13.5	Equipment for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts specified in 17.3.....	44
13.5.1	Extension pieces.....	44
13.5.2	Test equipment to perform static compression loading – (Compression testing machine or other equipment)	44
13.6	Equipment for the separate tests on knee locks specified in 17.4	44
13.6.1	End attachments	44
13.6.2	Jig (optional).....	44
13.6.3	Test equipment.....	44

14	Accuracy.....	45
14.1	General.....	45
14.2	Accuracy of equipment	45
14.3	Accuracy of procedure.....	45
15	Test principles.....	46
15.1	General.....	46
15.2	Static test procedure	46
15.3	Cyclic test procedure	46
16	Test procedures – Principal structural tests	46
16.1	Test loading requirements.....	46
16.1.1	Preparation for test loading.....	46
16.1.2	Application of test loading.....	46
16.2	Principal static test procedure	48
16.2.1	Principal static proof test.....	48
16.2.2	Principal static ultimate strength test.....	53
16.3	Principal cyclic test procedure.....	57
16.3.1	General requirements	57
16.3.2	Test method.....	57
16.3.3	Performance requirements	61
16.3.4	Compliance conditions	61
17	Test procedures – Separate structural tests	65
17.1	Separate static test in torsion	65
17.1.1	General.....	65
17.1.2	Purpose of test.....	65
17.1.3	Test method.....	65
17.1.4	Performance requirements	67
17.1.5	Compliance conditions	67
17.2	Separate tests on ankle-foot devices and foot units	69
17.2.1	General.....	69
17.2.2	Purpose of tests	69
17.2.3	Separate static proof test for ankle-foot devices and foot units	69
17.2.4	Separate static ultimate strength test for ankle-foot devices and foot units	73
17.2.5	Separate cyclic test for ankle-foot devices and foot units	78
17.3	Separate static ultimate strength test in maximum knee flexion for knee joints and associated parts.....	83
17.3.1	General.....	83
17.3.2	Purpose of test.....	83
17.3.3	Applicability of the test to specific test samples	83
17.3.4	Test method.....	84
17.3.5	Performance requirement	84
17.3.6	Compliance conditions	85
17.4	Separate tests on knee locks	86
17.4.1	General.....	86
17.4.2	Purpose of tests	86
17.4.3	Separate static proof test for knee locks	86
17.4.4	Separate static ultimate strength test for knee locks	90
17.4.5	Separate cyclic test for knee locks	92
18	Test laboratory/facility log	101
18.1	General requirements	101
18.2	Specific requirements	101
19	Test report	101
19.1	General requirements.....	101
19.2	Specific requirements	102
19.3	Options	102
20	Classification and designation.....	102
20.1	General.....	102
20.2	Examples of classification and designation	102

21	Labelling.....	103
21.1	General.....	103
21.2	Use of mark "*" and warning symbol.....	104
21.3	Examples of label layout.....	104
21.4	Label placement.....	104
Annex A (informative) Description of internal loads and their effects.....		106
Annex B (informative) Reference data for the specification of test loading conditions and test loading levels of principal cyclic tests.....		110
Annex C (informative) Guidance on the application of an alternative static ultimate strength test.....		114
Annex D (informative) Guidance on the application of an additional test loading level P6.....		115
Annex E (informative) Summary of the records to be entered in the test laboratory/facility log.....		118
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.....		133
Annex G (informative) Reference to the essential principles of safety and performance of medical devices according to ISO/TR 16142.....		135
Bibliography.....		136
Figure 1	— Coordinate systems for right and left-sided application.....	6
Figure 2	— Coordinate systems according to Figure 1 with reference planes.....	6
Figure 3	— Specific configuration with $u_B = 0$, showing coordinate systems with reference planes (see Figures 1 and 2), reference lines, reference points and test force, F , for right and left-sided application.....	7
Figure 4	— Determination of longitudinal axis of foot (see 6.7.2), effective ankle-joint centre (see 6.7.3) and effective ankle-joint centreline (see 6.7.4) for test loading conditions I and II and of combined bottom offset s_B (see 6.8.2) for test loading condition II [see 7.1.2 b)].....	9
Figure 5	— Position of effective knee-joint centreline for prosthetic knee units of different types.....	10
Figure 6	— Application of a specific test configuration with $u_B = 0$ to a left-sided sample specified in 10.2.1.....	27
Figure 7	— Position of foot in test equipment (see 10.5.2, 13.4 and 17.2).....	30
Figure 8	— Test configuration for the separate static ultimate strength test in maximum knee flexion on knee joints and associated parts (see 10.5.3.1, 13.5 and 17.3.4).....	31
Figure 9	— Load cycle parameters for the principal cyclic test.....	39
Figure 10	— Load cycle parameters for the separate cyclic test for ankle-foot devices and foot units.....	43
Figure 11	— Illustration of test loading principle applied to a knee unit with attachments, aligned to simulate a left-sided test sample (see 16.1.1).....	47
Figure 12	— Method of calculating offsets at any height $u = u_x$ (see 16.1.1).....	48
Figure 13	— Flowchart for the principal static proof test, specified in 16.2.1.1.....	52
Figure 14	— Flowchart for the principal static ultimate strength test, specified in 16.2.2.1.....	56
Figure 15	— Flowchart for the principal cyclic test, specified in 16.3.2 Continued on Figures 16 and 17.....	62
Figure 16	— Flowchart for the principal cyclic test, specified in 16.3.2 Continued from Figure 15 and continued on Figure 17.....	63
Figure 17	— Flowchart for the principal cyclic test, specified in 16.3.2 Continued from Figure 16.....	64

Figure 18 — Flowchart for the separate static test in torsion, specified in 17.1.3.....	68
Figure 19 — Flowchart for the separate static proof test for ankle-foot devices and foot units, specified in 17.2.3.1	72
Figure 20 — Flowchart for the separate static ultimate strength test for ankle-foot devices and foot units, specified in 17.2.4.1	77
Figure 21 — Flowchart for the separate cyclic test for ankle-foot devices and foot units, specified in 17.2.5.1 Continued on Figure 22.....	81
Figure 22 — Flowchart for the separate cyclic test for ankle-foot devices and foot units, specified in 17.2.5.1 Continued from Figure 21.....	82
Figure 23 — Flowchart for the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts, specified in 17.3.4	85
Figure 24 — Flowchart for the separate static proof test for knee locks, specified in 17.4.3.1.....	89
Figure 25 — Flowchart for the separate static ultimate strength test for knee locks, specified in 17.4.4.1	92
Figure 26 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1 Continued on Figures 27 and 28.....	98
Figure 27 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1 Continued from Figure 26 and continued on Figure 28	99
Figure 28 — Flowchart for the separate cyclic test for knee locks, specified in 17.4.5.1 Continued from Figure 27.....	100
Figure 29 — General concept for the label layout.....	103
Figure 30 — Models for the label layout.....	105
Figure A.1 — Test loading condition I [see 7.1.2 a)].....	108
Figure A.2 — Test loading condition II [see 7.1.2 b)].....	109
Table 1 — Designations and symbols of test forces and moments.....	3
Table 2 — Categories of strength addressed in this International Standard, together with the related performance requirements and test methods for their verification	4
Table 3 — Test loads and relevant references.....	14
Table 4 — Test forces of the proof test of end attachments for test loading levels P5, P4 and P3 (see 13.2.1.2).....	15
Table 5 — Total length and segmental lengths of different types of test samples for principal tests and separate tests on knee locks, for all test loading conditions and test loading levels (see also 10.2, 10.3, 16.2, 16.3, 17.4 and Figure 2).....	15
Table 6 — Values of offsets for all principal tests (see 16.2 and 16.3).....	16
Table 7 — Values of combined offsets related to the values of offsets listed in Table 6 (see 10.1.2 and 13.2.1.2.3)	16
Table 8 — Test forces of all principal tests and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3 (see 16.2 and 16.3).....	17
Table 9 — Twisting moments of the separate static test in torsion (see 17.1).....	18
Table 10 — Angles of directions of loading of all separate tests on ankle-foot devices and foot units, for test loading levels P5, P4 and P3 (see 17.2 and Figure 7)	18
Table 11 — Test forces of all separate tests on ankle-foot devices and foot units and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3 (see 17.2)	19

Table 12 — Loading parameters of the separate static ultimate strength test in maximum knee flexion for knee joints and associated parts (see 17.3 and Figure 8).....	19
Table 13 — Offsets of all separate tests on knee locks, for test loading levels P5, P4 and P3 (see 17.4)	20
Table 14 — Test forces of all separate tests on knee locks and prescribed number of cycles of the cyclic test, for test loading levels P5, P4 and P3 (see 17.4)	20
Table 15 — Tests required to claim compliance with this International Standard for prosthetic structures representing complete assemblies, partial assemblies or individual components	23
Table 16 — Number of tests and test samples required to claim compliance with this International Standard	24
Table 17 — Option for end attachments of specific design	37
Table A.1 — Positive internal forces and moments with descriptions of their effects.....	107
Table B.1 — Values of ankle and knee moments related to test force $F = F_{cr}$ for different test loading conditions and test loading levels of principal cyclic tests	111
Table B.2 — Calculated values of axial force and twisting moment related to test force $F = F_{cr}$ for different test loading conditions and test loading levels of principal cyclic tests.....	111
Table B.3 — Values of ankle and knee moments related to test force $F = F_{cmax}$ for different test loading conditions and test loading levels of principal cyclic tests	112
Table B.4 — Calculated values of axial force and twisting moment related to test force $F = F_{cmax}$ for different test loading conditions and test loading levels of principal cyclic tests.....	112
Table D.1 — Test forces of the proof test of end attachments for test loading level P6 (see 13.2.1.2)	116
Table D.2 — Test forces of all principal tests and prescribed number of cycles of the cyclic test, for test loading level P6 (see 16.2 and 16.3)	116
Table D.3 — Test forces of all separate tests on ankle-foot devices and foot units and prescribed number of cycles of the cyclic test, for test loading level P6 (see 17.2)	117
Table G.1 — Correspondence between this International Standard and the essential principles of ISO/TR 16142	135

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 10328 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

This first edition cancels and replaces the eight parts of the first edition (ISO 10328-1:1996 to ISO 10328-8:1996), which have been technically revised and combined into one single document.

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.

In order to allow continuity of testing by checking the test methods for ankle-foot devices and foot units specified in Clause 16 of ISO 22675:2006 against those specified in this International Standard, 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 this International Standard and ISO 22675:2006 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 ISO 22675:2006 have demonstrated their suitability.

Prosthetics — Structural testing of lower-limb prostheses — Requirements and test methods

1 Scope

IMPORTANT — This International Standard is *suitable* for the assessment of the conformity of lower limb prosthetic devices/structures 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 ISO 22675:2006.

WARNING — This International Standard is *not suitable* to serve as a guide for the selection of a specific lower limb prosthetic device/structure 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 specifies procedures for static and cyclic strength tests on lower-limb prostheses (see NOTE 2) which typically produce compound loadings by the application of a single test force. The compound loads in the test sample relate to the peak values of the components of loading which normally occur at different instants during the stance phase of walking.

The tests described in this International Standard comprise

- principal static and cyclic tests for all components;
- a separate static test in torsion for all components;
- separate static and cyclic tests on ankle-foot devices and foot units for all ankle-foot devices as single components including ankle units or ankle attachments and all foot units as single components;
- a separate static ultimate strength test in maximum knee flexion on knee joints and associated parts for all knee units or knee-shin-assemblies and adjacent components that normally provide the flexion stop on a complete prosthesis;
- separate static and cyclic tests on knee locks for all mechanisms which lock the knee joint in the extended position of the knee unit or knee-shin-assembly.

The tests described in this International Standard apply to specific types of ankle-disarticulation prostheses (see NOTE 3), to transtibial (below-knee), knee-disarticulation and transfemoral (above-knee) prostheses and to the distal (lower) part of hip-disarticulation and hemi-pelvectomy prostheses (see NOTE 4).

NOTE 1 ISO 22523 (formerly EN 12523) addresses those of the Essential Requirements listed in Annex 1 of the European Medical Device Directive 93/42/EEC that are applicable to external limb prostheses and external orthoses.

NOTE 2 The tests can be performed on complete structures, on part structures or on individual components.

NOTE 3 The tests only apply to ankle-disarticulation prostheses which include (foot) components of prosthetic ankle-foot devices taken from the normal production line.

NOTE 4 The distal part comprises the knee unit, the ankle-foot device and all parts between. Tests on hip units are described in ISO 15032.

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/TR 16142:1999, *Medical devices — Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices*

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

ISO 22675:2006, *Prosthetics — Testing of ankle-foot devices and foot units — Requirements and test methods*

3 Terms and definitions

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

**3.1
proof strength**
static load representing an occasional severe event, which can be sustained by the prosthetic device/structure 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 prosthetic device/structure but which could render it thereafter unusable

**3.3
fatigue strength**
cyclic load which can be sustained by the prosthetic device/structure for a given number of cycles

**3.4
batch**
set of test samples of a prosthetic device/structure submitted together to a test laboratory/facility to undertake tests to demonstrate compliance with one or more requirements of this International Standard