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

AMENDMENT 1

Prothèses — Essais d'articulations cheville-pied et unités de pied — Exigences et méthodes d'essai
AMENDEMENT 1

ICS 11.040.40

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

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To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Foreword

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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.

Amendment 1 to ISO 22675:2006 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics* and by Technical Committee CEN/TC 293, *Assistive products for persons with diasbility* in collaboration.

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

AMENDMENT 1

Page 8, 7.2.3

Replace 7.2.3 with the following text:

Test loading levels: P3, P4, P5, P6, P7 and P8

NOTE 1   Field experience has shown that there is a need for lower limb prostheses which sustain loads above the level covered by test loading level P5. In order to allow the structural testing of such prostheses on a uniform basis, test loading levels P6, P7 and P8 have been developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units (see Annex C).

NOTE 2   The values of the dimensions and loads of test loading levels P3, P4 and P5 are specified in separate tables in Clause 8. It is suggested that the values of the dimensions and loads specified in C.3 and Table C.2 are appropriate for test loading level P6 and as an interim measure, pending validation, P7 and P8. Further test loading levels will be defined, if necessary.

Page 10, Table 5

Delete the NOTE and replace by the following:

For the additional test loading levels P6, P7 and P8 the test forces are specified in Table C.1.

Page 11, Table 6

Delete the NOTE and replace by the following:

The total length and the segmental lengths also apply to the additional test loading levels P6, P7 and P8 specified in Annex C [see C.3 a)].

Page 12, Table 7

Delete the NOTE and replace by the following:

The specified dimensions also apply to the additional test loading levels P6, P7 and P8 specified in Annex C [see C.3 a)].

Page 12, Table 8

Delete the NOTE and replace by the following:

The specified dimensions also apply to the additional test loading levels P6, P7 and P8 specified in Annex C [see C.3 a)].

Page 13, Table 9

Replace the footnote a in Table 9 by the following:

a   For the additional test loading level P6, P7 and P8 the values of the test forces and the prescribed number of cycles are specified in Table C.2.

Page 15, Table 10

Replace Table 10 by the following:

Reference point	Instant (Time after heel contact) ms	Interval of time ms	Rate of loading/unloading (Value relevant to test loading level) kN/s						Test force $F_c(t)$ at reference point N						
										Value relevant to test loading level					
			P8	P7	P6	P5	P4	P3	Symbol	P8	P7	P6	P5	P4	P3
a	0								$F_c(t_a)$	0	0	0	0	0	0
		115	17,8	15,4	13,3	11,1	10,2	8,0							
b	115								F_{1cmax}	2038	1760	1521	1273	1173	915
		51													
c	166								F_{1cmax}	2038	1760	1521	1273	1173	915
		103	- 6,5	- 5,6	- 4,9	- 4,1	- 3,8	- 2,9							
d	269								F_{cmin}	1361	1175	1016	850	783	611
		62													
e	331								F_{cmin}	1361	1175	1016	850	783	611
		102	6,4	5,6	4,8	4,0	3,7	2,9							
f	433								F_{2cmax}	2011	1737	1501	1256	1166	903
		51													
g	484								F_{2cmax}	2011	1737	1501	1256	1166	903
		116	-17,4	-15,0	-13,0	-10,8	- 9,9	- 7,9							
h	600								$F_c(t_h)$	0	0	0	0	0	0

NOTE   The loading period of 600 ms corresponds to the average stance phase time of a typical walking cycle of 1 second duration. (The remaining time of 400 ms of the walking cycle corresponds to the swing phase.) Simulating this stance phase time–swing phase time–relationship in a cyclic test, a loading period of 600 ms corresponds to a test frequency f = 1 Hz. For other test frequencies, preferably between 0,5 Hz and 3 Hz (see 16.4.1.6 and 16.4.1.7), the time intervals between each instant after heel contact, for which rates of loading/unloading or test force are specified in this table, can easily be adapted by linear scaling.

Page 44, 16.2.1.2

Replace the last sentence in the third paragraph by the following:

Make specific reference if the additional test loading level P6, P7 or P8 specified in Annex C are to be applied.

Page 47, 16.3.1.2

Replace the last sentence in the fourth paragraph by the following:

Make specific reference if the application of the additional test loading levels P6, P7 or P8 specified in Annex C are to be applied.

Page 48, 16.3.1.5

In the second sentence of the fourth paragraph replace [12.3.3 a)] by [12.3.4 a)]

Page 48, 16.3.1.8

Replace the second sentence in the fourth paragraph by the following:

Make specific reference if the application of the additional test loading levels P6, P7 or P8 specified in Annex C are to be applied.

Page 52, 16.4.1.3

Replace the second sentence in the second paragraph by the following:

Make specific reference if the application of the additional test loading levels P6, P7 or P8 specified in Annex C are to be applied.

Page 59, 18.2.1

Replace the second sentence in the first paragraph by the following:

This particularly applies to tests that are conducted at the additional test loading level P6, P7 or P8 according to Annex C (see 16.2.1.2, 16.3.1.2 and 16.4.1.3), and to the alternative static ultimate strength test according to Annex B (see 16.3.1.1, 16.3.1.5 and 16.3.1.11).

Page 63, A.1

Replace the second and third paragraph by the following:

The test loading level P5 is based on data from all amputees including a few whose body mass exceeded 100 kg. The test loading level P6 and P7 is based on locomotion data from amputees of whose body mass is less than 125 kg and 150 kg, simulations and field observations; P8 is extrapolated form these two levels to amputees whose body mass is less than 175 kg . The test loading levels P4 and P3 are based on locomotion data from amputees whose body mass is less than 80 kg and 60 kg, respectively.

For the proposed additional test loading levels P6, P7 and P8 see Annex C.

Page 65, Equation (A.4)

Replace by the following:

$$D_{\mathrm{PT}} = \sqrt{\frac{f_{\mathrm{T},26}^2 + u_{\mathrm{T},26}^2}{26}}$$

Page 66, Table A.1

Replace Table A.1 by the following:

Resultant reference forces F_{R1x} and F_{R2x} of static and maximum cyclic heel and forefoot reference loading	Symbol	Related test forces F_{1x} and F_{2x} of the separate tests on ankle-foot devices and foot units specified in ISO 10328 (see Tables 11 and D.3 of ISO 10328:2006/DAM 1)										
		Test loading level										
		P8		P7		P6		P5		P4		P3	
		Numerical values for heel loading (F_{1x}) and forefoot loading (F_{2x})											
		F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}
		N											
F_{R1sp}	F_{1sp}	3200	–	2900	–	2490	–	2240	–	2065	–	1610	–
F_{R2sp}	F_{2sp}	–	3200	–	2900	–	2490	–	2240	–	2065	–	1610
$F_{R1su, lower level}$	$F_{1su, lower level}$	4450	–	4100	–	3760	–	3360	–	3098	–	2415	–
$F_{R2su, lower level}$	$F_{2su, lower level}$	–	4450	–	4100	–	3760	–	3360	–	3098	–	2415
$F_{R1su, upper level}$	$F_{1su, upper level}$	5700	–	5300	–	4880	–	4480	–	4130	–	3220	–
$F_{R2su, upper level}$	$F_{2su, upper level}$	–	5700	–	5300	–	4880	–	4480	–	4130	–	3220
F_{R1cmax}	F_{1cr}	2050	–	1770	–	1530	–	1280	–	1180	–	920	–
F_{R2cmax}	F_{2cr}	–	2050	–	1770	–	1530	–	1280	–	1180	–	920
F_{R1fin}	F_{1fin}	3200	–	2900	–	2490	–	2240	–	2065	–	1610	–
F_{R2fin}	F_{2fin}	–	3200	–	2900	–	2490	–	2240	–	2065	–	1610

Page 72, Annex C

Change the Annex from informative to normative and change the title by the following:

Application of an additional test loading level P6

Page 72, C.1

Replace the second paragraph by the following:

In order to allow the structural testing of such prostheses on a uniform basis, additional test loading levels, P6, P7 and P8 are proposed in this annex. They are derived, amongst others, from measurements of overweight prosthetic patients, normals and wobbling mass simulations.

Page 72, Table C.1

Replace Table C.1 by the following:

Table C.1 — Test forces of the proof test of end attachments for test loading level P6, P7 and P8
(see 13.2.1)

Test procedure	End attachments for		Stabilizing test force, F_{stab}; (F_{Rstab})[b]	Settling test force, F_{set}; (F_{Rset})[b]	Proof test force, F_{pa}; (F_{Rpa})[b]
	Test loading condition[a]				
	Heel loading F_1 **at** γ = - 15°	Forefoot loading F_2 **at** γ = 20°	N		
All tests[1]	P8		50	1630 (1640)	6800 (6840)
		P8		1609 (1640)	6711 (6840)
	P7			1408 (1416)	6323 (6360)
		P7		1389 (1416)	6240 (6360)
	P6			1217 (1224)	5822 (5856)
		P6		1201 (1224)	5746 (5856)

[a] End attachments that satisfy the stiffness requirements of the proof test of end attachments for proof test force F_{pa} = 1,2 $F_{su, upper\ level}$ of a test loading level specified in this table are suitable for all static and cyclic tests of this International Standard carried out at this test loading level and at all lower levels.

For sets of end attachments, individually designed to the specific requirements of the test loading conditions of the static and cyclic tests of this International Standard and/or to the specific requirements of the ankle-foot devices or foot units submitted for test, particular conditions apply (see the OPTION described in 13.2.2.1).

[b] The relationship between the values of F_x and F_{Rx} (placed in parentheses) is determined by equation (A.5), using the values of α_1 and α_2 specified in A.2.3. The values of F_{Rx} are calculated from the relevant values listed in Table A.1, using the factors specified in Table 4 (see A.2.3). Which set of values applies depends on how the assembly of end attachments is placed in the test equipment (see 13.2.1.2.3).