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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

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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The committee responsible for this document is ISO/TC 168, *Prosthetics and orthotics*.

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 for P7 and P8 (pending validation), as an interim measure. 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 Table 9 by the following:

Test procedure and test force			Unit	Test loading level (P_x) [a] and test loading condition (F_{1x}; F_{2x})					
				P5		P4		P3	
				Heel loading, F_{1x}	**Forefoot loading, F_{2x}**	**Heel loading, F_{1x}**	**Forefoot loading, F_{2x}**	**Heel loading, F_{1x}**	**Forefoot loading, F_{2x}**
Static test procedure	Static proof test force	F_{1sp}	N	2 227	—	2 053	—	1 601	—
		F_{2sp}		—	2 198	—	2 026	—	1 580
	Static ultimate test force	$F_{1su,\ lower\ level}$	N	3 340	—	3 079	—	2 401	—
		$F_{2su,\ lower\ level}$		—	3 297	—	3 039	—	2 369
		$F_{1su,\ upper\ level}$	N	4 454	—	4 106	—	3 201	—
		$F_{2su,\ upper\ level}$		—	4 396	—	4 052	—	3 159
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax}	N	1 273	—	1 173	—	915	—
	Intermediate minimum value of pulsating test force	F_{cmin}	N	850		783		611	
	2nd maximum value of pulsating test force	F_{2cmax}	N	—	1 256	—	1 158	—	903
	Final static test force	F_{1fin} (= F_{1sp})	N	2 227	—	2 053	—	1 601	—
		F_{2fin} (= F_{2sp})		—	2 198	—	2 026	—	1 580
	Prescribed number of cycles		1	2×10^6					

NOTE The specific values of the different test forces are based on reference values described in A.2.3 and specified in Table A.1.

[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	Threshold													
	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						
			P8	P7	P6	P5	P4	P3	**Symbol**	**Value relevant to test loading level**					
										P8	P7	P6	P5	P4	P3
a	0								$F_c(t_a)$	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.

Reference point	Threshold													
	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					
			P8	P7	P6	P5	P4	P3	Symbol	Value relevant to test loading level				
										P8	P7	P6	P5	P4	P3
		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	1158	903
		51													
g	484								F_{2cmax}	2011	1737	1501	1256	1158	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 is 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 is 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 is 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 levels P6 and P7 are based on locomotion data from amputees whose body mass is less than 125 kg and 150 kg respectively, obtained from simulations and field observations; P8 is extrapolated from 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:

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

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	**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)											
	Symbol	**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, P7 and P8

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)**

End attachments for Test procedure	**Test loading condition**[a]		**Stabilizing test force,** F_{stab}; (F_{Rstab})[b]	**Settling test force,** F_{set}; (F_{Rset})[b]	**Proof test force,** F_{pa}; (F_{Rpa})[b]
	Heel loading F_1 **at** γ = - 15°	**Forefoot loading** F_2 **at** γ = 20°	N		
All tests[a]	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).

Page 73, Table C.2

Replace Table C.2 by the following:

Table C.2 — Test forces for all tests and prescribed number of cycles for the cyclic test, for test loading level P6, P7 and P8 (see 16.2, 16.3 and 16.4)

Test procedure and test load			Unit	Test loading level					
				P8		P7		P6	
				Heel loading (F_{1x}) and forefoot loading (F_{2x})					
				F_{1x}	F_{2x}	F_{1x}	F_{2x}	F_{1x}	F_{2x}
Static test procedure	Static proof test force	F_{1sp}	N	3181	–	2883	–	2476	–
		F_{2sp}		–	3140	–	2845	–	2443
	Static ultimate test force	$F_{1su,\ lower\ level}$	N	4424	–	4076	–	3738	–
		$F_{2su,\ lower\ level}$		–	4366	–	4023	–	3689
		$F_{1su,\ upper\ level}$	N	5667	–	5269	–	4852	–
		$F_{2su,\ upper\ level}$		–	5593	–	5200	–	4788
Cyclic test procedure	1st maximum value of pulsating test force	F_{1cmax},	N	2038	–	1760	–	1521	–
	Intermediate minimum value of pulsating test force	F_{cmin}	N	1361		1175		1016	
	2nd maximum value of pulsating test force	F_{2cmax}	N	–	2011	–	1737	–	1501
	Final static force	F_{1fin} (= F_{1sp})	N	3181	–	2883	–	2476	–
		F_{2fin} (= F_{2sp})		–	3140	–	2845	–	2443
	Prescribed numbers of cycles		1	2×10^6					
NOTE The specific values of the different test forces are based on reference values, as described in A.2.2.2.									

Page 76, D.3.2.1 c)

Replace the text by the following:

c) the test loading level to be applied, together with the corresponding values of tilting angles of the foot platform and test forces, making specific reference to the application of the additional test loading level P6, P7 or P8 specified in Annex C, if appropriate, in accordance with 16.2.1.2;