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AMENDMENT

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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/CEN PARALLEL PROCESSING

This final 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. The final draft was established on the basis of comments received during a parallel enquiry on the draft.

This final draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel two-month approval vote in ISO and formal vote in CEN.

Positive votes shall not be accompanied by comments.

Negative votes shall be accompanied by the relevant technical reasons.

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Foreword

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

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

AMENDMENT 1

Page 2, Clause 2

Update the normative reference to ISO 10328 to the 2015 version with the following text:

ISO 10328:2015, *Prosthetics — Structural testing of lower limb prostheses — Requirements and test methods*

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

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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 as 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 as 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 as specified in Annex C [see C.3 a)].

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}	N	—	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}	N	—	3 297	—	3 039	—	2 369
		F _{1su, upper level}	N	4 454	—	4 106	—	3 201	—
		F _{2su, upper level}	N	—	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})	N	—	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
		115	17,8	15,4	13,3	11,1	10,2	8,0								
b	115									F_{1cmax}	2 038	1 760	1 521	1 273	1 173	915
		51														
c	166									F_{1cmax}	2 038	1 760	1 521	1 273	1 173	915
		103	- 6,5	- 5,6	- 4,9	- 4,1	- 3,8	- 2,9								
d	269									F_{cmin}	1 361	1 175	1 016	850	783	611
		62														
e	331									F_{cmin}	1 361	1 175	1 016	850	783	611
		102	6,4	5,6	4,8	4,0	3,7	2,9								
f	433									F_{2cmax}	2 011	1 737	1 501	1 256	1 158	903
		51														
g	484									F_{2cmax}	2 011	1 737	1 501	1 256	1 158	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 s 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 is based on locomotion data from amputees of whose body mass is less than 125 kg and 150 kg, respectively and 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, Formula (A.4)

Replace by the following:

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

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(A.4)

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:XXXX)												
	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}	3 200	-	2 900	-	2 490	-	2 240	-	2 065	-	1 610	-
F_{R2sp}	F_{2sp}	-	3 200	-	2 900	-	2 490	-	2 240	-	2 065	-	1 610
F_{R1su} , lower level	F_{1su} , lower level	4 450	-	4 100	-	3 760	-	3 360	-	3 098	-	2 415	-
F_{R2su} , lower level	F_{2su} , lower level	-	4 450	-	4 100	-	3 760	-	3 360	-	3 098	-	2 415
F_{R1su} , upper level	F_{1su} , upper level	5 700	-	5 300	-	4 880	-	4 480	-	4 130	-	3 220	-
F_{R2su} , upper level	F_{2su} , upper level	-	5 700	-	5 300	-	4 880	-	4 480	-	4 130	-	3 220
F_{R1cmax}	F_{1cr}	2 050	-	1 770	-	1 530	-	1 280	-	1 180	-	920	-
F_{R2cmax}	F_{2cr}	-	2 050	-	1 770	-	1 530	-	1 280	-	1 180	-	920
F_{R1fin}	F_{1fin}	3 200	-	2 900	-	2 490	-	2 240	-	2 065	-	1 610	-
F_{R2fin}	F_{2fin}	-	3 200	-	2 900	-	2 490	-	2 240	-	2 065	-	1 610

Page 72, Annex C

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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.