FINAL
DRAFT

AMENDMENT

ISO 10328:2006 FDAM 1

ISO/TC **168**

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

AMENDMENT 1

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

AMENDEMENT 1

Please see the administrative notes on page iii

Reference number
ISO 10328:2006/FDAM 1:2013(E)

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.

Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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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 10328:2006 was prepared by Technical Committee ISO/TC 168, *Prosthetics and orthotics*.

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

AMENDMENT 1

Page 13, 7.2.3

Replace 7.2.3 by 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 D).

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 D.3 and D.4 and Tables D.2 and D.3 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 15, Table 4

Replace the NOTE by the following:

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

Page 15, Table 5

Replace the NOTE by the following:

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

Page 16, Table 6

Replace the NOTE by the following:

NOTE The offsets specified for P5 also apply to the additional test loading levels P6, P7 and P8 specified in Annex D [see D.3 a)].

Page 16, Table 7

Replace the NOTE by the following:

NOTE The combined offsets specified for P5 also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 17, Table 8

Replace the NOTE by the following:

NOTE For the additional test loading levels P6, P7 and P8 the values of the test forces and the prescribed number of cycles are specified in Table D.2.

Page 18, Table 9

Replace the NOTE by the following:

NOTE The specified test loads also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 18, Table 10

Replace the NOTE by the following:

NOTE The specified directions of loading also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 19, Table 11

Replace the NOTE by the following:

NOTE For the additional test loading levels P6, P7 and P8 the values of the test forces and the prescribed number of cycles are specified in Table D.3.

Page 19, Table 12

Replace the NOTE by the following:

NOTE The specified loading parameters also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 20, Table 13

Replace the NOTE by the following:

NOTE The specified offsets also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 20, Table 14

Replace the NOTE by the following:

NOTE The specified test forces and the prescribed number of cycles also apply to the additional test loading levels P6, P7 and P8 specified in Annex D.

Page 49, 16.2.1.1.2

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

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

Page 53, 16.2.2.1.2

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

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

Page 57, 16.3.2.2

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

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

Page 69, 17.2.3.1.2

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

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

Page 73, 17.2.4.1.2

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

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

Page 74, 17.2.4.1.8

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

Make specific reference if the additional test loading levels P6, P7 and P8 specified in Annex D are to be applied.

Page 78, 17.2.5.1.3

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

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

Page 102, 19.2.1

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

This particularly applies to tests that are conducted at the additional test loading levels P6, P7 or P8 according to Annex D (see 16.2.1.1.2, 16.2.2.1.2 and 16.3.2.2 and/or 17.2.3.1.2, 17.2.4.1.2, 17.2.4.1.8 and 17.2.5.1.3), and to the alternative static ultimate strength test according to Annex C (see 16.2.2.1.1 and 16.2.2.1.6 and/or 17.2.4.1.1 and 17.2.4.1.5/17.2.4.1.11).

Page 110, B.1

Replace the third and fourth 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 D.

Page 110, B.2

Replace the second and third paragraph by the following:

Tables B.1 and B.3 present the values of the test force F and the related values of the ankle and knee bending moments (see NOTE) for test loading conditions I and II and test loading levels (P8, P7, P6), P5, P4 and P3 of the principal cyclic tests.

Tables B.2 and B.4 present the values of the axial force and the twisting moment (see NOTE) related to the test force F for test loading conditions I and II and test loading levels (P8, P7, P6), P5, P4 and P3 of the principal cyclic tests, calculated with the formulae given in B.3.

Page 111, Table B.1

Replace Table B.1 by the following:

Parameter		Loading condition I						Loading condition II					
		(P8)	(P7)	(P6)	P5	P4	P3	(P8)	(P7)	(P6)	P5	P4	P3
Test force	F_{cr} [N]	2050	1770	1530	1280	1180	920	1950	1700	1400	1150	1035	797
Ankle bending moment	M_{Ao} [Nm]	-63,2	-54,5	-47,2	-39,5	-39,5	-36,1	232,4	202,6	166,8	137,0	118,0	91,0
Ankle bending moment	M_{Af} [Nm]	-59,3	51,2	-44,2	-37	-28	-21,3	42,6	37,1	30,6	25,1	25,1	20,5
Knee bending moment	M_{Ko} [Nm]	102,8	88,7	76,7	64,2	64,2	43,0	139,4	121,6	99,6	81,8	70,0	53,6
Knee bending moment	M_{Kf} [Nm]	98,8	85,3	73,8	61,7	54,9	50,0	67,8	59,7	48,7	40,0	40,0	34,0

Page 111, Table B.2

Replace Table B.2 by the following:

Parameter		Loading condition I						Loading condition II					
		(P8)	(P7)	(P6)	P5	P4	P3	(P8)	(P7)	(P6)	P5	P4	P3
Axial force	F_u [N]	1976	1706	1475	1234	1137	884	1936	1688	1390	1142	1028	791
Twisting moment	M_u [Nm]	-0,2	-0,2	-0,2	-0,1	-0,8	-2,4	12,1	10,5	8,7	7,1	6,9	6,0

Page 112, Table B.3

Replace Table B.3 by the following:

Parameter		Loading condition I						Loading condition II					
		(P8)	(P7)	(P6)	P5	P4	P3	(P8)	(P7)	(P6)	P5	P4	P3
Test force	F_{cr} [N]	2100	1820	1580	1330	1230	970	2000	1750	1450	1200	1085	847
Ankle bending moment	M_{Ao} [Nm]	-64,8	-56,1	-48,7	-41,0	-41,2	-38,1	238,3	208,5	172,8	143,0	123,7	96,7
Ankle bending moment	M_{Af} [Nm]	-60,7	-52,6	-45,6	-38,4	-29,2	-22,5	43,7	38,2	31,7	26,2	26,3	21,8
Knee bending moment	M_{Ko} [Nm]	105,3	91,2	79,2	66,7	66,9	45,3	143,0	125,1	103,2	85,4	73,4	57,0
Knee bending moment	M_{Kf} [Nm]	101,2	87,7	76,2	64,1	57,2	52,7	69,5	60,8	50,4	41,7	41,9	36,1

Page 112, Table B.4

Replace Table B.4 by the following:

Parameter		Loading condition I						Loading condition II					
		(P8)	(P7)	(P6)	P5	P4	P3	(P8)	(P7)	(P6)	P5	P4	P3
Axial force	F_u [N]	2024	1754	1523	1282	1185	932	1986	1738	1440	1192	1078	841
Twisting moment	M_u [Nm]	-0,2	-0,2	-0,2	-0,1	-0,8	-2,5	12,4	10,8	9,0	7,4	7,2	6,4

Page 115, Annex D

Change the Annex from informative to normative and change the title as follows:

Application of additional test loading levels P6, P7 and P8

Page 115, D.1

Replace the second and third 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 have been developed for the principal structural tests and the separate structural tests on ankle-foot devices and foot units.

The additional test loading level P6 is derived from data acquired from measurements and testing of existing products in service. P7 and P8 are derived, among others, from measurements of overweight prosthetic patients, normals and wobbling mass simulations. The relationships between cyclic, proof and ultimate values do not follow those set out for test loading levels P3, P4 and P5 (see Table 3).

Page 116, Table D.1

Replace Table D.1 by the following:

Table D.1 — Test forces of the proof test of end attachments for test loading levels P6, P7 and P8 (see 13.2.1.2)

End attachments for			Stabilizing test force, F_{stab}	Settling test force, F_{set}	Proof test force, F_{pa}
Test procedure	Test loading level	Test loading condition	N	N	N
Principal structural tests	P8	I	50	1640	6840
		II		1560	6300
	P7	I		1416	6360
		II		1360	5808
	P6	I		1224	5856
		II		1120	5310

Page 116, Table D.2

Replace Table D.2 by the following: