

Test Report No.: P - 08 - 237 - MP - PA 009 - E

Prosthetics - Structural testing of lower limb prostheses - foot prostheses / English Version

Page 1/3, 2008-08-19



Test institute: Berlin Cert - Prüf- und Zertifizierstelle für Medizinprodukte GmbH
an der Technischen Universität Berlin
Dovestr. 6, D-10587 Berlin
Tel.: +49(0)30-314-25111, Fax: -23719

Client: American Prosthetic Components, Inc., 900 Ontario Road,
Green Bay, WI 54311, United States of America

Manufacturer: American Prosthetic Components, Inc., 900 Ontario Road,
Green Bay, WI 54311, United States of America

Test sample: Type / model: prosthetic foot unit / DuroFlex
Quantity / identification: 2 / product label
Receipt / condition: 2008-06-20 / new



Test standard: DIN EN ISO 10328:2007 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods

Accreditation: Accredited by the "Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten" ZLG-P-946.97.02

Type of testing: Complete test

Test period: 2008-07-03 to 2008-08-18

Test location: Rooms of the test institute

Test result: The requirements of load level P5 are fulfilled.

established: 2008-08-19

released: 2008-08-19

S. Stuke

Dr.-Ing. P. Diesing

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This report is the result of a single examination of the object in question and is not generally applicable evaluation of the other products in regular production.

FB152_20060802R02MG



Test Report No.: P - 08 - 237 - MP - PA 009 - E

Prosthetics - Structural testing of lower limb prostheses - foot prostheses / English Version

Page 2/3, 2008-08-19



Explanation to Compliance:

Yes: The tested unit was *found to comply* with the requirement.

No: The tested unit *does not comply* with the requirement.

N/A: The tested unit was *not applicable*.

Test methods and -requirements:	Compliance:			Comments:		
	Yes	No	N/A			
Load Level: P5						
1: Test in torsion						
Sample 1: The values of relative angular movement between the ends of the test sample after applying of a torque of 50Nm shall not exceed 3°.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				right	left	
				Start-angle	0,0°	0,0°
				End-angle	0,1°	-0,2°
Sample 2: The values of relative angular movement between the ends of the test sample after applying of a torque of 50Nm shall not exceed 3°.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
				right	left	
				Start-angle	0,1°	0,0°
				End-angle	0,1°	-0,1°
Resulting angle				0,1°	0,2°	
				0,0°	0,1°	
2. Cyclic testing						
Sample 1: The sample has to withstand 2x10 ⁶ cycles at a frequency of 1 Hz. F _{cmax} = 1330 N F _{sp} = 2240 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Start on: 2008-07-04 sample: DF-000508		
Sample 2: The sample has to withstand 2x10 ⁶ cycles at a frequency of 1 Hz. F _{cmax} = 1330 N F _{sp} = 2240 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Start on: 2008-07-25 sample: DF-000507		
3. Principal static ultimate strength test						
Sample 1 – Heel: F _{su, lower level} = 3360 N F _{su, upper level} = 4480 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tested on: 2008-08-18 sample: DF-000508		
Sample 1 – Forefoot: F _{su, lower level} = 3360 N F _{su, upper level} = 4480 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tested on: 2008-08-18 sample: DF-000508		
Sample 2 – Heel: F _{su, lower level} = 3360 N F _{su, upper level} = 4480 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tested on: 2008-08-18 sample: DF-000507		
Sample 2 – Forefoot: F _{su, lower level} = 3360 N F _{su, upper level} = 4480 N	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Tested on: 2008-08-18 sample: DF-000507		

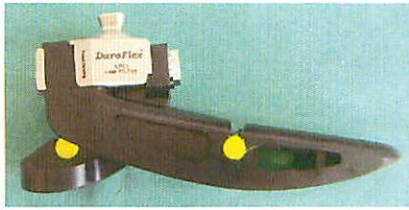
Test Report No.: P - 08 - 237 - MP - PA 009 - E

Prosthetics - Structural testing of lower limb prostheses - foot prostheses / English Version

Page 3/3, 2008-08-19



Description of samples from proximal to distal:

Sample / Model name:	prosthetic foot unit / DuroFlex	
Weight [g]:	620,5 (w/o cosmetic cover)	
Height [mm]:	104	
Length-AP [mm]:	225	
Width-ML [mm]:	58	
Screw torque [Nm]:	-	

Test equipment:		used
PM 0071	test in torsion test bench	<input checked="" type="checkbox"/>
PM 1067	weights 100g to 2000g	<input checked="" type="checkbox"/>
PM 1063	weight holder (use with PM 1067)	<input checked="" type="checkbox"/>
PM 0076	digital goniometer	<input checked="" type="checkbox"/>
PM 0074	caliper (150 mm)	<input checked="" type="checkbox"/>
PM 0078	caliper (350 mm)	<input checked="" type="checkbox"/>
PM 0075	torque wrench	<input checked="" type="checkbox"/>
PM 2012	weighing machine	<input checked="" type="checkbox"/>
PM 3022	dynamic foot unit test bench	<input checked="" type="checkbox"/>
PM 3027	ZWICK universal testing machine	<input checked="" type="checkbox"/>

Comments: