


BIODEX MEDICAL SYSTEMS, INC.

20 Ramsey Road



Shirley, New York 11967-4704




D.O.T. SPECIFICATION 7A, TYPE A


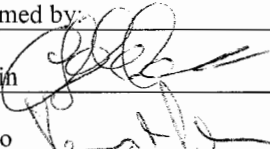

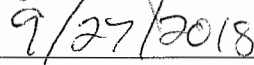
PACKAGING TEST RECORD

Date: June 24, 2009 Package Identification: Intego Vial Shipping Container with Intego Vial Shield Model #001-723 with Model #001-708 Testing was performed at: Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, New York 11967-4704		
Package	Description	Signed Off By
Outer Case: Manufacturer of case Construction material Wall strength, lb test Dimensions, inches Closure Internal cushioning	Zero Plastic rotation molded polyethylene N/A 11.75x11.75x12.5 (h) hinged lid, 2 clasps high density polyethylene foam	
Lead insert Shielding Package: Material	<ul style="list-style-type: none"> Cast lead in a contoured shape to supply appropriate shielding to inner pig – open top and bottom of lead 1 inch lead in bottom of case under contoured cast lead Contoured lead varies from .375” to 1.12”, with 1” lead in bottom of case Removable cover with knob has PVC shell with stainless and lead inside with knob over Intego’s pig contains 0.188” lead on side and 0.25” lead on top 	
Inner support	<ul style="list-style-type: none"> Metal plate to hold and position contoured lead 	
Intego Vial Shield (Model #001-708): Material	<ul style="list-style-type: none"> Vial Shield Body: 0.75” tungsten Vial Shield Cap: Primary pig cap with secondary pig cap has combined tungsten of 1.4” over septum and 1.19” minimum over rest of vial shield opening 	
Closure	<ul style="list-style-type: none"> Double O-ring for primary cap Single O-ring for secondary cap Spring clamp for secondary cap 	
Cushioning	<ul style="list-style-type: none"> N/A 	
Lead Shielding Combined: Outer shield 0.375” to 1.12”	Bottom: 1” lead + 0.75” tungsten Top: 0.25” lead + 1.19” tungsten Sides: Varies depending on location 0.375” to 1.12” + 0.75” tungsten	
Weight: Outer shield and case Intego™ Vial Shield Total Weight	42.8 lbs 15.4 lbs 58.2 lbs	

Package	Description	Signed Off By
Primary Container Unit Dose Pig: Vial / Bottle Nominal volume ml in vial Closure Content Simulation Absorbent Material	Glass vial 30ml, Hospira Approximately 20ml Crimp seal septum Colored water Absorbent Pad #14176-11	
Examination of test sample before tests: Describe: Defects Distortions Deterioration Printing imperfections	None None None None	

TESTS	NOTES	SIGNED OFF BY
WATER SPRAY TEST: 49CFR 173.465(b) (must be performed before remaining tests)		
Spray package:		
	<p>Two (2) cases were sprayed. Case 1 and 2 at the same time. A nozzle was placed on each side of the cases and water sprayed for more than one (1) hour at a rate greater than two (2) inches per hour.</p> <p>A hose was connected to the pipe for a shower head was run and then split into four (4) hoses – each with a nozzle on the end. The hose nozzles were on the four (4) sides of the cases.</p>	
Spray Package: From 1 or 4 sides Rate approx. 2 inches / hour Time – at least 1 hour	Spray from 4 simultaneously greater than 2 inches/hour Sprayed for 1 hour	
Describe Results	<p>The water spray did not affect the plastic shipping container.</p> <p>There was some water inside the case.</p>	
	<p>NOTE: If the package was sprayed from 4 sides simultaneously, the other tests may begin up to 2 hours after the water is turned off.</p> <p>If the spray is from 1 direction on each side sequentially, the Compression Test must begin within 1 hour.</p>	
FREE DROP TESTS (3 TESTS): Onto flat concrete surface		
TEST 1 of 3: DROP TEST 30 FEET 49CFR 173.466(a) (1) (CASE 2) Describe Results:	<p>Zip tie case closed</p> <p>Drop onto latches for maximum damage</p> <hr/> <p>a) Scratched lid of case, held together and stayed closed</p> <p>b) When opened, the vial pig is OK The pig lifts straight out No damage to pig The vial is undamaged The knob on lead cover broke</p>	

TESTS	NOTES	SIGNED OFF BY
TEST 2 of 3: DROP TEST 1 FOOT ONTO 8 CORNERS 49CFR 173.465(c) (2) (CASE 1)	Dropped on all 8 corners	
Describe Results:	Small scratches on corners of case Where dropped – no other damage Opened case Vial pig is undamaged Vial is undamaged Knob on lead case was chipped	
TEST 3 of 3: DROP TEST 4 FEET for maximum damage 49CFR 173.465 (c) (1) (CASE 1)	Zip tie case closed Case taken to top of building & dropped 30 feet onto concrete	
Describe Results:	Case hit on bottom corner <ul style="list-style-type: none"> • The case was bent some • There was a hole in the back of the case • The inner lead shifted from impact of hitting • The inner knob on the lead shield of the removable cover broke • The vial shield and vial were OK and lifted out without any issues • PASSES TEST 	
PENETRATION TEST 49CFR 173.466 (a) (2) and IATA 10.6.3.5.2 (CASE 1)		
Using 1.25 inch diameter bar with hemispherical end weighing 13.2 lbs.		
Drop from 67 inches: Strike point Clock time	Top of case off center touched one rib N/A	
Describe Results:	<ul style="list-style-type: none"> • The bar bounced off – caused crack and hole in the lid – foam not punctured • Case stayed together • The rod hit the handle of the vial pig cover knob and cracked the knob • The vial pig had no other damage • It lifted out of the case • The vial is undamaged and did not leak • PASSES TEST 	

TESTS	NOTES	SIGNED OFF BY
COMPRESSION TEST 49CFR 173.465(d) (CASE 1) Performed December 1999 with same style case		
24 hours compression: Weight in lbs. Clock time – start Clock time – finish	Greater than 400 lbs N/A timer, 24 hours	
Note:	Compression Test was performed by placing a sheet of plywood with lead bricks onto the top of the plastic case. The case weighs 50 lbs. The weight calculation is either (2 lb./in ² x vertical projected area of package, which would be 277 lbs) Or (5x's the weight of the package, which is 295 lbs) We used over 400 lbs of lead bricks on top of the shipping system.	
Describe Results:	There as no damage or effect to the plastic case. The vial shield was not damaged during this test. PASSES TEST	
ACCEPTANCE CRITERIA	<ol style="list-style-type: none"> 1. Damage to the packaging may not cause loss or dispersal of simulated contents. 2. Damage to the packaging may not cause an increase in calculated surface radiation exposure. 3. The test record must be complete and accurate and the photographic record attached. 	
Tests Performed by:		
Clyde Schlein 	Vice President, Regulatory Affairs & Compliance	Clyde Schlein
Ken Paladino 	Engineer	Ken Paladino
Date:		

Note:

Additional tests were performed by Dayton T. Brown. These tests were for compliance to:

- Temperature Test IATA 10.6.2.4.1.4 and 49CFR 178.608
- Pressure Test IATA 10.6.1.3; IATA 5.0.2.9 and 49CFR 173.410(c)
- Vibration Test IATA 5.0.4.3 (also 49CFR 178.608 and 173.24 (a) (5))

These tests are available from Biodex upon request.

Rev. 8-22-18