



BIODEX MEDICAL SYSTEMS, INC.
20 Ramsey Road
Shirley, New York 11967-4704 USA

D.O.T. SPECIFICATION 7A, TYPE A
PACKAGING TEST RECORD



DATE: MAY 26, 2006
PACKAGE IDENTIFICATION: SINGLE OR MULTIPLE DOSE SHIPPING SYSTEM,
MODEL #001-724

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 insert support	<ul style="list-style-type: none"> ▪ cast lead in a contoured shape to supply appropriate shielding to inner pig - open top and bottom on lead ▪ 2 lead sheets in bottom of case under contoured lead ▪ contoured lead varies from 0.232" to 0.699", bottom lead is 0.75" ▪ metal plate to hold and position lead 	
Vial Pig (Model #001-706): material closure cushioning dimensions, "	Pig bottom section: lead encased in .065" steel outer shell top section: aluminum shell filled with lead Lead: body 1" top 1.75" bottom 1" plastic threads on bottom section aluminum threads on top section N/A 6.72" tall x 4.13" diameter	
Lead Shielding Combined: outer shield 0.232" to 0.699"	bottom: 1" + 0.75" = 1.75" top: 1.75" + 0" = 1.75" sides: varies depending on location from 1.232" to 1.699 "	
Weight: outer shield and case vial pig Total Weight	28.4 lbs 21.3 lbs 49.7 lbs	

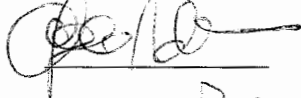
<p>Primary Container Unit Dose Pig: vial/bottle nominal volume ml in vial closure content simulation absorbent materials</p>	<p>glass vial 30ml approximately 20ml crimp seal septum colored water absorbent sheet (001-771)</p>	
<p>Examination of test sample before tests: Describe: defects distortions deterioration printing imperfections</p>	<p>none none none none</p>	
TESTS	NOTES	SIGNED OFF BY
<p>TEST RECORD:</p>	<p>Perform tests in order and attach a photographic record</p>	
<p>WATER SPRAY TEST: 49 CFR 173.465 (b) (2 CASES) (must be performed before remaining tests)</p> <p>Spray Package: from 1 or 4 sides rate approx. 2 inches / hour time at least 1 hour</p> <p>Describe Results:</p>	<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> <p>spray from 4 simultaneously greater than 2 inches / hour sprayed for 1 hour</p> <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 hrs. 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>	<p></p>

TESTS	NOTES	SIGNED OFF BY
<p>FREE DROP TESTS: onto flat concrete surface</p> <p>Drop Test four feet for maximum damage: 49 CFR 173.465 (c) (1) (CASE 2)</p> <p>Describe Results:</p> <p>Drop Test one foot onto 8 corners: 49 CFR 173.465 (c) (2) (CASE 2)</p> <p>Describe Results:</p> <p>Drop Test 30 feet: 49 CFR 173.466 (a) (1) (CASE 1)</p> <p>Describe Results:</p>	<p>zip tie case closed drop onto latches for maximum damage</p> <p>a) scratched case, but held together and stayed closed b) when opened, the vial pig is OK the pig lifts straight out no damage to pig the vial is undamaged</p> <p>dropped on all 8 corners</p> <p>small scratches on corners of case where dropped – no other damage opened case vial pig is undamaged vial is undamaged</p> <p>zip tie case closed case taken to top of building and dropped 30 feet onto concrete</p> <p>case hit on right side . one rivet on the handle popped . the DOT metal label bracket bent . there was a small hole in the side of the case caused by the metal plate inside shifting from the impact putting a dent line in the side of the case and the corner of the bracket coming thru the case . the vial pig is stuck in the contoured shaped outer piece of lead . we were able to unscrew the top of the vial and the vial is OK . there is no damage to the vial and it did not leak</p> <p>PASSES TESTS</p>	<p><u>CS</u></p>

<p>PENETRATION TEST: 49 CFR 173.466 (a) (2) and IATA 10.6.3.5.2 (CASE 2) using 1.25 in. diameter bar with hemispherical end weighing 13.2 lbs.</p> <p>Drop from 67 inches: strike point clock time</p> <p>Describe Results:</p>	<p>Determined the top was the weakest location so dropped the rod onto the top center of the case.</p> <p>top of case between ribs N/A</p> <ul style="list-style-type: none"> ▪ the bar bounced off - caused slight indentation and a small crack in top ▪ case stayed together ▪ the rod hit the handle of the vial pig and bent the handle ▪ the vial pig had no other damage ▪ it lifted out of the case ▪ the pig top unscrewed without a problem ▪ the vial is undamaged and did not leak <p>PASSES TEST</p>	
<p>TESTS</p>	<p>NOTES</p>	<p>SIGNED OFF BY</p>
<p>COMPRESSION TEST: 49 CFR 173.465 (d) (CASE 2) performed December 1999</p> <p>24 hours compression: weight in lbs. clock time - start clock time - finish</p> <p>Describe Results:</p>	<p>greater than 400 lbs N/A timer, 24 hours</p> <p>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</p> <p>The weight calculation is either (2 lb./in² x vertical projected area of package, which would be 277 lbs) or (5x's the weight of the package, which is 250 lbs.)</p> <p>We used over 400 lbs of lead bricks on top of the shipping system.</p> <p>There was no damage or effect to the plastic case. The vial shield was not damaged during this test.</p> <p>PASSES TEST</p>	

ACCEPTANCE CRITERIA:	<p>1. Damage to the packaging may not cause loss or dispersal of simulated contents.</p> <p>2. Damage to the packaging may not cause an increase in calculated surface radiation exposure.</p> <p>3. The test record must be complete and accurate, and the photographic record attached.</p>	
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Tests performed by:



Initials CS



Initials R

Date: June 21, 2006

Rev: August 14, 2018

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) (a) (5))

These tests are available from Biodex upon request.