


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

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

DATE: DECEMBER 17, 2004
PACKAGE IDENTIFICATION: TRIPLE UNIT DOSE PIG SHIPPING SYSTEM
MODEL #001-739

Testing was performed at: Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, New York 11967-4704

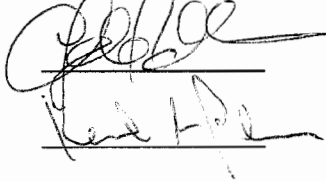
PACKAGE	DESCRIPTION	SIGNED OFF BY
Outer Case: manufacturer of case construction material wall strength, lb test dimensions, inches closure internal cushioning	Zero Plastic rotation molded polyethylene N/A 11.75x11.75x12.5 (h) hinged lid, 2 clasps high density polyurethane foam	
Lead Insert Shielding Package: material insert support	cast lead in a contoured shape to supply appropriate shielding to inner pig - open top and bottom on lead - holds 3 pigs two lead sheets in top and one in bottom of case held in place by the foam metal plate to hold and position lead	
Unit Dose Pig: material closure cushioning dimensions, "	lead encased in plastic shell with integral liner Lead: body .5" top 1.44" bottom 1.2" plastic screw threads between top and bottom sections, single turn twist lock N/A 10.2" long x 2.4" diameter	
Lead Shielding Combined:	bottom: 1.2" + .125" = 1.325" top: 1.44" + .25" = 1.690" sides: varies depending on location from .651" to 1.73"	
Weight: outer shield and case unit dose pig #1 unit dose pig #2 unit dose pig #3 Total Weight	78 lbs 8.9 lbs 8.9 lbs 8.9 lbs 105 lbs	
Primary Container Unit Dose Pig: syringes nominal volume ml closure content simulation absorbent materials	one 5 cc B-D one 5 cc B-D one 5 cc B-D syringe used in pigs Case #1 contained 3.2 ml, 3.4 ml, 3.6 ml used in syringes Case #2 contained 3.4 ml, 3.5 ml, 3.4 ml used in syringes needle and needle cover water, colored absorbent sheet (001-771)	
Examination of test sample before tests: Describe: defects distortions deterioration printing imperfections	none none none none	

TESTS	NOTES	SIGNED OFF BY
<p>TEST RECORD:</p> <p>WATER SPRAY TEST: 49 CFR 173.465 (b) (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>Perform tests in order and attach a photographic record</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. There was some water on the case lip.</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. If the spray is from 1 direction on each side sequentially, the compression test must begin within 1 hour.</p>	<p><u>CS</u></p>
<p>FREE DROP TESTS: onto flat concrete surface</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 four feet for maximum damage: 49 CFR 173.465 (c) (1) (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>used Case #2 dropped on all 8 corners</p> <p>small scratches on corners of case case is OK opened case pigs are OK</p> <p>i) 5 cc B-D dry needle cap ii) 5 cc B-D dry needle cap iii) 5 cc B-D - dry needle cap</p> <p>zip tie case closed thru hasp drop onto latches and hasp for maximum damage</p> <p>a) scratched case, but held together and stayed closed, but plastic wire tie broke b) hasp is slightly bent – case is OK c) pigs are OK and lift straight out d) syringes all have dry needle caps - no leakage</p> <p>Case #1 taken to top of building and dropped 30 feet onto concrete</p> <p>case hit on top case plastic bent – top bulged out, but stayed closed outer lead slightly deformed all three tops were cracked, but were in place – removed tops, but bottoms stuck in lead removed tops</p> <p>a) the 5 cc B-D syringe – needle cap and absorbent material are dry – no leakage b) the 5 cc B-D syringe – needle cap and absorbent material are dry – no leakage c) the 5 cc B-D syringe – the ears and thumb portion of plunger broke off – needle cap and absorbent material are dry – no leakage</p> <p>PASSES TEST</p>	<p><u>CS</u></p>

TESTS	NOTES	SIGNED OFF BY
<p>PENETRATION TEST: 49 CFR 173.466 (a) (2) and IATA 10.6.3.5.2 (CASE 2)</p> <p>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>hit center of top lid N/A</p> <p>the bar put indent in center of top case stayed together pigs are OK syringes: 5 cc B-D syringe is OK 5 cc B-D syringe is OK 5 cc B-D syringe is OK</p> <p>PASSES TEST</p>	<p><u>CS</u></p>
<p>COMPRESSION TEST: 49 CFR 173.465 (d) (CASE 2)</p> <p>performed December 1999 24 hours compression: weight in lbs. clock time - start clock time - finish</p> <p>Describe Results:</p>	<p>greater than 600 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 heaviest system weighs 95 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 475 lbs.)</p> <p>We used over 600 lbs. of lead bricks on top of the shipping system.</p> <p>There was no damage or effect to the plastic container. None of the inner shields were damaged during this test.</p> <p>PASSES TEST</p>	<p><u>CS</u></p>

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. 	
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Tests performed by:



Initials CS

Initials R

Date: December 21, 2004

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.

Rev: Aug 22 2018