


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

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

**DATE:** DECEMBER 22, 2003  
**PACKAGE IDENTIFICATION:** COMPACT DOUBLE-ENDED SINGLE DOSE PIG SHIPPING SYSTEM, MODEL #001-794

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

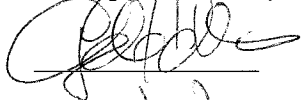
PACKAGE	DESCRIPTION	SIGNED OFF BY
Outer Case: manufacturer of case construction material wall strength, lb test dimensions, inches closure internal cushioning	Zero Plastic rotation molded polyethylene N/A 11.75 x 11.75 x 12.5 (h) hinged lid, 2 clasps high density polyurethane foam	
Lead Insert Shielding Package: material   insert support	cast lead in a contoured shape to supply appropriate shielding to inner pig - open top and bottom   metal plate to hold and position lead	
Unit Dose Pig: Double-Ended Model #001-793 material   closure  cushioning dimensions, inches	lead encased in plastic shell with epoxy coating on lead Lead: body .6 " top .875 tungsten bottom 1.5" 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: 1.5" top: .875" tungsten sides: varies depending on location from .6 to 1.8"	
Weight: lead insert and case unit dose pig Total Weight	32.2 lb 9.8 lb 42.0 lb	
Primary Container Unit Dose Pig: syringe nominal volume ml closure content simulation absorbent materials	One 5 cc syringe 2.6 ml needle and needle cover or luer cap 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
TEST RECORD:	Perform tests in order and attach a photographic record	
<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>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 1.5 hours</p> <p>The water spray did not affect the plastic shipping container.</p> <p>There was no water inside the overlapping seal.</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><u>CS</u></p>

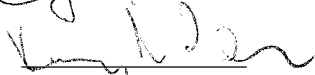
TESTS	NOTES	SIGNED OFF BY
<p>FREE DROP TEST: onto flat concrete surface</p> <p>Drop Test one foot onto 8 corners: 49 CFR 173.465 (c) (2) (CASE 2)</p> <p>Describe Results:</p> <p>Drop Test four feet for maximum damage: 49 CFR 173.465 (c) (1) (CASE 2)</p> <p>Describe Results:</p> <p>Drop Test 30 feet: 49 CFR 173.465 (a) (1) (CASE 1)</p> <p>Describe Results:</p>	<p>dropped in sequence</p> <p>corners have small scratches pig is OK no leakage into needle cap</p> <p>dropped onto latches - plastic zip tie seal used</p> <p>case stayed closed – case is scratched pig is OK - no leakage syringe is OK – no leakage into needle cap</p> <p>case taken to top of building and dropped 30 feet onto concrete apron</p> <p>case hit on top corner lead is bent top of case has split and bent in corner need to bend lead pig comes out both female pig caps have broken threads syringe is OK – needle cap is dry absorbent material is dry</p>	<p><u>CS</u></p>
<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>near center of top lid N/A</p> <p>the bar hit and punched small hole syringe is OK – no leakage into needle cap</p>	<p><u>CS</u></p>

TESTS	NOTES	SIGNED OFF BY
<p>COMPRESSION TEST: 49 CFR 173.65 (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 600 pounds 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 55.2 lbs. The stacking test is (2 lb./in<sup>2</sup> x vertical projected area of package, which would be 277 lbs. or 5x's the weight of the package) which is 276 lbs. 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><u>CS</u></p>
<p>ACCEPTANCE CRITERIA:</p>	<ol style="list-style-type: none"> <li>1. Damage to the packaging may not cause loss or dispersal of simulated contents.</li> <li>2. Damage to the packaging may not cause an increase in calculated surface radiation exposure.</li> <li>3. The test record must be complete and accurate, and the photographic record attached.</li> </ol>	

Tests performed by:



Initials CS



Initials CS

Date: 9/27/2018

**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.

Rev: 8-14-18