


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

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

DATE: DECEMBER 22, 2003		
PACKAGE IDENTIFICATION: COMPACT SINGLE UNIT DOSE PIG SHIPPING SYSTEM, MODEL #001-786		
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: 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" top: 1.44" sides: varies depending on location from .56 to 1.8"	
Weight: lead insert and case unit dose pig Total Weight	33.1 lb 8.9 lb 42 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 Quick Solid 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 data-bbox="240 268 685 359">WATER SPRAY TEST: 49 CFR 173.465 (b) (must be performed before remaining tests)</p> <p data-bbox="272 680 613 804">Spray Package: from 1 or 4 sides rate approx. 2 inches / hour time at least 1 hour</p> <p data-bbox="334 842 513 867">Describe Results:</p>	<p data-bbox="773 268 1187 426">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 data-bbox="773 464 1195 615">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 data-bbox="773 716 1060 804">spray from 4 simultaneously greater than 2 inches / hour sprayed for 1.5 hours</p> <p data-bbox="773 842 1187 905">The water spray did not affect the plastic shipping container.</p> <p data-bbox="773 940 1076 999">There was no water inside the overlapping seal.</p> <p data-bbox="773 1035 1192 1157">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 data-bbox="773 1192 1166 1276">If the spray is from 1 direction on each side sequentially, the compression test must begin within 1 hour.</p>	<p data-bbox="1276 289 1349 338">CS</p> <hr data-bbox="1230 352 1349 359"/>

TESTS	NOTES	SIGNED OFF BY
<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 173.465 (a) (1) (CASE 1)</p> <p>Describe Results:</p>	<p>dropped in sequence on all eight (8) corners</p> <p>corners have small scratches pig is OK no leakage</p> <p>dropped onto latches - plastic zip tie seal used for maximum damage</p> <p>case stayed closed pig is OK - no leakage into needle caps syringe is OK scratches on case front</p> <p>case taken to top of building and dropped 30 feet onto concrete apron</p> <p>case hit on bottom corner corner bent – case lid remained closed and intact lead is OK pig can be lifted out of case top unscrews pig is OK syringe has trace amount of liquid in needle cap absorbent material is dry</p>	<p><u>ES</u></p>
<p>PENETRATION TEST: 49 CFR 173.466 (a) (2) and IATA 10.6.3.5.2 using 1.25 in. diameter bar with hemispherical end weighing 13.2 lbs.(CASE 1 and CASE 2)</p> <p>Drop from 67 inches: strike point</p> <p>clock time</p> <p>Describe Results:</p>	<p>Determined the top was weakest location so dropped the rod onto the top of the cases</p> <p>first case hit near rib on top second case hit near center of top lid N/A</p> <p>case 1 – rod penetrated top case had hole in it pig looks OK syringe is OK – no leaks</p> <p>case 2 - the bar hit and bounced off plastic case has small dent pig looks OK syringe is OK - no leaks</p>	<p><u>ES</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./in² 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>	<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>	

Tests performed by:



Clyde Schlein



Kenneth Paladino

Initials CS

Initials KP

Date: December 22, 2003

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: August 14, 2018