



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

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

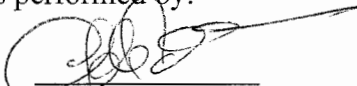
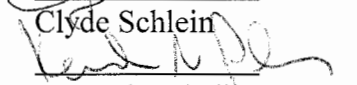
DATE: DECEMBER 22, 2003		
PACKAGE IDENTIFICATION: DOUBLE UNIT DOSE PIG SHIPPING SYSTEM, MODEL #001-787		
Testing was performed at: Biodex Medical Systems, Inc., 20 Ramsey Road, Shirley, NY 11967-4704 USA		
PACKAGE	DESCRIPTION	SIGNED OFF BY
Outer Case: manufacturer of case construction material wall strength, 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	<u>CS</u>
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 2 pigs 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: outer shield and case unit dose pig #1 unit dose pig #2 Total Weight	40.1 lbs 8.9 lbs 8.9 lbs 58 lbs	
Primary Container Unit Dose Pig: syringe nominal volume ml closure content simulation absorbent materials	Two 5 cc syringes used in individual pigs 2.4 ml and 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 more than 1 hour</p> <p>The water spray did not affect the plastic shipping container.</p> <p>The case had some water in it.</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 173.466 (a) (1) (CASE 1)</p> <p>Describe Results:</p>	<p>dropped on all 8 corners</p> <p>pigs are OK, small scratches on case corners syringes did not lose any material into caps absorbent material is dry</p> <p>plastic zip tie case closed drop onto latches for maximum damage</p> <p>case stayed closed – case is scratched pigs are OK syringes are OK – no leakage into needle caps</p> <p>case taken to top of building and dropped 30 feet onto concrete apron</p> <p>case hit on bottom near edge case stayed closed pigs stayed together lead was bent tapped pigs forward to remove one pig can lift out bottom section plastic is cracked syringe is OK second pig bottom is stuck in case tapped to move threads in top and bottom are cracked. syringe is OK – needle cap is dry. absorbent material was dry. some water from outer case Spray Test leaked onto ground</p>	<p><u>CS</u></p> <p><u>CS</u></p> <p><u>CS</u></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 of the case</p> <p>hit off center near rib N/A</p> <p>the bar penetrated the top plastic lid of case case stayed together pigs are OK syringes are OK - no leakage into needle caps</p> <p>PASSES TEST</p>	<p><u>CS</u></p> <p><u>CS</u></p> <p><u>CS</u></p> <p><u>CS</u></p>

TESTS	NOTES	SIGNED OFF BY
<p>COMPRESSION TEST: 49 CFR 173.465 (d) (CASE 2) performed December 1999 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> CS CS</p> <p></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. 	

Tests performed by:


Clyde Schlein

Kenneth Paladino

Initials CS

Initials KP

Date: January 22, 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: August 14, 2018