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TABLE OF CONTENTS

REFERENCE

ASTM D4169	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM D6344	Standard Test Method for Concentrated Impacts to Transport Packages
ENG-WI-007	Operation of Vibration Table and Drop Test Equipment
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories

1. APPENDIX

Appendix I	Shipping Test Log Sheet
Appendix II	Damage Inspection Log Sheet

2. SCOPE

This protocol evaluates the ability of the Zip Pen 2525-10BN shipping containers to withstand the anticipated distribution environment and protect the product.

3. PURPOSE

The purpose of this protocol is to define the product ship testing requirements and evaluate the carton performance after ship testing. Successful completion of this testing provides confidence that the product will withstand the anticipated distribution environment and meet DMR requirements after distribution.

4. BACKGROUND

The Zip Pen is currently marketed in a packaged sterile configuration. Megadyne has initiated a project to sell a bulk non-sterile version for kit packers. These bulk non-sterile cartons are packed 30 per box. The cartons are shipped in Gaylord's from overseas to Megadyne where they are warehoused and then shipped in individual cartons to customers.

5. DEFINITIONS AND ACRONYMS

DMR Device Master Record

6. APPARATUS

6.1. Environmental Chamber

6.2. LAB AccuDrop 160

6.3. Martin Vibration Systems Vibration Table

6.4. Metal shim 0.06 in thick, approximately 2 in wide

6.5. ENG-DWG-768 Concentrated Impact Test Equipment

7. RISK ASSESSMENT

7.1. A review of the Risk Analysis Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risks associated with packaging. The highest severity rating is 10 attributable to damaged pencil fails in use. The following is a list of failure modes, causes, mitigations and verifications.

Failure Mode	Cause	Mitigation	Verification
Damaged Pencil fails in use	Box sized incorrectly – does not protect product adequately	Product validation	ASTM D4169 shipping test
Zip Pen material breakdown from exposure to extreme temperature	Transport and storage outside of accepted limits	Product validation	Shipping Test report

8. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION

8.1. Two cartons of product will be subject to the ship test protocol. This sample size will allow for two boxes and 60 units to be evaluated after the shipping cycle.

Type	Test Type	Sterile Samples 2525-10
Shipping Test/Conditioning	Protocol	2 Cartons (contains 60 total samples)
Product damage	Visual Inspection	2 Cartons and 60 units

8.2. Prior to evaluation, the samples will be subjected to a shipping and storage cycle. This cycle includes temperatures from -40°C to 70°C and humidity's from 15% to 95%. This temperature and humidity cycling is designed to run consecutively with the ASTM D4169 pre-conditioning.

8.3. A summary of the experimental design is as follows:

Shipping and storage cycle and preconditioning
Shipping test
Damage Inspection

9. GENERAL REQUIREMENTS

9.1. Tests shall be performed under typical warehouse conditions. Typical warehouse conditions are:

Temperature: 23°C ±5°C
Relative Humidity: 50% ±35%

Note that these conditions are a wider range than is called out in ASTM D4169. This deviation from standards is considered acceptable because actual warehouse, transport and storage conditions will vary greatly from the range listed in the standard.

9.2. The ASTM D4169 standard requires the choice of an assurance level. For this test assurance level II will be used except where noted. This is the recommended starting level in the standard.

9.3. The test schedule for this test will follow Distribution Cycle 3. This cycle has seven elements performed in the following order; Pre-conditioning, Manual Handling, Vehicle Stacking, Vehicle Vibration, Loose Load Vibration, Concentrated Impact, and Manual Handling. This cycle is followed by evaluation of the product.

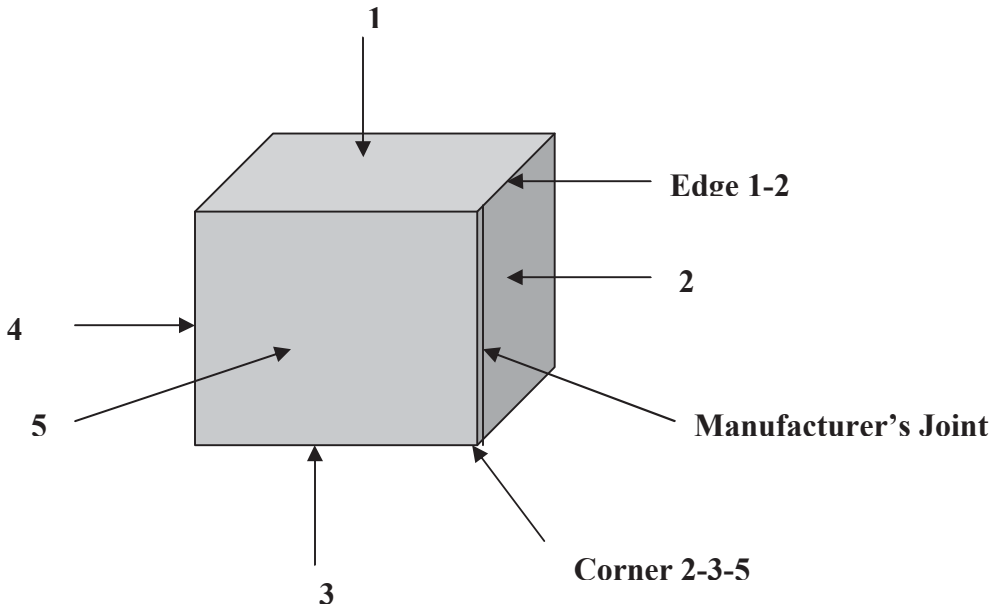
10. SHIPPING AND STORAGE CYCLE AND PRECONDITIONING

10.1. Pre-Conditioning will follow the temperature and humidity schedule listed below.

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to70°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 70°C to70°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 95%RH	4 hours
Transition from 70°C and 95% RH to 70°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 15%RH	4 hours
Transition from 70°C and 15% RH to 23°C and 50% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

11. SHIPPING TEST

11.1. Following the conditioning, using a permanent marker, identify the faces of the shipping boxes according to the following diagram.



11.2. Record the gross weight (Wt.) of the shipper box containing product in pounds.

11.3. Record the Catalog number of the product.

11.4. Record the Lot Number of the product.

11.5. Perform the Handling test (drop test) as follows.

11.5.1. The required drop height from ASTM D4169 paragraph 10.2.3 using assurance level II is 15 inches for packages from 0 to 20 pounds. Package weight is 14 pounds.

11.5.2. Set the height on the LAB AccuDrop 160 to 15 inches. Drop the test package in the following sequence.

Drop	Drop Height	Orientation	Specific face, edge or corner
1	15 in.	Top	Face 1
2	15 in.	Edge	Edge 5-3
3	15 in.	Edge	Edge 6-3
4	15 in.	Corner	Corner 2-3-5
5	15 in.	Corner	Corner 4-3-6
6	15 in.	Bottom	Face 3

11.5.3. Record package drops on the data sheet in Appendix I.

11.6. Perform the compression test. For the compression test, use ASTM D4169 paragraph 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level III will be applied. The justification for this adjustment is that the Zip Pen cartons will be shipped from the supplier in large Gaylord boxes. The Gaylord box carries a portion of the load when they are stacked for overseas shipment. The maximum stack is three boxes high (10.6 inches per box) in each of two Gaylord's, therefore a height of 63.6 inches will be used in the formula. The formula for the weight of the compression is as follows:

$$L = M \times Jx((H-h)/h)xF$$

Where the mass M =14 lbs., J = 1 lbf/lb, H=63.6 inches, h= 10.6 inches and F = 3.0, a factor to account for the combined effect of the individual factors taken from paragraph 11.2 of ASTM D4169. Record information in Appendix I.

Catalog Number	Carton Weight (lbs.)	Stack Height (ft.)	Compression (lbs.)
2525-10BN	14	5.3	210

11.6.1. Place *Face 3* of the shipper box on the ground.

11.6.2. Place a wood board on top of the shipper box, such that the shipper box is centered underneath the board. The wood board must extend a minimum of two inches on all sides of the box.

11.6.3. Place the test load (determined above) on the center of the wood board.

11.6.4. Allow the weight to remain on the wood board for a minimum of 3 seconds.

11.6.5. Inspect the package for damage. Record observed shipper box damage, if applicable.

11.7. Following the compression test perform the Vehicle Vibration test, record information in Appendix I.

11.7.1. Place the shipper box containing packaged product on the vibration table so that *Face 3* rests on the platform.

11.7.2. Start the vibration system beginning at the lowest frequency.

11.7.3. Slowly increase the frequency of the vibration until the shipper box begins to momentarily leave the surface of the platform.

11.7.4. Check the frequency using the shim.

11.7.4.1. Swipe the shim under the shipping box along the longest side from one end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other.

11.7.4.2. If the shim does not travel uninterrupted, increase the frequency of the vibration table.

11.7.5. Leave the box on the vibration table for a period of 10 minutes.

11.7.6. After 10 minutes of Loose Load Vibration, reduce the frequency for the Loose Load vibration.

11.7.7. Check the frequency using the shim.

11.7.7.1. Swipe the shim under the shipping box along the longest side from one end to the other. The shim should be able to travel uninterrupted on the long side of the box from one end of the box to the other. At this low frequency the movement of the shim will be interrupted movement.

11.7.8. Leave the box on the vibration table for a period of 40 minutes.

11.8. Following the vibration test, perform the Concentrated Impact test per ASTM D6344.

11.8.1. The impact test will be done on the faces 1, 2, and 3 from the figure in 11.1. Use the impact equipment identified in ENG-DWG-768.

11.8.2. The impact energy applied to each face will be 4.0 ft-lbf. This energy is applied by dropping the cylinder of mass 1.5 lbf. from a height of 32 in.

11.9. Following the concentrated impact test, perform the second package handling (drop test). Follow the sequence listed below. Make all of the drops from 15 inches except the final drop which is from 30 inches.

Drop	Drop Height	Orientation	Specific face, edge or corner
1	15 in.	Edge	Edge 4-6
2	15 in.	Face	Face 4
3	15 in.	Face	Face 6
4	15 in.	Corner	Corner 2-1-5
5	15 in.	Edge	Edge 2-1
6	30 in.	Bottom	Face 3inches.

11.10. Following the shipping test, evaluate the product as follows:

11.11. Inspect the exterior of each box and note any damage. Record pass/fail results in Appendix I.

12. PRODUCT DAMAGE AND PARTICULATE INSPECTION

12.1. Open each bag one at a time and remove the Zip Pen.

12.2. Visually inspect the Zip Pen, electrode, Holster and Bag for damage. Damage includes cracks, rub marks, bent electrodes and holes in the unit bag. Also inspect for particulate in the bag and on the product.

12.3. Record pass/fail results in Appendix II. If a product is considered to fail, describe the failure in the comments on the log sheet.

12.4. All visual inspections are to be performed using 10X magnification, under the microscope lighting, with a maximum of 30 second time limit for visual inspection.

13. ACCEPTANCE CRITERIA

13.1. Shipping Test

13.1.1. Each box shall remain intact and not collapse or break open during the test. Indentations on edges or corners are acceptable.

13.2. Product Damage

13.2.1. There shall be no damage as described in 12.2 to the Zip Pen, electrode, holster or bag on any of the samples.

APPENDIX I

Shipping Test Log Sheet

Preconditioning:

Start Date: _____ Chamber Number:_____

Completion Date: _____ Last Calibration:_____

Signature/Date: _____ Calibration due:_____

Drop Test:

Catalog _____ Weight _____ Drop Height: _____

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Top	Face 1	
2	15 in.	Edge	Edge 5-3	
3	15 in.	Edge	Edge 6-3	
4	15 in.	Corner	Corner 2-3-5	
5	15 in.	Corner	Corner 4-3-6	
6	15 in.	Bottom	Face 3	

Comments: _____

Signature: _____ Date: _____

Compression Test:

Catalog _____ Pounds Force _____

Comments: _____

Signature: _____ Date: _____

Appendix I Continued
Shipping Test Log Sheet

Vibration:

High Frequency, 10 minutes, Initials_____ Low frequency 40 minutes, Initials _____

Completion Date: _____

Signature: _____ Date: _____

Concentrated impact test

Package dimensions: Length_____ Width _____ Height _____

# of units tested _____ Test Mass _____ Drop Height _____

Completion Date: _____

Signature: _____ Date: _____

Second Drop Test:

Catalog_____Weight _____ Drop Height: _____

Drop Sequence	Drop Height	Orientation	Specific face, edge or corner	Initials/Date
1	15 in.	Edge	Edge 4-6	
2	15 in.	Face	Face 4	
3	15 in.	Face	Face 6	
4	15 in.	Corner	Corner 2-1-5	
5	15 in.	Edge	Edge 2-1	
6	30 in.	Bottom	Face 3	

Comments: _____

Signature: _____ Date: _____

Appendix II
Product Damage Inspection Log Sheet

Inspect the product per paragraph 12.2 in the protocol and enter the number of units that pass or fail in the box below. Note the description of any failures in the comments section.

Catalog #	Pass	Fail
Damage		

Comments:_____

_____

_____

Inspected by: Date completed