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DOCUMENT NUMBER: ENG-PRT-425

DOCUMENT TITLE: ZIP ACE 6-Pack Ship Test Protocol

DOCUMENT NOTES:

The rationale in Section 4 was updated to improve the comparison between the 20-p

Document Information

Revision: 002	Vault: MEG-Rel
Status: Release	Document Type: ENG-PRT

Date Information

Effective Date: 21 Feb 2018	Expiration Date:
Release Date: 21 Feb 2018	Next Review Date:

Control Information

Author: CCROOK	Owner: TSKINNER
Previous Number:	Change Number: 2017-ENG-DCO-124

Signature Manifest

Document Number: ENG-PRT-425 **Revision:** 002
Title: ZIP ACE 6-Pack Ship Test Protocol

All dates and times are in Mountain Standard Time.

ZIPACE Pckg Protocol Update

Change Request

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		01 Nov 2017, 09:49:39 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		16 Feb 2018, 09:28:38 AM	Complete
Christian Crook (CCROOK)		16 Feb 2018, 11:52:57 AM	Complete
Darlene Hull (DHULL)	Regulatory	16 Feb 2018, 12:51:33 PM	Complete
Curt Doel (CDOEL)	Quality Manager	19 Feb 2018, 03:50:23 PM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	20 Feb 2018, 10:57:44 AM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		20 Feb 2018, 01:17:22 PM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	20 Feb 2018, 01:22:38 PM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	21 Feb 2018, 01:57:04 PM	Approved

ENG-Approval

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		20 Feb 2018, 02:13:06 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		21 Feb 2018, 03:10:55 PM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason

Lucy Richards (LRICHARDS)	21 Feb 2018, 03:11:08 PM	Approved

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1. SCOPE

This protocol evaluates the ability of the proposed 6-pack Zip Pen shipping boxes and sterile packaging (see drawing ME7251C) to withstand the anticipated distribution environment.

2. PURPOSE

The purpose of this protocol is to define the product ship testing requirements and verify package performance post ship testing. The protocol also verifies that the Tyvek pouch integrity is maintained and that there is an absence of product damage. Successful completion of this testing provides confidence that the product will withstand the anticipated distribution environment and meet DMR requirements in ENG-DMR-012 after distribution.

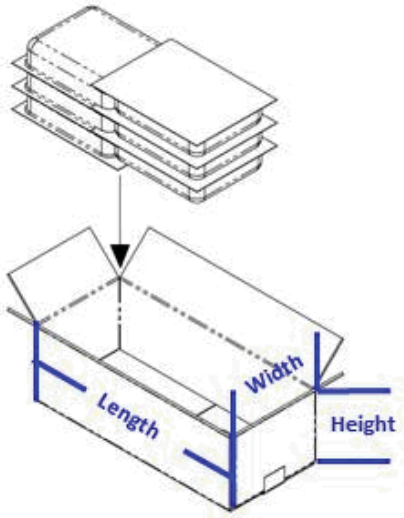
3. REFERENCES

IEC 60601-2-2 Ed. 5	Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment
ASTM D4169	Performance Testing of Shipping Containers and Systems
ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-WI-007	Operation of Vibration Table and Drop Test Equipment
OPER-FRM-004	Inspection Form, Peel Pouch Burst Test
ENG-PRT-229	Shipping Test – Zip Pen 2525-10
ENG-RPT-330	Shipping Test – Zip Pencil
2010421-01	ASTM D6344 Guided Free Fall Concentrated Impact Test Equipment
ME7251C	Zip Pen, Electrosurgical Pencil w/ ACE12, Holster, 10 ft. Tubing
2525-10	Zip Pen, Electrosurgical Pencil w/ E-Z Clean, Holster, 10 Foot Tubing

4. BACKGROUND

Zip Pens are currently shipped in a 20-unit shipping container (see Product Code: 2525-10, ENG-PRT-229, and ENG-RPT-330). In an effort to provide smaller quantities of product to customers, marketing has identified a need to distribute Zip Pens in 6-unit shipping containers (see drawing ME7251C).

A close review of the packaging dimensions between the 252510 20-pack and the ME series 6-Pack shows that the dimensions are not significantly different.



Box Height: The package height for a stack of 5 products is 9 inches, for 3 products it is 5.4 inches. The box height was scaled to fit three products exactly as they are held in the current 20-pack.

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The tolerance on box dimensions of both the 20-Pack box 3900231-01 and the 6-Pack box 3900316-01 is ± .25 inches. No additional per unit height was introduced into the packaging by the 6-pack box. There is no additional opportunity for pouch wear in the vertical direction within the box.

Box Width: The width of the 20-pack box is 16 inches; the width of the 6-pack box is 8 inches. The box width was scaled to half in the 6-pack box.

The 20-pack box includes a double-walled divider which slides freely within the box. Pouches can slide within an 8 inch width. The divider splits structural support between the halves of the box.

The tolerance on box dimensions of both the 20-Pack box 3900231-01 and the 6-Pack box 3900316-01 is ± .25 inches. No additional width was introduced into the packaging by the 6-pack box. There is no additional opportunity for pouch wear

in the width direction within the box. No box structural support is lost changing to the 6-pack box.

Box Length: The pouches are packaged so that a pair of pouches has a length of approximately 18.5 inches for both the 20-pack and 6-pack box. The box length was not scaled because the package length is constant between the 20-pack and 6-pack. The tolerance on box dimensions of both the 20-Pack box 3900231-01 and the 6-Pack box 3900316-01 is ± .25 inches.

The divider mentioned above removes about .125 inches from each side of the length (total of .25 inches). An additional 0.25 inch of package movement is introduced into the packaging by the 6-pack box. This additional length is evaluated in this test protocol. Therefore t=0 testing after conditioning and shipping simulation will be sufficient to qualify the efficacy of the proposed 6-unit shipping configuration.

5. EQUIPMENT

- (6) 6-unit box as seen in drawing ME7251C
- (36) Zip Pens (PN: 6020190-01) pulled from product code 2525-10
- Environmental Chamber
- LAB AccuDrop 160
- Martin Vibration Systems Vibration Table
- Metal shim 0.06 in thick, approximately 2 in wide
- Model F100-2600-3 Test-A-Pack Seal Strength Tester
- Guided Free Fall Concentrated Impact Test Equipment (PN: 2010421-01)

6. RISK ASSESSMENT

The FMEA for Smoke Accessories (ENG-RMF-045) was reviewed while considering the proposed 6-unit shipping box. The following line items were found to be applicable:

Line Item	Failure Mode
42-D	Product unsterile – Holes in package - Product damaged
43-D	Product is contaminated – Inner bag opens unexpectedly
45-D	Damaged pencil fails in use – Box sized incorrectly

After review, the following risk controls will be done to address each line item above:

- For line items 42-D and 43-D, Bubble leak testing, Dye testing, Burst testing, and Minimum seal width testing will be performed post ship testing.
- For line item 45-D, product damage inspection will be performed post ship testing.

7. EXPERIMENTAL DESIGN/SAMPLE SIZE JUSTIFICATION

7.1. Experimental Design

All testing will be performed using the proposed 6-unit shipping configuration described in drawing ME7251C. Zip Pens with standard connectors and 0012 capped blades (PN: 6020190-01), pulled from product code 2525-10, will be used for testing and can be considered a representative sample for all Zip product codes as the "standard" proximal adapter (PN: 5800302-01) is bulkier than the "EC" proximal adapter (PN: 5800099-01) found in other Zip Pen configurations and thus represents a worst-case shipping scenario. In addition, the difference between the 0012 blade found in product code 2525-10 and the ACE Blades (ACE12BN5) found in ZIP ACE codes can be considered negligible as it minimally affects shipping weight, the blades are the same length, capped, and have no impact on shipping configuration.

7.1.1. Shipping Test

Ship Testing shall be performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C

Relative Humidity: 50% ±35%

These conditions are a wider range than stated in ASTM D4169. This deviation from the standard is considered acceptable because actual warehouse, transport, and storage conditions will vary greatly from the range listed in the standard.

The ASTM D4169 standard requires the choice of an assurance level. For this test, assurance level II will be used. This level was chosen because it is the recommended starting level in the standard.

The test schedule for this test will follow Distribution Cycle 3: Pre-conditioning, Handling, Vehicle Stacking, Loose load Vibration Vehicle Vibration, Concentrated Impact, and Handling. This distribution cycle has been chosen because the product may be shipped as a single package without a pallet or skid.

NOTE: This product will normally be shipped on a pallet. However, the chosen cycle (without a pallet) is considered to be a worst-case scenario and therefore should be sufficient to test all foreseeable shipping conditions.

7.1.2. Bubble Leak Testing

Bubble Leak Testing will be performed as outlined in ENG-PRT-229 Rev. 002 Section 16.

7.1.3. Dye Testing

Dye Testing will be performed as outlined in ENG-PRT-229 Rev. 002 Section 17.

7.1.4. Burst Testing

Burst Testing will be performed as outlined in ENG-PRT-229 Rev. 002 Section 18.

7.1.5. Minimum Seal Width Testing

Minimum Seal Width Testing will be performed as outlined in ENG-PRT-229 Rev. 002 Section 19.

7.1.6. Product Damage Inspection

Product Damage Inspection will be performed as outlined in ENG-PRT-229 Rev. 002 Section 20.

7.2. Sample Size Justification

Thirty-six (36) Zip Pens will be packaged in the proposed 6-unit shipping configuration and ship tested. This will provide 36 samples to be used for the required Bubble Leak Testing, Dye Testing, Burst Testing, Minimum Seal Width Testing, and Product Damage Inspection.

7.2.1. Bubble Leak Testing

Bond Strength Testing: A sample size of 35 for Bubble Leak Testing will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5. Although normally this defect classification is Critical (per QA-SOP-012), a classification of major will be used since Bubble Leak Testing data for the same production density, production configuration, packaging materials, and manufacturing process has previously been obtained (ENG-RPT-330).

7.2.2. Dye Testing

Dye Testing: A sample size of 35 for Dye Testing will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5. Although normally this defect classification is Critical (per QA-SOP-012), a classification of major will be used as Dye Testing data for the same production density, production configuration, packaging materials, and manufacturing process has previously been obtained (ENG-RPT-330).

7.2.3. Burst Testing

Burst Testing: A sample size of 35 for Burst Testing will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5. Although normally this defect classification is Critical (per QA-SOP-012), a classification of major will be used as Burst Testing data for the same

production density, production configuration, packaging materials, and manufacturing process has previously been obtained (ENG-RPT-330).

7.2.4. Minimum Seal Width Testing

Minimum Seal Width Testing: A sample size of 35 for Minimum Seal Width Testing will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5. Although normally this defect classification is Critical (per QA-SOP-012), a classification of major will be used as Minimum Seal Width Testing data for the same production density, production configuration, packaging materials, and manufacturing process has previously been obtained (ENG-RPT-330).

7.2.5. Product Damage Inspection

Product Damage Inspection: A sample size of 35 for Product Damage Inspection will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5. Although normally this defect classification is Critical (per QA-SOP-012), a classification of major will be used as Product Damage Inspection data for the same production density, production configuration, packaging materials, and manufacturing process has previously been obtained (ENG-RPT-330).

8. SHIPPING TEST

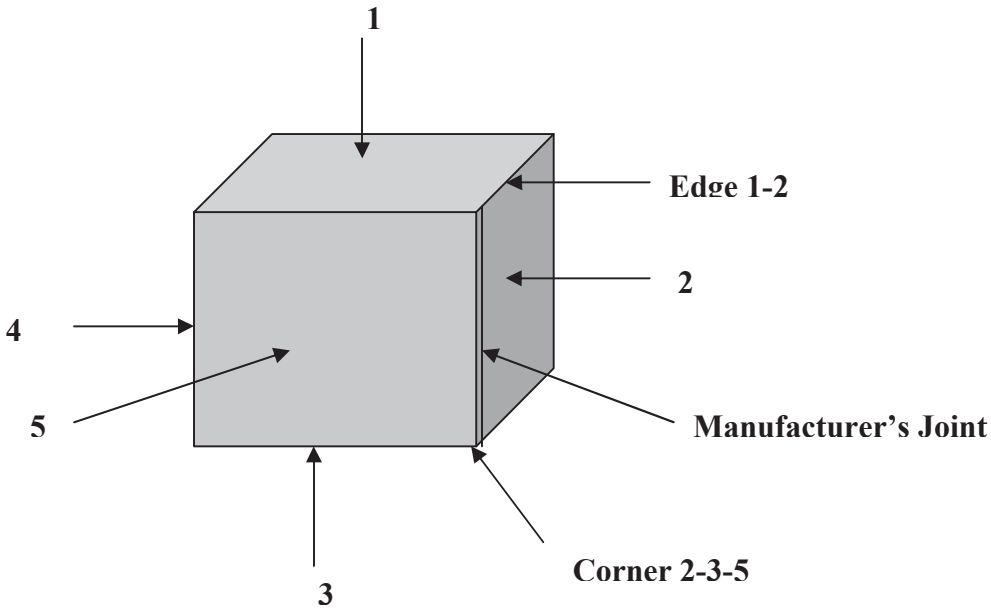
8.1. Preconditioning

8.1.1. Using sterile product that has received maximum dosage, precondition the product following the schedule 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 to 55°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 55°C to 55°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 95%RH	4 hours
Transition from 55°C and 95% RH to 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 15%RH	4 hours
Transition 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

8.2. Handling – Manual

8.2.1. Use a permanent marker to identify the faces of the shipping boxes according to the following diagram.



8.2.2. Record the gross weight (M) of the shipper box containing product in pounds.

8.2.3. Record the Catalog Number of the product.

8.2.4. Record the Lot Number of the product.

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

8.2.6. 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 approximately 3.5 pounds.

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

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

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

8.3. Vehicle Stacking

8.3.1. Perform the Vehicle Stacking test (compression test). For the compression test, use ASTM D4169 section 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level II will be applied. The formula for the weight of the compression is as follows:

$L = M \times J \times ((H-h)/h) \times F$

Where:

L is the computed load (lbf)
M is the mass (lb)
J = 1 lbf/lb
H= 108 in
h = height of package (in)
F = 3.0 (see section 11.2 of ASTM D4169)

8.3.2. Place Face 3 of the shipper box on the ground.

8.3.3. 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.

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

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

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

8.4. Loose Load Vibration and Vehicle Vibration

8.4.1. Following the Vehicle Stacking test, perform the Loose Load Vibration test per ENG-WI-007. Record the information in Appendix I.

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

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

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

8.4.5. Check the frequency using the shim.

8.4.5.1. Swipe the shim under the shipping box along the longest side from one of the 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. At this low frequency, the movement of the shim will be interrupted movement.

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

8.4.7. After 40 minutes of Loose Load Vibration, increase the frequency for the Vehicle Vibration Test.

8.4.8. Check the frequency using the shim.

8.4.8.1. Swipe the shim under the shipping box along the longest side from one of the 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.

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

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

8.5. Concentrated Impact

8.5.1. Following the Vibration tests, perform a Concentrated Impact test.

8.5.2. The Impact test will be done on the following faces using the Impact test equipment identified in ENG-DWG-768.

8.5.3. The impact energy applied to each surface will be 4.0 ft-lbf (5.4 J). This energy will be achieved by dropping the cylinder mass defined within the 2010421-01 equipment at a height of 32 in (0.8 m).

8.6. Handling – Manual (2nd)

8.6.1. 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 Sequence	Orientation	Specific face, edge or corner
1	Edge	Edge 4-6
2	Face	Face 4
3	Face	Face 6
4	Corner	Corner 2-1-5
5	Edge	Edge 2-1
6	Bottom	Face 3, Increase height to 30 inches.

8.7. Record completion of Shipping Test in Appendix I.

9. PROCEDURE

9.1. Bubble Leak Testing

9.1.1. Perform Bubble Leak Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 16.

9.1.2. Record data in Appendix II and attach results to test report.

9.2. Dye Testing

9.2.1. Perform Dye Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 17.

9.2.2. Record data in Appendix III and attach results to test report.

9.3. Burst Testing

9.3.1. Perform Burst Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 18.

9.3.2. Record data on form OPER-FRM-004 and attach results to test report.

9.4. Minimum Seal Width Testing

9.4.1. Perform Minimum Seal Width Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 19.

9.4.2. Record data in Appendix IV and attach results to test report.

9.5. Product Damage Inspection

9.5.1. Perform Product Damage Inspection on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 20.

9.5.2. Record data in Appendix V and attach results to test report.

10. ACCEPTANCE CRITERIA

10.1. Shipping Test

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

10.2. Bubble Leak Testing

There shall be no tears, holes or open seals in any pouch that compromise sterility after the ship test exposure.

10.3. Dye Testing

The primary reason for the dye test is to make the seal edge more visible and to insure there are no breaches in the seal. There shall be no breaches in the seal.

10.4. Burst Testing

The minimum allowable burst value is 19 in. H_2O. All package burst test values shall be above this limit.

10.5. Minimum Seal Width Testing

The minimum seal width is 0.20”. All Seals shall meet or exceed this dimension.

10.6. Product Damage Inspection

There shall be no damage to the electrode or any other part of the Zip Pen on any of the samples.

11. APPENDIX I – SHIPPING TEST

Preconditioning:

Start Date:Chamber Number:

Completion Date:Last Calibration:

Signature/Date:Calibration due:

Drop Test:

Catalog Number:Weight:Drop Height:

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

Comments:

Signature:Date:

Compression Test:

Catalog Number:Pounds Force:

Comments:

Signature:Date:

Appendix I Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials:

High frequency 10 minutes, Initials:

Completion Date:

Signature:Date:

Concentrated Impact Test:

Completion Date:

Signature:Date:

Second Drop Test:

Catalog Number:Weight:Drop Height:

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	
2	Face	Face 4	
3	Face	Face 6	
4	Corner	Corner 2-1-5	
5	Edge	Edge 2-1	
6	Bottom	Face 3, Increase height to 30 inches.	

Comments:

Signature:Date:

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number ENG-PRT-425
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12. APPENDIX II – BUBBLE LEAK TEST

Catalog # _____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			

Sample	Pass	Fail	Comment
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			

Signature: _____ Date: _____

13. APPENDIX III – DYE PENETRATION TEST

Catalog # _____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			

Sample	Pass	Fail	Comment
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			

Signature: _____ Date: _____

14. APPENDIX IV – MINIMUM SEAL WIDTH TESTING

Catalog #			Lot #		
Sample	Cavity	Front	Back	Right	Left
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
Signature:				Date:	

15. APPENDIX V – PRODUCT DAMAGE INSPECTION

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Damage		

Comments:

_____

_____

_____

Signature_____ Date: _____