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1. ABSTRACT

Test Protocol ENG-PRT-425 was completed successfully. Testing was limited to Bubble Leak testing, Dye testing, Burst testing, Minimum Seal Width testing, and a Product Damage Inspection in order to verify the proposed 6-Pack shipping configuration. Only t=0 testing was performed as the changes to the packaging configuration were minimal. All tests were completed successfully.

These results demonstrate that the proposed 6-Pack shipping configuration maintains the Tyvek pouch integrity, protects the product from damage, and provides confidence that the product will meet DMR requirements, as outlined in ENG-DMR-012, after distribution.

Section 8 from test protocol ENG-PRT-425 was repeated due to an error in calculation of the load (100 lb) in the Vehicle Stacking (Compression Test) in section 5.1.3. New load computation has been corrected in section 5.1.3 of this report. The remainder of the data from the first revision of this report is still valid as the compression affects only the outer box not the integrity of the pouch. Section 9.5 Product Damage inspection of ENG_PRT-425 was also conducted and included in Appendix VII to assure integrity of the outer box after the shipping test.

NOTE: ENG-PRT-425 was revised during the testing to clarify rationale of the T=0 testing. The method or acceptance criteria did not change from revision 001 to 002.

2. REFERENCES

ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
XENG-PRT-425	ZIP ACE 6-Pack Ship Test Protocol
ME7251C	Ace Blade 700, 2.5" Zip Pen, "C" Connector, 10 ft. Tubing

3. OBJECTIVE

This Test Report documents that using the proposed 6-Pack shipping configuration to distribute Zip Pens has no effect on the packaging integrity of the sterile product.

4. APPENDICES

Appendix I – Preconditioning and Ship Testing Appendix II – Bubble Leak Testing Appendix III – Dye Testing

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Appendix IV – Burst Testing

Appendix V – Minimum Seal Width Testing

Appendix VI – Product Damage Inspection

**Appendix VII – Preconditioning and Ship Testing with 210 lb Vehicle Stacking (Compression Test) load

5. RESULTS

5.1. Ship Conditioning

A total of n=36 Zip Pen samples, SKU: 2525-10 Lot # 1507120, were pulled from stock and used for testing. The Zip Pen samples were placed in die cut boxes (New Dean PN: B108200 LOT#: 17063001) and arranged in the proposed 6-unit shipping configuration along with ACE IFUs (PN: 3000149-01 Rev 002) and ZIP IFUs (PN: MKT-LBL-531 Rev 002) as shown in Megadyne drawing ME7251C.

The ship test was performed as outlined in ENG-PRT-425. See Appendix I for a complete summary of testing.

Tests were performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C

Relative Humidity: 50% ±35%

5.1.1. Preconditioning

Preconditioning followed the schedule below (see Appendix I for Cycle Data):

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to55°C	Set time to 0:00 and set the standard deviation to 1°C
^U Transition from 70°C to 55°C and a 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 Ho 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
aHold 55°C and 15%RH	4 hours
nTransition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
5Hold 23°C and 50%RH	72 hours

.1.2 Handling - Manual (Drop Test)

The Manual Handling (Drop Test) was performed using a drop height of 15 in as outlined in ENG-PRT-425.

5.1.3. Vehicle Stacking (Compression Test)

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The Vehicle Stacking (Compression Test) was performed using a computed load (L) of 210 lb as outlined in ENG-PRT-425, and below.

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

Where:

L is the computed load (lbf)

M = 3.5 lb

J = 1 lbf/lb

H=108 in

h = 5.5

F = 3.0 (see section 11.2 of ASTM D4169)

This formula results in a testing weight (L) of 195.68. Using 210 lbs. is okay as this is more weight than required by ASTM 4169. See Appendix VII.

5.1.4. Vehicle Vibration and Loose Load Vibration Tests

The Vehicle Vibration test was performed for 10 min as outlined in ENG-PRT-425. Following the Vehicle Vibration test, the Loose Load Vibration Test was performed for 40 min as outlined in ENG-PRT-425.

5.1.5. Concentrated Impact Test

The Concentrated Impact Test was performed as outlined in ENG-PRT-425.

5.1.6. Manual - Handling (2nd Drop Test)

The Manual Handling (2nd Drop Test) was performed using a drop height of 15 in with the final drop at a height of 30 in as outlined in ENG-PRT-425.

5.1.7. Each box remained intact and did not break open during the test. See **Appendix V1I.

5.2. Bubble Leak Testing

The Bubble Leak test was performed on 35 samples as outlined in ENG-PRT-425. There will no tears, holes, or open seals in any pouch. See Appendix II.

5.3. Dye Testing

The Dye Test was performed on 35 samples as outlined in ENG-PRT-425. There were no breaches in the seal and no signs of separation or degradation. See Appendix III.

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5.4. Burst Testing

The Burst Test was performed on 36 samples as outlined in ENG-PRT-425. Thirty-five samples exceeded the passing criteria of 19 in H₂O with an average of 25.95 in H₂O and a low of 22.0 in H₂O. A single sample failed the test with a burst pressure of 12.2 in H₂O. The test operator noted that this failure was possibly linked to an Operator Error. See Appendix IV.

5.5. Minimum Seal Width Testing

The Minimum Seal Width Test was performed on 35 samples as outlined in ENG-PRT-425. The minimum seal width of all edges exceeded the passing criteria of 0.20" with an average of 0.33" and a minimum of 0.26". See Appendix IV for a complete summary of testing. See Appendix V.

5.6. Product Damage Inspection

Product Damage Inspection was performed on 35 samples as outlined in ENG-PRT-425. No damage to the electrode or any other part of the Zip Pen was observed. See Appendix VI.

6. DISCUSSION

6.1. Ship Test Conditioning

Preconditioning and Ship Testing with 210 lb Vehicle Stacking (Compression Test) load passed all tests.

NOTE: The data sheets used to document this testing were mistakenly pulled from XENG-PRT-441 (Ship Testing for Modified) instead of ENG-PRT-425, however the data sheets used are the same as what are documented in ENG-PRT-425.

- 6.1.1. Pencils are traceable and conform to the design with regard to all testing performed.
- 6.1.2. Shipping and storage conditions reached all extremes required by the test protocol for all test groups.
- 6.1.3. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.2. Bubble Leak Testing

6.2.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

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6.3. Dye Testing

6.3.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

6.4. Burst Testing

While testing the original 36 samples, a single sample failed the test with a burst pressure of 12.2 in H_2O . The test operator noted that this failure was possibly linked to an Operator Error in which the burst test needle may have not been fully inserted into the pouch prior to beginning testing.

This failure mode was investigated by repeating the burst test on a new set of 54 samples (PN: 6020190-01 and Lot # 1507120 pulled from SKU: 2525-10). A sample size of 53 was chosen using a C=0 sampling plan based on a lot size of up to 3200 and an AQL of 0.65. An AQL of 0.65 was used, instead of the original AQL of 1.5 for the 35 samples, as defect classification is critical (per QA-SOP-012) and the previous failure merited additional testing. It should be noted that 54 samples were used in place of 53 for convenience as the Zip Pens are packaged in boxes of 6.

The 54 samples to be used for burst testing were packaged, preconditioned, and ship tested as outlined in ENG-PRT-425 with the exception of the vibration testing. Both loose load vibration testing and vehicle vibration testing were performed by Rocky Mountain Testing Solutions (RMTS) in accordance with ASTM D4169-14 Assurance Level II. The samples were sent to RMTS because Megadyne's vibration table is more aggressive than the standard and is considered a worst-case scenario.

The Burst test was performed on 54 samples as outlined in ENG-PRT-425 Section 9.3. Fifty-three samples exceeded the passing criteria of 19 in H₂O with an average of 27.15 in H₂O and a low of 22.6 in H₂O. A single sample failed the second burst test with a burst pressure of 16.3 in H₂O.

An investigation into these two failures (one from the original 36 samples, and one from the second burst test of 54 samples) determined that the root cause of the failures could be attributed to an operator error. This error resulted from not fully inserting the needle into the packaging. In this case, when the burst tester attempts to the fill the bag, the pressure sensor located on the needle does not read an increase in pressure. This causes an increase in the flow rate in an effort to receive positive feedback that the pouch is inflating. At a certain point, when enough air has entered the pouch, the needle abruptly penetrates the Tyvek lid, resulting in the air tight seal needed to properly burst test. At this point, the air flow rate is much greater than the proper flow setting (#9). This increased flow rate causes the pouch to almost instantaneously burst and results in inaccurate

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results because the pressure sensor does not register the change in pressure quickly enough.

6.4.1. To further verify this root cause hypothesis, three additional Zip Pen samples (PN: 6020190-01 and Lot # 1507120 pulled from SKU: 2525-10) were burst tested in an attempt to replicate the proposed failure. For these three samples, there was an attempt to not fully insert the needle into each package. As a result, two of the packages did burst at values of 17.9 in H₂O and 17.6 in H₂O, which is below specification of 19 in H₂O. See Appendix IV for a complete summary of all testing.

Thus, it is reasonable that the root cause for the failed burst test results was that the needle was not fully inserted into the packaging. Therefore, the resulting failed burst test results are not valid burst test failures.

- 6.5. Minimum Seal Width Testing
 - 6.5.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.
- 6.6. Product Damage Inspection
 - 6.6.1. The acceptance criteria were satisfied for the 6-Pack shipping configuration.

7. CONCLUSIONS

- 7.1. Ship Test Conditioning
 - 7.1.1. The 6-Pack box meets ASTM D4169.
 - 7.1.2. The ZIP Pencils are representative of the final product and product packaging after ship conditions.
- 7.2. Bubble Leak Testing
 - 7.2.1. The 6-Pack shipping configuration does not add additional risk of leaks in the product packaging.
- 7.3. Dye Testing
 - 7.3.1. The 6-Pack shipping configuration does not add additional risk of breaches in the seal of the product packaging.

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7.4. Burst Testing

7.4.1. The 6-Pack shipping configuration does not add additional risk of burst product packaging.

7.5. Minimum Seal Width Testing

7.5.1. The 6-Pack shipping configuration does not reduce the seal width of the product packaging.

7.6. Product Damage Inspection

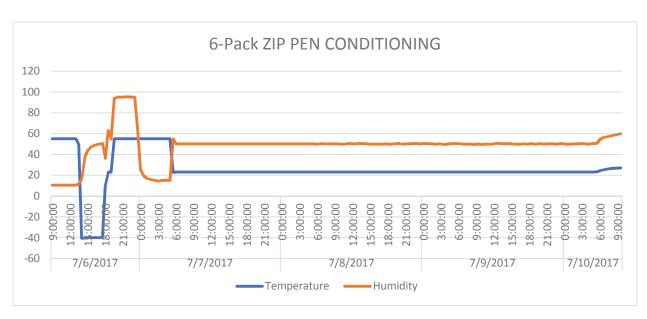
7.6.1. The 6-Pack shipping configuration does not add additional risk of damage to the product.

8. RECOMMENDATIONS

Based on these test results, it is recommended that product codes ME7251C and ME7251E be released for distribution as the 6-Pack shipping configuration.

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9. APPENDIX I – PRECONDITIONING AND SHIP TESTING



Summary Table

Maximum Temperature (°C)	55.1 °C
Minimum Temperature (°C)	-40.6 °C
Maximum Humidity (%RH)	95.2%RH
Minimum Humidity (%RH)	10.3%RH
Chamber condition held at -40 °C and no	13:45 to 17:45 on 7/6/17
humidity control for a duration of 4 hours.	
Chamber condition held at 55 °C and 95%RH	19:15 to 23:15 on 7/6/17
for a duration of 4 hours.	
Chamber condition held at 55 °C and 15%RH	1:15 to 5:15 on 7/7/17
for a duration of 4 hours.	
Chamber condition held at 23 °C and 50%RH	5:45 on 7/7/17 to 5:45 on 7/10/17
for a duration of 72 hours.	

Raw Data

Date	Time	Air Temp	Humidity
7/6/2017	9:00:00	55	10.3
	9:30:00	55	10.3
	10:00:00	55	10.4
	10:30:00	55	10.3
	11:00:00	55	10.4

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	11:30:00	55	10.3
	12:00:00	55	10.3
	12:30:00	55	10.3
	13:00:00	55	10.3
	13:30:00	49.2	11.9
	14:00:00	-40.6	16.9
	14:30:00	-40	37.9
	15:00:00	-40	44
	15:30:00	-40	46.9
	16:00:00	-40	48.4
	16:30:00	-40	49.5
	17:00:00	-40	50
	17:30:00	-39.9	50.5
	18:00:00	10.6	36.3
	18:30:00	23	63.1
	19:00:00	23	54.8
	19:30:00	55.1	94.1
	20:00:00	55	94.9
	20:30:00	55	95
	21:00:00	55	95.1
	21:30:00	55	95.2
	22:00:00	55	95.2
	22:30:00	55	95.1
	23:00:00	55	95.1
	23:30:00	54.9	64.1
7/7/2017	0:00:00	54.9	25.1
	0:30:00	55	19.4
	1:00:00	55	17.2
	1:30:00	55	16.2
	2:00:00	55	15.5
	2:30:00	55.1	15.1
	3:00:00	55	14.5
	3:30:00	55.1	15
	4:00:00	55	14.9
	4:30:00	55	15.1
	5:00:00	55	15
	5:30:00	22.6	55.1
	6:00:00	23	50

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	7:00:00	23	49.9
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	8:00:00	23	49.9
	8:30:00	23	49.9
	9:00:00	23	50.1
	9:30:00	23	50
	10:00:00	23	50
	10:30:00	23	50
	11:00:00	23	50
	11:30:00	23	50
	12:00:00	23	49.9
	12:30:00	23	50
	13:00:00	23	50
	13:30:00	23	50.1
	14:00:00	23	50
	14:30:00	23	50
	15:00:00	23	49.9
	15:30:00	23	50.1
	16:00:00	23	50
	16:30:00	23	50
	17:00:00	23	49.9
	17:30:00	23	50
	18:00:00	23	50
	18:30:00	23	50
	19:00:00	23	50
	19:30:00	23	50
	20:00:00	23	50
	20:30:00	23	50
	21:00:00	23	50
	21:30:00	23	50
	22:00:00	23	50
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4:30:00 23 49.9 5:00:00 23 50.1 5:30:00 23 49.9 6:00:00 23 49.7 6:30:00 23 50.2 7:00:00 23 50.1 7:30:00 23 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:30:00 23 50.1 12:30:00 23 50.3 13:00:00 23 50.3 13:00:00 23 50.3 13:00:00 23 50.3 15:00:00 23 50.5 14:00:00 23 50.4 15:00:00 23 50.4 15:00:00 23 49.8 15:30:00 23 49.8 16:30	3:30:00	22.9	49.9
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5:30:00 23 49.9 6:00:00 23 49.7 6:30:00 23 50.2 7:00:00 23 50.1 7:30:00 23 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:30:00 23 50.3 13:00:00 23 50.3 13:30:00 23 50.3 13:30:00 23 50.3 14:00:00 23 50.3 15:00:00 23 50.4 14:00:00 23 50.5 14:00:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:	4:30:00	23	49.9
6:00:00 23 49.7 6:30:00 23 50.2 7:00:00 23 50.1 7:30:00 23 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.3 12:30:00 23 50.1 12:30:00 23 50.3 13:00:00 23 50.3 13:30:00 23 50.3 13:30:00 23 50.3 15:00:00 23 50.4 15:00:00 23 50.4 15:00:00 23 49.8 15:30:00 23 49.8 16:30:00 23 49.8 17:30:00 23 49.8 17:30:00 23 49.8 17	5:00:00	23	50.1
6:30:00 23 50.2 7:00:00 23 50.1 7:30:00 23 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:00:00 23 50.3 12:30:00 23 50.3 13:00:00 23 50.3 14:00:00 23 50.3 14:00:00 23 50.3 15:00:00 23 50.4 15:00:00 23 50.4 15:00:00 23 49.8 15:30:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.8 19:00:00 23 49.8 1	5:30:00	23	49.9
7:00:00 23 50.1 7:30:00 23.1 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 50.3 13:00:00 23 50.3 13:00:00 23 50.3 13:00:00 23 50.3 15:00:00 23 50.3 15:00:00 23 50.4 15:00:00 23 50.4 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 50 18:00:00 23 49.8	6:00:00	23	49.7
7:30:00 23 50 8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:30:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:00:00 23 50.3 14:00:00 23 50.4 14:00:00 23 50.4 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 50 18:00:00 23 49.8 19:00:00 23 49.8 19:00:00 23 50 19:30:00 23 50	6:30:00	23	50.2
8:00:00 23.1 50 8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.3 14:00:00 23 50.4 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 18:00:00 23 49.8 19:00:00 23 49.8 19:00:00 23 50.2	7:00:00	23	50.1
8:30:00 23 50 9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 12:00:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 17:30:00 23 49.6 17:30:00 23 49.8 19:00:00 23 49.8 19:00:00 23 50 19:30:00 23 50	7:30:00	23	50
9:00:00 23 49.9 9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 17:30:00 23 49.6 17:30:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	8:00:00	23.1	50
9:30:00 23 50 10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	8:30:00	23	50
10:00:00 23 49.7 10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	9:00:00	23	49.9
10:30:00 22.9 49.6 11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	9:30:00	23	50
11:00:00 23 50.3 11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 17:30:00 23 49.6 18:00:00 23 49.8 19:00:00 23 49.8 19:00:00 23 50 19:30:00 23 50 19:30:00 23 50.2	10:00:00	23	49.7
11:30:00 23 50.3 12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.6 17:30:00 23 49.6 17:30:00 23 49.6 17:30:00 23 49.8 19:00:00 23 49.8 19:00:00 23 49.8 19:30:00 23 50 19:30:00 23 50.2	10:30:00	22.9	49.6
12:00:00 23 50.1 12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50	11:00:00	23	50.3
12:30:00 23 49.9 13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.8 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50 19:30:00 23 50.2	11:30:00	23	50.3
13:00:00 23 50.3 13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.6 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50 19:30:00 23 50	12:00:00	23	50.1
13:30:00 23 50.5 14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.6 16:00:00 23 49.8 17:00:00 23 49.8 17:30:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 50 19:00:00 23 50 19:30:00 23 50	12:30:00	23	49.9
14:00:00 23 50.4 14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.6 16:00:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50 19:30:00 23 50	13:00:00	23	50.3
14:30:00 23 50.1 15:00:00 23 49.8 15:30:00 23 49.6 16:00:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50	13:30:00	23	50.5
15:00:00 23 49.8 15:30:00 23 49.6 16:00:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	14:00:00	23	50.4
15:30:00 23 49.6 16:00:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	14:30:00	23	50.1
16:00:00 23 49.8 16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50	15:00:00	23	49.8
16:30:00 23 49.8 17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	15:30:00	23	49.6
17:00:00 23 49.6 17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	16:00:00	23	49.8
17:30:00 23 50 18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	16:30:00	23	49.8
18:00:00 23 49.7 18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	17:00:00	23	49.6
18:30:00 23 49.8 19:00:00 23 50 19:30:00 23 50.2	17:30:00	23	50
19:00:00 23 50 19:30:00 23 50.2	18:00:00	23	49.7
19:30:00 23 50.2	18:30:00	23	
	19:00:00	23	50
20:00:00 23 50.4	19:30:00	23	50.2
	20:00:00	23	50.4

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	20:30:00	23	49.6
	21:00:00	23	49.9
	21:30:00	23	50.1
	22:00:00	23	50.2
	22:30:00	23	50.2
	23:00:00	23	50.3
	23:30:00	23	50
7/9/2017	0:00:00	23	50.3
	0:30:00	23	50.5
	1:00:00	23	50.2
	1:30:00	23	49.9
	2:00:00	23	49.7
	2:30:00	23	50
	3:00:00	23	50.1
	3:30:00	23.1	49.5
	4:00:00	23	49.8
	4:30:00	23	49.9
	5:00:00	23	50.2
	5:30:00	23	50.4
	6:00:00	23	50.4
	6:30:00	23	49.9
	7:00:00	23	49.8
	7:30:00	23	49.6
	8:00:00	23	49.6
	8:30:00	23	49.5
	9:00:00	23	49.8
	9:30:00	23	49.6
	10:00:00	23	49.5
	10:30:00	23	49.7
	11:00:00	23.1	49.6
	11:30:00	23	49.7
	12:00:00	23	50.3
	12:30:00	23	50.6
	13:00:00	23	50.5
	13:30:00	23	50.4
	14:00:00	23	50.1
	14:30:00	23	50.5
	15:00:00	23	50

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		T	T
	15:30:00	23	49.8
	16:00:00	23	49.6
	16:30:00	23	49.7
	17:00:00	23	50.4
	17:30:00	23	49.7
	18:00:00	23	49.9
	18:30:00	23	50.3
	19:00:00	23	49.6
	19:30:00	23	49.9
	20:00:00	23	50.4
	20:30:00	23	49.8
	21:00:00	23	50
	21:30:00	23	49.9
	22:00:00	23	50
	22:30:00	23	49.7
	23:00:00	23	49.9
	23:30:00	23	50.4
7/10/2017	0:00:00	23	50.1
	0:30:00	23	49.7
	1:00:00	23	49.8
	1:30:00	23	49.9
	2:00:00	23	49.9
	2:30:00	23	49.9
	3:00:00	23	50.5
	3:30:00	23	49.9
	4:00:00	23	49.8
	4:30:00	23	50.4
	5:00:00	23	50.4
	5:30:00	23.4	50.7
	6:00:00	24.6	54.8
	6:30:00	25.2	56.3
	7:00:00	25.7	56.9
	7:30:00	26	57.4
	8:00:00	26.3	58
	0.00.00		
	8:30:00	26.6	58.7
		26.6 26.8	58.7 59.3

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11. APPENDIX I - SHIPPING TEST

Precond	litionin	g
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Start Date: 7-6-2017

Chamber Number: 01268

Completion Date: 7-10 - 2017 Last Calibration: 5-23-2017

Signature/Date: Paul Valpade Calibration due: 5-31-2018

Drop Test:

Catalog Number: 2525-10

Weight: 3.5 lbs. Drop Height: 15"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Тор	Face 1	PV 7-13-17
2	Edge	Edge 5-3	PV 7-13-17
3	Edge	Edge 6-3	PV 7-13-17
4	Corner	Corner 2-3-5	PV 7-13-17
5	Corner	Corner 4-3-6	PY 7-13-17
6	Bottom	Face 3	PV 7-13-17

Comments:

Signature: Paul Valpuele

Date: 7-13-2017

Compression Test:

Catalog Number: 2525-10

Pounds Force: 100

Comments: No Failures.

Signature: Paul Valgreda Date: 7-13-2017

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Megadyne Medical	TEST PROTOCOL	Document Number XENG-PRT-425
Products, Inc.	ZIP ACE 6-Pack Ship Test Protocol	Revision: C
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Appendix I Continued Shipping Test Log Sheet

Vibration:			
Low Frequency, 40	minutes, Initials	:_ PV	
High frequency 10 n	ninutes, Initials:	PV	
Completion Date:	1-13-2017	_	
Signature: Paul V	alpreda	Date:	7-13-2017
Concentrated Impa	ict Test:		
Completion Date:	7-13-2017	_	
Signature: Paul V	alpreda	Date:	1-13-2017
Second Drop Test:	*		
Catalog Number: 25	525-10	Weight: 3.5 lbs.	Orop Height: <u>15" + 3</u> 0
Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	PV 7-13-17

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	PV 7-13-17
2	Face	Face 4	PV 7-13-17
3	Face	Face 6	DV 7-13-17
4	Corner	Corner 2-1-5	PV 7-13-17
5	Edge	Edge 2-1	PV 7-13-17
6	Bottom	Face 3, Increase height to 30 inches.	PV 7-13-17

Comments:

Signature: Paul Valpuda Date: 7-13-2017

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10. APPENDIX II – BUBBLE LEAK TESTING

	Bubble Leak Test Log Sheet					
	Catalog - ZIP ACE Packaging Evaluation					
		35	pcs Total			
Sample	Pass	Fail	Comments			
1	Х					
2	Х					
3	Х					
4	Х					
5	Х					
6	Х					
7	X					
8	Х					
9	Х					
10	Х					
11	Х					
12	X					
13	X					
14	X					
15	X					
16	X					
17	X					
18	Х					
19	X					
20	Х					
21	X					
22	X					
23	X					
24	X					
25	X					
26	X					
27	X					
28	Х					
29	X					
30	X					
31	Х					
32	X					
33	X					
34	X					
35	Х					

No failures were observed - PV

 Paul Valpreda
 7/17/2017

 OPERATOR NAME
 DATE

Yallyalar 7-17-2017
OPERATOR SIGNATURE DATE

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11. APPENDIX III – DYE TESTING

		etration Ev	aiuation
Sample #	PASS	FAIL	Comments
1	X		
2	X		
3	X		
4	X		
5	X		
6	X		
7	X		
8	X		
9	X		
10	X		
11	X		
12	X		
13	X		
14	X		
15	X		
16	X		
17	X		
18	X		
19	X		
20	X		
21	X		
22	X		
23	X		
24	X		
25	X		
26	X		
27	X		
28	X		
29	X		
30	X		
31	Х		
32	X		
33	X		
34	Х		
35	Х		

No failures were observed; all seals looked intact with no signs of separation or other degradation as a result of the dye test - PV

 Paul Valpreda
 7/14/2017

 Operator Name
 Date

Paul Valpuele 7-14-2017
Operator Signature Date

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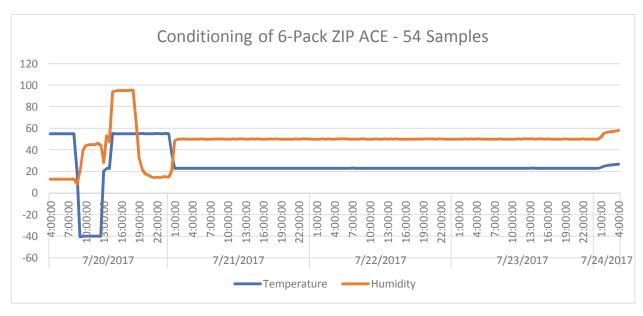
12. APPENDIX IV – BURST TESTING

<u>1st Burst Test – 36 Samples</u>

	Pro	Products, Inc.				RST TEST			Revision: 002	2003		
			PE	PEEL POUCH – SEAL BURST TEST FORM	-SEAL BU		FORM	Н	Page 3 of 5	5 Jc		
				2	Appendix I MultiVac Test Samples	Appendix I Vac Test Samp	les					
Lot Number	83.1		Catalog Number		Descr	Description		Date	Date Tested	Lot Size	Min	Min. Burst Pressure (in H.0)
trost	7418-63	2 4125	25-10	218	P PEN			7.18.	41.5	4/14	10	3
15051	20				Burst 7	Burst Test Data						
B/M/E C#	_	2	3	4	5	9	7	80	6	10	=	12
Value	24.	8	.6 24.0	242	23.5	23.6	23.2	23.3	18	7.4.5	22	24.4
B/M/E C#	5	1 (7	õ	77	18	19	20	21	00	22	7.4
Value	24.	6 23.	2.42 6	13.8	0.47	73.4	23.1	30.1	24.7	24.8	ノナイ	600
B/M/E C#	52	5 2	42	38	25	30	6	32	4	7, 7	1	J. Y.
Value	25.	.1 23.	7 30.7	F 29.3	28.1	28.6	74.1	78.4	7.7	24.0	23.8	
B/M/E C#))
Value												
B/M/E C#												
Value												
B/M/E C#												
Value												
Burst Test Settings:		Note: C= Ca	Note: C= Cavity (MultiVac cavity location), B/M/E=Beginning/Middle/End, Value=Measured Burst Value	cavity location), B/M/E=Be	eginning/Mi	iddle/End, V	alue=Meas	sured Burst \	/alue		
FLOW (#)		0		SENSIT (#)	(H)			Ь	PREFILL (Y/N)	2	11	
Burst Test Equipment:	ent:										2	
Calibration Due Date	ate	3.31-	2018	Equip. Id. #	# .bI	0/39	46					
Lot disposition: Qu	uantity Te	Quantity Tested 35	Accept		Reject (NCMR# M	# W/A		QA/Mf	QA/Mfg initials &date: (late: C	7.	7.18-17
Comments:	-	Failure	165517	(m)	er testing	,	to Bre	Investigation	steel			
)						

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Ship Testing Preconditioning – 54 Samples



Summary Table

Maximum Temperature (°C)	55.1 °C
Minimum Temperature (°C)	-40.6 °C
Maximum Humidity (%RH)	95.2%RH
Minimum Humidity (%RH)	8.3%RH
Chamber condition held at -40 °C and no	8:45 to 12:45 on 7/20/17
humidity control for a duration of 4 hours.	
Chamber condition held at 55 °C and 95%RH	14:15 to 18:15 on 7/20/17
for a duration of 4 hours.	
Chamber condition held at 55 °C and 15%RH	20:15 on 7/20/17 to 0:15 on 7/21/17
for a duration of 4 hours.	
Chamber condition held at 23 °C and 50%RH	0:45 on 7/21/17 to 1:00 on 7/24/17
for a duration of 72 hours.	

Raw Data

Date	Time	Air Temp	Humidity
7/20/2017	4:00:00	55	12.9
	4:30:00	55	12.9
	5:00:00	55	12.9
	5:30:00	55	12.9
	6:00:00	55	12.8
	6:30:00	55	12.8

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22:30:00 23 50 23:00:00 23 50 23:30:00 23 50 7/23/2017 0:00:00 23 50 0:30:00 23 50 1:00:00 23 50 1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50.1 3:00:00 23 50.1 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50.1 5:30:00 23 50 6:00:00 23 50 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50		21:30:00	23	50.1
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23:30:00 23 50 7/23/2017 0:00:00 23 50 0:30:00 23 50 1:00:00 23 50 1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50.1 3:00:00 23 50.1 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 50 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50		22:30:00	23	50
7/23/2017 0:00:00 23 50 0:30:00 23 50 1:00:00 23 50 1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50.1 3:00:00 23 50.1 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50		23:00:00	23	50
0:30:00 23 50 1:00:00 23 50 1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50.1 3:00:00 23 50.1 3:30:00 22.9 49.9 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		23:30:00	23	50
1:00:00 23 50 1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50 3:00:00 23 50.1 3:30:00 22.9 49.9 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50	7/23/2017	0:00:00	23	50
1:30:00 23 50 2:00:00 23 50.1 2:30:00 23 50 3:00:00 23 50.1 3:30:00 22.9 49.9 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50		0:30:00	23	50
2:00:00 23 50.1 2:30:00 23 50 3:00:00 23 50.1 3:30:00 22.9 49.9 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		1:00:00	23	50
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3:30:00 22.9 49.9 4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50		2:30:00	23	50
4:00:00 23 50.1 4:30:00 23 50.1 5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		3:00:00	23	50.1
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5:00:00 23 50 5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		4:00:00	23	50.1
5:30:00 23 50 6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		4:30:00	23	50.1
6:00:00 23 49.9 6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		5:00:00	23	50
6:30:00 23 50 7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		5:30:00	23	50
7:00:00 23 49.9 7:30:00 23 50 8:00:00 23 50.1		6:00:00	23	49.9
7:30:00 23 50 8:00:00 23 50.1		6:30:00	23	50
8:00:00 23 50.1		7:00:00	23	49.9
		7:30:00	23	50
8:30:00 23 50		8:00:00	23	50.1
		8:30:00	23	50
9:00:00 23 50		9:00:00	23	50
9:30:00 22.9 50		9:30:00	22.9	50
10:00:00 23 50		10:00:00	23	50
10:30:00 23 50		10:30:00	23	50

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	11:00:00	23	50.1
	11:30:00	23	50
	12:00:00	23	50.1
	12:30:00	23	50.1
	13:00:00	23	50.2
	13:30:00	23.1	50.1
	14:00:00	23	50
	14:30:00	23	50.1
	15:00:00	23	50.1
	15:30:00	23	50
	16:00:00	23	50.1
	16:30:00	23	50
	17:00:00	23	50
	17:30:00	23	49.9
	18:00:00	23	50
	18:30:00	23	50
	19:00:00	23	50.2
	19:30:00	23	50
	20:00:00	23	50
	20:30:00	23	50
	21:00:00	23	50
	21:30:00	23	50
	22:00:00	23	50.1
	22:30:00	23	50
	23:00:00	23	50
	23:30:00	23	50
7/24/2017	0:00:00	23	50
	0:30:00	23	50
	1:00:00	23.8	51.6
	1:30:00	24.9	55.4
	2:00:00	25.6	56.4
	2:30:00	26	56.7
	3:00:00	26.3	57.1
	3:30:00	26.5	57.7
	4:00:00	26.8	58.2
			50.2

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Ship Testing – 54 Samples

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Medical Products, Inc.	ZIP ACE 6-Pack Ship Test Protocol	Revision: C
Troutets, Ther	Zir ACE 0-rack Sinp rest riotocor	Page 12 of 17

APPENDIX I - SHIPPING TEST

**	** . *	
Precon	litior	ing:
I I CCOII	TICIOI	ming.

Start Date: 7-20-2017 Chamber Number: 01268

Completion Date: 7-24-2017 Last Calibration: 5-23-2017

Signature/Date: Paul Valprade 7-24-2017 Calibration due: 5-31-2018

Drop Test:

Weight: 3.5 16s. Drop Height: 15" Catalog Number: 2525 -10

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Тор	Face 1	PV 7-26-17
2	Edge	Edge 5-3	PV 7-26-17
3	Edge	Edge 6-3	PV 7-26-17
4	Corner	Corner 2-3-5	PV 7-26-17
5	Corner	Corner 4-3-6	PV 7-26-17
6	Bottom	Face 3	PV 7-26-17

Comments:

Date: 7-26-17

Compression Test:

Catalog Number: 2525-10 Pounds Force: 100

Comments: No failures.

Signature: Paul Valoreda Date: 7-26-17

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Megadyne Medical	TEST PROTOCOL	Document Number XENG-PRT-425
Products, Inc.	ZIP ACE 6-Pack Ship Test Protocol	Revision: C
2.1 outlets, Inci	Zii ACL 0-1 ack Ship Test Flotocol	Page 13 of 17

5

Appendix I Continued Shipping Test Log Sheet

Frequency, 40-		Mountain in Ogden	Testing S
npletion Date:			
nature:			
ncentrated Impa	act Test:		
npletion Date:			2-2017
nature: \aul\	Repude		
nature: \frac{\text{Cauly}}{\text{ond Drop Test:}}	Represa		
	,	Weight: 3-5 llos. D	
ond Drop Test:	,		
ond Drop Test: alog Number: 2	525-10	Weight: 3.5 llos. D	rop Height:
ond Drop Test: alog Number: 2 Drop Sequence	525-10 Orientation	Weight: 3-5 los. D Specific face, edge or corner	rop Height: 15" Initials/Date PV 8-2-17
ond Drop Test: alog Number: 2 Drop Sequence	Orientation Edge	Weight: 3-5 los. D Specific face, edge or corner Edge 4-6	rop Height: 15" Initials/Date PV 8-2-17 PV 8-2-17
ond Drop Test: alog Number: 2 Drop Sequence 1 2	Orientation Edge Face	Weight: 3-5 los. D Specific face, edge or corner Edge 4-6 Face 4	rop Height: 15" Initials/Date PV 8-2-17 PV 8-2-17
ond Drop Test: alog Number: 2 Drop Sequence 1 2 3	Orientation Edge Face Face	Weight: 3-5 los. D Specific face, edge or corner Edge 4-6 Face 4 Face 6	rop Height: 15" Initials/Date PV 8-2-17 PV 8-2-17

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<u>Vibration Testing – 54 Samples</u>

ENVIRONMENTAL TEST REPORT

PO#: 29025 Quote #: MEGA170404aLJ Test #: MEGA170404 REV000

Megadyne Medical

July 28, 2017



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Megadyne Medical **ASTM 4169-14 Level II Testing**

APPROVALS

Approved By: Aleisha Spenst Date: 8/9/2017 **Operations Assistant**

Date: 8/2/2017 Written By: Kandra Hansen

Operations Assistant

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1.0 PURPOSE

The purpose of this report is to present the test procedures used and the test results obtained during the performance of an environmental test program. The results included in this report relate only to the items tested. The objective of the test was for (9) boxes to undergo testing according to document ASTM 4169-14 Assurance Level II.

2.0 REFERENCES

- 2.1 RMTS Quote #: MEGA170404aLJ
- 2.2 Document: ASTM 4169-14 Assurance Level II.
- 2.3 Product: 9 boxes, 6" x 12" x 6", 3 lbs.
- 2.4 The articles tested were (9) boxes hereafter referred to as "Product." The Product was tested by Rocky Mountain Testing Solutions, LLC located in Pleasant View, Utah to the requirements listed in References 2.1 and 2.2.
- 2.5 Test #: MEGA170404

3.0 TEST CONDITIONS AND TEST EQUIPMENT

3.1 TEST CONDITIONS

Unless otherwise specified herein, all tests were performed at room ambient conditions defined as a temperature of $73^{\circ} \pm 18^{\circ}$ F ($23^{\circ} \pm 10^{\circ}$ C), with a relative humidity of $40\% \pm 30\%$.

3.2 TEST EQUIPMENT

The required test equipment presented in Appendix A was calibrated in accordance with established standards set by Rocky Mountain Testing Solutions, LLC. The calibration records are maintained on file.

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4.0 TEST PROCEDURES AND TEST RESULTS

- 4.1 Vibration Rotary Schedule F
 - Reference 2.2, Document: ASTM 4169-14 Assurance Level II, Section 12
 - Reference 2.3, Product: 9 boxes

Date Commenced: July 27, 2017
Date Completed: July 27, 2017

- 4.1.1 The test product was placed on a rotary vibration table and tested.
- 4.1.2 Rotary vibration table was set at 245 rpm for 20 minutes bottom down, and then rotated 90 degrees and set at 210 for another 20 minutes.
- 4.1.3 No significant damage to test product during testing.
- 4.1.4 See Appendix B for test photos.

4.2 Vehicle Vibration - Random - Schedule E

- Reference 2.2, Document: ASTM 4169-14 Assurance Level II, Section 12
- Reference 2.3, Product: 9 boxes

Date Commenced: July 28, 2017 Date Completed: July 28, 2017

- 4.2.1 The test product was placed on a Hydraulic Vibration table and tested according to ASTM D4169-09, a 180 minute Truck vibration at Assurance Level. Total test time was 3 hours in the Normal Shipping orientation (top up).
- 4.2.2 No significant damage to test product during testing.
- 4.2.3 See Appendix B for test photos.
- 4.2.4 See Appendix D for Vibration Test plots.
- 4.3 This concludes the Vibration testing on the Megadyne Medical product.

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APPENDIX LISTING

APPENDIX A (Pages 7) Equipment List

APPENDIX B (Pages 9, 10) Photographs

APPENDIX C (Pages 12) Vibration Plots

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APPENDIX A EQUIPMENT LIST

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ENVIRONMENTAL LAB EQUIPMENT LIST

Instrument Accelerometer ACC-012

Manufacturer PCB
Model Number 352C68
Serial Number 66760
Calibration Date 5/19/2017
Calibration Due Date 5/19/2018

Instrument Accelerometer ACC-047

 Manufacturer
 PCB

 Model Number
 352C68

 Serial Number
 201242

 Calibration Date
 1/13/2017

 Calibration Due Date
 1/13/2018

Instrument Transportation Simulation Shaker VIB-001

Manufacturer L.A.B.

Model Number 4000V
Serial Number 241164
Calibration Date 1/17/2017
Calibration Due Date 1/17/2018

Instrument Vibration Controller VIB-010

Manufacturer Vibration Research Corporation

Model Number VR9500
Serial Number 950763D4
Calibration Date 7/28/2016
Calibration Due Date 7/28/2017

Instrument Hydraulic Shaker VIB-011

Manufacturer MTS
Model Number 206.3
Serial Number 163

Calibration Not Required

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APPENDIX B PHOTOGRAPHS

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Photograph 1. Loose Load Vibration.



Photograph 2. Loose Load rotated at 90°.

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Photograph 3. Truck Vibration.

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APPENDIX C

Vibration Test Record

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Customer: Megadyne Medical Job#: MEGA170404

Data: S:\Shared\Test Data\Megadyne Medical\2017\MEGA170404\Test Data\Run 1_ASTM Truck_3hrs .52 Grms\2017Jul28-0817-0018.vrd

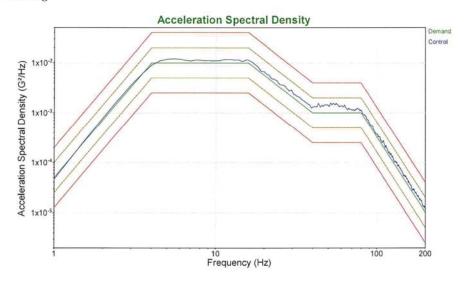
Test: S:\Shared\Vibration View\Vibration View Profiles\Vibration Profiles\ASTM D 4169 Truck Level

2.vrp

Data stored on Jul 28, 2017 11:17:58

ASTM D 4169 - Truck - Assurance Level 2

Running



Breakpoint table		
Frequency	G ² /Hz	dB/Octave
1 Hz	5e-05	11.51
4 Hz	0.01	0
16 Hz	0.01	-7.565
40 Hz	0.001	0
80 Hz	0.001	-15.13
200 Hz	1e-05	

Test level schedule:

	Duration	Level
1)	3:00:00	100 %

^{**} Test started Jul 28, 2017 08:17:58, running for 3:00:01

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^{**} Current level: 1, running at 100 % for 3:00:00 of 3:00:00

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ROCKY MOUNTAIN TESTING SOLUTIONS, LLC 2758 N 1600 W
Pleasant View, UT 84404
801-612-9156
877-899-7687

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2nd Burst Test – 54 Samples + 3 samples to investigate improper testing technique

		Megadyne	lyne			FORM			-	OPER-FRM-004	M-004		
		Medical Products, Inc.	s, Inc.	PEEL	PEEL POUCH - SEAL BURST TEST FORM	SEAL BU	RST TEST	FORM		Revision: 002 Page 3 of 5	: 002 of 5		
					M	Appendix I MultiVac Test Samples	ndix I est Samp	les					
2	Lot Number		Catalog Number	Vumber		Description	iption		Date Tested	Fested	Lot Size	Min	Min. Burst Pressure (in H.0)
7	8/1507	\$ 23.17	01-5252	01-	200	と同り			2.8	41.2	AN	0/	,
-	1507120	0	Ш			1	Burst Test Data						
B/M/E	# C	1	2	3	4	5	9	7	8	6	10	=	12
	Value	27.8	255	28.3	27.7	23.3	77.4	24.6	3.8	37.8	5.92	29.3	5.92
B/M/E	# D	13	71	14	9	+	18	10	02	20	22	233	24
	Value	28,0	26.95	23.7	23.5	76.3	27.5	Ct2	24.3	34.7	283	242	13-61
B/M/E	# D	25	26	27	28	8	30	E.	25	23	24	38	36
	Value	26-5	27.2	1.42	0. 52.	27.5	25.55	1.92	8.92	33.7	18.4	24.0	15.52
B/M/E	#2	33	×	39	940	1 /2	75	43	hh	74	96	617	34
	Value	32.7	73.4	0.62	5.92	26.2	72.4	0-92	26.8	26.00	2525	24.1	1.52
B/M/E	#2	49	20	5	Jan J	53	54						
	Value	22.6	25.6	1-62	163/	2:52	34.0						
B/M/E	# C										Smyle 1	Suphz	Sanyle
	Value										17.6	6-41	74.72
urst Tes	Burst Test Settings:	Note	Note: C= Cavity (MultiVac cavity location), B/M/E=Beginning/Middle/End, Value=Measured Burst Value	MultiVac car	vity location)	, B/M/E=Be	ginning/Mi	ddle/End, V	/alue=Meas	ured Burst	Value		
FL	FLOW (#)		G	_	SENSIT (#)	(#)	-		Ь	PREFILL (Y/N)	2	C V	
urst Tes	Burst Test Equipment	٠,	-				7		-		(1))	
Calibrat	Calibration Due Date	S	3777	1	Equip. Id. #		the sta	899	010	24010	Listel D	10	11.
ot dispo	Lot disposition: Quantity Tested	ntity Tested	6.17.18	Accept	Rejex	Reject (NCMR#	1	MA WA	QA/MÉ	QA/Mfg initials &date:_	date:	15 8.7 15 8.7	41-2-8
Comments:	7	Tailer S	dux to	7.4	2 Semole	terting to 3.	Taller Invo	Live Stigueted	regionalist	7 5	additions	200	Senjaro
		,			-								
ossession c	Possession of this document is an acknowledgment that the contents berein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form	is an acknow	ledgment that t	he contents her	rein are the exc	lusive property	of Megadyne	Medical Produ	acts, Inc. This	document ma	y not be reprod	uced in any for	Е

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13. APPENDIX V – MINIMUM SEAL WIDTH TESTING

Package Seal Width Evaluation Data Collection Form

		2525-10 L	OT 1507118			
Sample	Part/Lot	Cavity	Front	Back	Right	Left
1	2525-10 - LOT 1507120	2		0.33		
2	2525-10 - LOT 1507120	1			0.33	Tax Part
3	2525-10 - LOT 1507120	1	WATER TO THE		0.35	
4	2525-10 - LOT 1507120	2			0.32	p=5/10/1
5	2525-10 - LOT 1507120	1			0.35	
6	2525-10 - LOT 1507120	2			0.32	0.01
7	2525-10 - LOT 1507120	1			0.34	
8	2525-10 - LOT 1507120	2			0.28	
9	2525-10 - LOT 1507120	1		0.35		
10	2525-10 - LOT 1507120	2			0.31	
11	2525-10 - LOT 1507120	1			0.35	
12	2525-10 - LOT 1507120	2			0.32	
13	2525-10 - LOT 1507120	1				0.36
14	2525-10 - LOT 1507120	2			0.35	
15	2525-10 - LOT 1507120	1			0.36	
16	2525-10 - LOT 1507120	1			0.34	
17	2525-10 - LOT 1507120	2			0.33	
18	2525-10 - LOT 1507120	1	No. of the last		0.33	
19	2525-10 - LOT 1507120	2			0.33	
20	2525-10 - LOT 1507120	1			0.36	
21	2525-10 - LOT 1507120	2			0.34	
22	2525-10 - LOT 1507120	1		0.32		
23	2525-10 - LOT 1507120	1		0.35		
24	2525-10 - LOT 1507120	2			0.31	
25	2525-10 - LOT 1507120	2			0.31	
26	2525-10 - LOT 1507120	2				0.33
27	2525-10 - LOT 1507120	2			0.33	
28	2525-10 - LOT 1507120	1			0.34	
29	2525-10 - LOT 1507120	1		0.34		
30	2525-10 - LOT 1507120	1			0.34	
31	2525-10 - LOT 1507120	1		0.26		
32	2525-10 - LOT 1507120	2			0.34	
33	2525-10 - LOT 1507120	1			0.33	
34	2525-10 - LOT 1507120	2			0.33	901/46
35	2525-10 - LOT 1507120	2			0.32	THE PARTY

Burst Side

CALIBRATION INFORMATION

Calipers

Starrett MMP-1003

Serial Number: 723

Megadyne Number: 01039

Calibration Date: 5/18/2016

Calibration Due: 5/31/2018

 Paul Valpreda
 7/20/2017

 Operator Name
 Date

Paul alipseds 7-20-2017
Operator Signature Date

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14. APPENDIX VI – PRODUCT DAMAGE INSPECTION

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15. APPENDIX V - PRODUCT DAMAGE INSPECTION

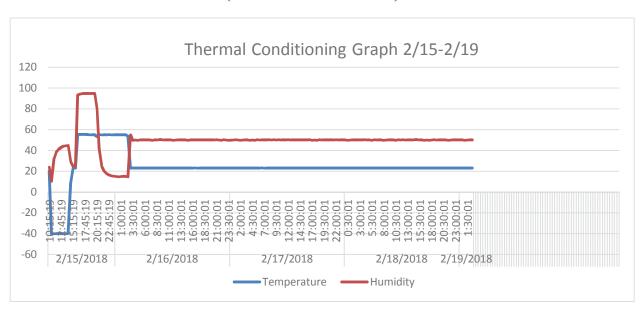
Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Damage	35	
Comments: No Failures Wa	ere observed.	
Signature: Paul V	alsuda	Date: 7-20-2017

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15. APPENDIX VII – PRECONDITIONING AND SHIP TESTING WITH 210 LB VEHICLE STACKING (COMPRESSION TEST) LOAD



Summary Table

Maximum Temperature (°C)	55.3 °C
Minimum Temperature (°C)	-40.6 °C
Maximum Humidity (%RH)	94.7%RH
Minimum Humidity (%RH)	10.4%RH
Chamber condition held at -40 °C and no	yes
humidity control for a duration of 4 hours.	
Chamber condition held at 55 °C and 95%RH	yes
for a duration of 4 hours.	
Chamber condition held at 55 °C and 15%RH	yes
for a duration of 4 hours.	
Chamber condition held at 23 °C and 50%RH	yes
for a duration of 72 hours.	

Thermotron SN: 42012 and Calibration Due: 5-31-2018

RAW DATA

Date	Time	Air	Humidity
		Temp	
2/15/2018	10:15:19	20.1	23.8
	10:45:19	-40.6	10.4

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	11:15:19	-40	32.1
	11:45:19	-40	38.7
	12:15:19	-40	41
	12:45:19	-40	42.9
	13:15:19	-40.1	44.1
	13:45:19	-40.1	44.5
	14:15:19	-39.9	44.7
	14:45:19	8.4	29.1
	15:15:19	23	24.7
	15:45:19	23	25.1
	16:15:19	55.3	93.5
	16:45:19	55.1	94.2
	17:15:19	55.1	94.5
	17:45:19	55.1	94.5
	18:15:19	55.1	94.5
	18:45:19	55	94.6
	19:15:19	55	94.7
	19:45:19	55	94.7
	20:15:19	53.4	80.3
	20:45:19	55.1	41.9
	21:15:19	54.9	24.5
	21:45:19	55	20.2
	22:15:19	55	17.8
	22:45:19	55.1	16.4
	23:15:19	55	15.5
	23:45:19	55	15.1
2/16/2018	0:00:01	54.9	14.8
	0:30:01	55	14.7
	1:00:01	55	15
	1:30:01	55	15
	2:00:01	54.9	15
	2:30:01	53.7	14.7
	3:00:01	22.9	54.8
	3:30:01	22.9	49.7
	4:00:01	23	49.9
	4:30:01	23	49.7
	5:00:01	23	50
	5:30:01	23	50.1

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1:00:01	23	50.2
1:30:01	23	50
2:00:01	23	49.7
2:30:01	23	50
3:00:01	23	49.9
3:30:01	23	49.9
4:00:01	23	49.8
4:30:01	23	50
5:00:01	23	49.8
5:30:01	23	50.3
6:00:01	23	49.9
6:30:01	23.1	50
7:00:01	22.9	49.9
7:30:01	23	50
8:00:01	23	50.2
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9:00:01	23	50.2
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11:00:0	1 23	50
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12:00:0	1 23	50.2
12:30:0	1 23	50
13:00:0	1 23	50
13:30:0	1 23	49.9
14:00:0	1 23	50
14:30:0	1 23	49.9
15:00:0	1 23	50
15:30:0	1 23	50.1
16:00:0	1 22.9	49.9
16:30:0	1 23	50.3
17:00:0	1 23	49.7
17:30:0	1 23	50.1
18:00:0	1 23	49.8
18:30:0	1 23	50.2
19:00:0	1 23	50
19:30:0	1 23	50

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	20:00:01	23	49.9
	20:30:01	23	50
	21:00:01	23	49.9
	21:30:01	23	50
	22:00:01	23	50.2
	22:30:01	23	49.9
	23:00:01	23	50.1
	23:30:01	23	50.1
2/18/2018	0:00:01	23	50.1
	0:30:01	23	49.8
	1:00:01	23	50
	1:30:01	23	50
	2:00:01	23	50
	2:30:01	23	50
	3:00:01	23	49.9
	3:30:01	23	49.9
	4:00:01	23	50.3
	4:30:01	23	49.9
	5:00:01	23	50.1
	5:30:01	23	49.8
	6:00:01	23	50.2
	6:30:01	23	50.1
	7:00:01	23	49.9
	7:30:01	23	49.9
	8:00:01	23	49.7
	8:30:01	23	50.1
	9:00:01	23	50
	9:30:01	23	49.9
	10:00:01	23	49.9
	10:30:01	23	49.8
	11:00:01	23	50.2
	11:30:01	23	50
	12:00:01	23	50.3
	12:30:01	23	50.1
	13:00:01	23	49.9
	13:30:01	23	50
	14:00:01	23	49.9
	14:30:01	23	50.2

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	15:00:01	23	50.2
	15:30:01	23	49.9
	16:00:01	23	50.1
	16:30:01	23	49.7
	17:00:01	23	50.1
	17:30:01	23	49.8
	18:00:01	23	49.9
	18:30:01	23	50.4
	19:00:01	22.9	50
	19:30:01	23	50.1
	20:00:01	23	50
	20:30:01	23	50
	21:00:01	23	49.9
	21:30:01	22.9	49.8
	22:00:01	23	50
	22:30:01	23	49.9
	23:00:01	23	50.1
	23:30:01	23	49.9
2/19/2018	0:00:01	22.9	50
	0:30:01	23	50
	1:00:01	23	49.7
	1:30:01	23	50.1
	2:00:01	22.9	49.9
	2:30:01	23	50

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APPENDIX II - SHIPPING TEST 11.

Preconditioning:

Start Date: 2-15-2018

Chamber Number: 01268

Completion Date: 2-19-2018

Last Calibration: 5-23-2017

Signature/Date: Paul Valpuda 2-20-2018

Calibration due: 5-31-2018

Drop Test:

Catalog Number: M€7251 C

Weight: 3.51 lbs. Drop Height: 15"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Тор	Face 1	PV 2-20-18
2	Edge	Edge 5-3	PV 2-20-18
3	Edge	Edge 6-3	PV 2-20-18
4	Corner	Corner 2-3-5	PV 2-20-18
5	Corner	Corner 4-3-6	PV 2-20-18
6	Bottom	Face 3	PV 2-20-18

Comments: All passed.

Signature: Paul Valpuda

Date: 2-20-2018

Compression Test:

Catalog Number: ME 7251 C

Pounds Force: 210

Comments: All passed.
Signature: Paul Valprada

Date: 2-20-2018

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Appendix II Continued Shipping Test Log Sheet

Vibration:
Low Frequency, 40 minutes, Initials: PV
High frequency 10 minutes, Initials: PV
Completion Date: 2 - 20 - 20 8
Signature: Paul Valpreda Date: 2-20-2018
Concentrated Impact Test:
Completion Date: 2-20-2018
Signature: Paul Valpreda Date: 2-20-2018
Second Drop Test:
Catalog Number: ME7251C Weight: 3.51 lbs. Drop Height: 15" + 30"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	PV Z-20-18
2	Face	Face 4	PV 2-20-18
3	Face	Face 6	PV 2-20-18
4	Corner	Corner 2-1-5	PV 2-20-18
5	Edge	Edge 2-1	PV 2.20-18
6	Bottom	Face 3, Increase height to 30 inches.	PV z-20-18

Comments: All boxes passed, no failures were observed. - PV
Signature: Paul Valpreda Date: 2-20-2018

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15. APPENDIX VI - PRODUCT DAMAGE INSPECTION

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

Catalog # ME7251C Damage	Pass 2/ ore	Fail	-
Daniage	All passed - 36 pcs.	1 8	
Comments: No failures were o	oservedPV		
·			
Signature: Paul Valgre	la	Date: 2-20-2018	