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| Lucy Richards (LRICHARDS) | | 21 Feb 2018, 09:29:53 AM | Approved |

Collaboration

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| Paul Borgmeier (PBORGMEIER) | | 22 Feb 2018, 08:56:55 AM | Approved |

Training Review

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| Stacey Castaneda (SCASTANEDA) | Associate Complaint Analyst | | |
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Authored By: Tyler Skinner

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 to 55°C | Set time to 0:00 and set the standard deviation to 1°C |
| Transition from 70°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 |

5.1.2 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 VII.

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 H₂O. 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 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

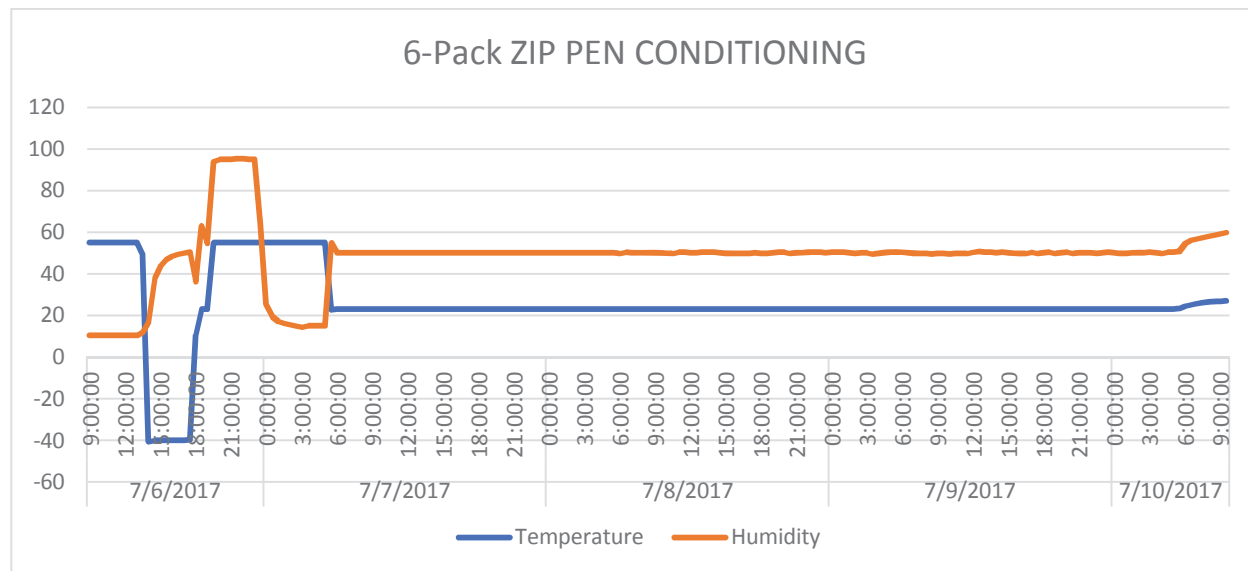
7.6.1. The 6-Pack shipping configuration does not add additional risk of damage to the product.

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 humidity control for a duration of 4 hours. | 13:45 to 17:45 on 7/6/17 |
| Chamber condition held at 55 °C and 95%RH for a duration of 4 hours. | 19:15 to 23:15 on 7/6/17 |
| Chamber condition held at 55 °C and 15%RH for a duration of 4 hours. | 1:15 to 5:15 on 7/7/17 |
| Chamber condition held at 23 °C and 50%RH for a duration of 72 hours. | 5:45 on 7/7/17 to 5:45 on 7/10/17 |

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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| | | | |
|----------|----------|----|------|
| | 6:30:00 | 23 | 50 |
| | 7:00:00 | 23 | 49.9 |
| | 7:30:00 | 23 | 50.1 |
| | 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 |
| | 22:30:00 | 23 | 50 |
| | 23:00:00 | 23 | 50 |
| | 23:30:00 | 23 | 50 |
| 7/8/2017 | 0:00:00 | 23 | 50 |
| | 0:30:00 | 23 | 50 |
| | 1:00:00 | 23 | 49.9 |

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| | | | |
|--|----------|------|------|
| | 1:30:00 | 23 | 50.1 |
| | 2:00:00 | 23 | 50 |
| | 2:30:00 | 23 | 49.9 |
| | 3:00:00 | 23 | 50 |
| | 3:30:00 | 22.9 | 49.9 |
| | 4:00:00 | 23 | 49.9 |
| | 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 |
| | 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 | 49.6 |
| | 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 |
| | 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 |
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| | 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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|-----------|----------|------|------|
| | 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 |
| | 8:30:00 | 26.6 | 58.7 |
| | 9:00:00 | 26.8 | 59.3 |
| | 9:30:00 | 27 | 59.9 |

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11. APPENDIX I – SHIPPING TEST

Preconditioning:

Start Date: 7-6-2017 Chamber Number: 01268
Completion Date: 7-10-2017 Last Calibration: 5-23-2017
Signature/Date: Paul Valpreda 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 | Top | 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 | PV 7-13-17 |
| 6 | Bottom | Face 3 | PV 7-13-17 |

Comments:

Signature: Paul Valpreda Date: 7-13-2017

Compression Test:

Catalog Number: 2525-10 Pounds Force: 100

Comments: No Failures.

Signature: Paul Valpreda Date: 7-13-2017

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**Appendix I Continued
Shipping Test Log Sheet**

Vibration:

Low Frequency, 40 minutes, Initials: PV

High frequency 10 minutes, Initials: PV

Completion Date: 7-13-2017

Signature: Paul Valpreda

Date: 7-13-2017

Concentrated Impact Test:

Completion Date: 7-13-2017

Signature: Paul Valpreda

Date: 7-13-2017

Second Drop Test:

Catalog Number: 2525-10 Weight: 3.5 lbs. Drop Height: 15" + 30"

| 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 | PV 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 Valpreda

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 | 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 | X | | |
| 32 | X | | |
| 33 | X | | |
| 34 | X | | |
| 35 | X | | |

No failures were observed - PV

Paul Valpreda
OPERATOR NAME

7/17/2017
DATE

Paul Valpreda
OPERATOR SIGNATURE

7-17-2017
DATE

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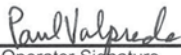
| | | |
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11. APPENDIX III – DYE TESTING

| Dye Penetration Evaluation | | | |
|----------------------------|------|------|----------|
| 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 | X | | |
| 32 | X | | |
| 33 | X | | |
| 34 | X | | |
| 35 | X | | |

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

 7-14-2017
Operator Signature Date

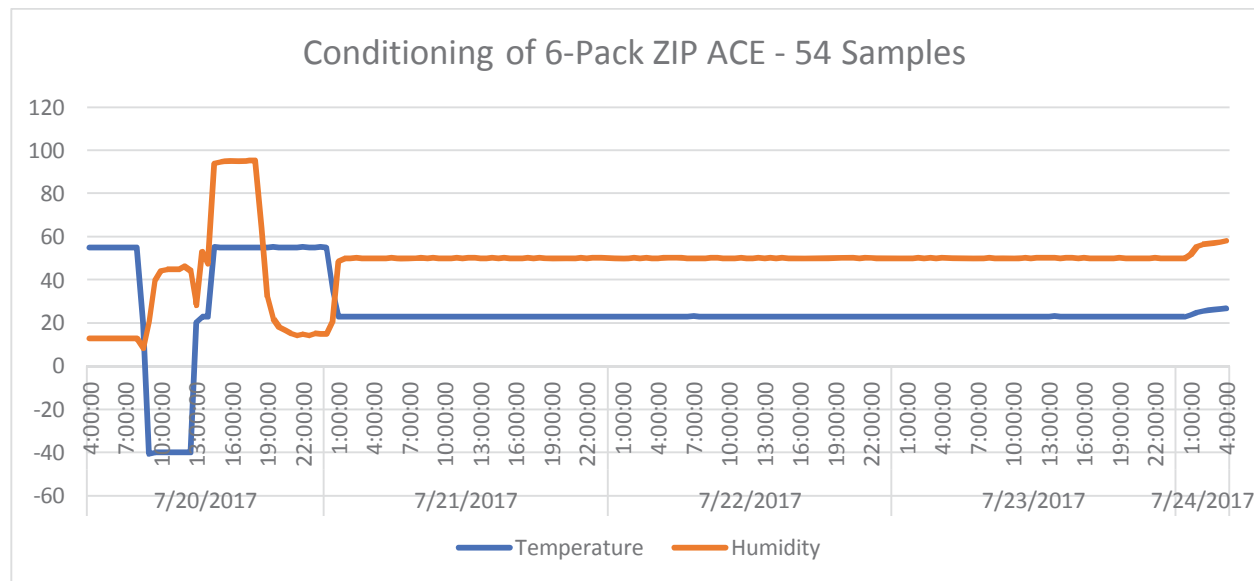
12. APPENDIX IV – BURST TESTING

1st Burst Test – 36 Samples

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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 humidity control for a duration of 4 hours. | 8:45 to 12:45 on 7/20/17 |
| Chamber condition held at 55 °C and 95%RH for a duration of 4 hours. | 14:15 to 18:15 on 7/20/17 |
| Chamber condition held at 55 °C and 15%RH for a duration of 4 hours. | 20:15 on 7/20/17 to 0:15 on 7/21/17 |
| Chamber condition held at 23 °C and 50%RH for a duration of 72 hours. | 0:45 on 7/21/17 to 1:00 on 7/24/17 |

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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| | | | |
|-----------|----------|-------|------|
| | 7:00:00 | 55 | 12.8 |
| | 7:30:00 | 55 | 12.8 |
| | 8:00:00 | 55 | 12.7 |
| | 8:30:00 | 19.5 | 8.3 |
| | 9:00:00 | -40.6 | 20.9 |
| | 9:30:00 | -40 | 39.8 |
| | 10:00:00 | -40 | 44.2 |
| | 10:30:00 | -39.9 | 44.8 |
| | 11:00:00 | -39.9 | 44.7 |
| | 11:30:00 | -40 | 44.7 |
| | 12:00:00 | -40 | 46.3 |
| | 12:30:00 | -40 | 44.3 |
| | 13:00:00 | 20.6 | 28.3 |
| | 13:30:00 | 23 | 53.2 |
| | 14:00:00 | 23 | 47.6 |
| | 14:30:00 | 55.1 | 94.1 |
| | 15:00:00 | 55 | 94.7 |
| | 15:30:00 | 55 | 94.9 |
| | 16:00:00 | 55 | 95 |
| | 16:30:00 | 55 | 95.1 |
| | 17:00:00 | 55 | 95.1 |
| | 17:30:00 | 55 | 95.2 |
| | 18:00:00 | 55 | 95.2 |
| | 18:30:00 | 54.9 | 64 |
| | 19:00:00 | 55 | 32 |
| | 19:30:00 | 55.1 | 21.9 |
| | 20:00:00 | 55 | 18.3 |
| | 20:30:00 | 55 | 16.8 |
| | 21:00:00 | 55 | 15.2 |
| | 21:30:00 | 55 | 14.4 |
| | 22:00:00 | 55.1 | 14.8 |
| | 22:30:00 | 55 | 14.4 |
| | 23:00:00 | 55 | 15.1 |
| | 23:30:00 | 55.1 | 14.9 |
| 7/21/2017 | 0:00:00 | 55 | 14.9 |
| | 0:30:00 | 35.2 | 21.2 |
| | 1:00:00 | 23 | 48.8 |
| | 1:30:00 | 23 | 49.9 |

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| | | | |
|--|----------|----|------|
| | 2:00:00 | 23 | 50 |
| | 2:30:00 | 23 | 50.2 |
| | 3:00:00 | 23 | 49.9 |
| | 3:30:00 | 23 | 50 |
| | 4:00:00 | 23 | 50 |
| | 4:30:00 | 23 | 49.9 |
| | 5:00:00 | 23 | 50 |
| | 5:30:00 | 23 | 50.1 |
| | 6:00:00 | 23 | 50 |
| | 6:30:00 | 23 | 50 |
| | 7:00:00 | 23 | 50 |
| | 7:30:00 | 23 | 50 |
| | 8:00:00 | 23 | 50.1 |
| | 8:30:00 | 23 | 50 |
| | 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 | 50.1 |
| | 11:30:00 | 23 | 50 |
| | 12:00:00 | 23 | 50.1 |
| | 12:30:00 | 23 | 50.1 |
| | 13:00:00 | 23 | 50 |
| | 13:30:00 | 23 | 50 |
| | 14:00:00 | 23 | 50.1 |
| | 14:30:00 | 23 | 50 |
| | 15:00:00 | 23 | 50.1 |
| | 15:30:00 | 23 | 50 |
| | 16:00:00 | 23 | 49.9 |
| | 16:30:00 | 23 | 50 |
| | 17:00:00 | 23 | 50.1 |
| | 17:30:00 | 23 | 50 |
| | 18:00:00 | 23 | 50.1 |
| | 18:30:00 | 23 | 50 |
| | 19:00:00 | 23 | 50 |
| | 19:30:00 | 23 | 49.9 |
| | 20:00:00 | 23 | 50 |
| | 20:30:00 | 23 | 49.9 |

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|-----------|----------|------|------|
| | 21:00:00 | 23 | 50 |
| | 21:30:00 | 23 | 50.1 |
| | 22:00:00 | 23 | 50 |
| | 22:30:00 | 23 | 50.1 |
| | 23:00:00 | 23 | 50.1 |
| | 23:30:00 | 23 | 50.1 |
| 7/22/2017 | 0:00:00 | 23 | 50 |
| | 0:30:00 | 23 | 50 |
| | 1:00:00 | 23 | 50 |
| | 1:30:00 | 23 | 49.9 |
| | 2:00:00 | 23 | 50.1 |
| | 2:30:00 | 23 | 50 |
| | 3:00:00 | 23 | 50.1 |
| | 3:30:00 | 23 | 50 |
| | 4:00:00 | 23 | 50 |
| | 4:30:00 | 23 | 50.1 |
| | 5:00:00 | 23 | 50.1 |
| | 5:30:00 | 23 | 50.1 |
| | 6:00:00 | 23 | 50.1 |
| | 6:30:00 | 23 | 50 |
| | 7:00:00 | 23.1 | 50 |
| | 7:30:00 | 23 | 50 |
| | 8:00:00 | 23 | 50 |
| | 8:30:00 | 23 | 50.1 |
| | 9:00:00 | 23 | 50.1 |
| | 9:30:00 | 23 | 49.9 |
| | 10:00:00 | 23 | 50 |
| | 10:30:00 | 23 | 50 |
| | 11:00:00 | 23 | 50.1 |
| | 11:30:00 | 23 | 50 |
| | 12:00:00 | 23 | 49.9 |
| | 12:30:00 | 23 | 50.1 |
| | 13:00:00 | 23 | 50 |
| | 13:30:00 | 23 | 50.1 |
| | 14:00:00 | 23 | 49.9 |
| | 14:30:00 | 23 | 50.1 |
| | 15:00:00 | 23 | 50 |
| | 15:30:00 | 23 | 50 |

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| | | | |
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| | 16:30:00 | 23 | 50 |
| | 17:00:00 | 23 | 49.9 |
| | 17:30:00 | 23 | 50 |
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| | 19:30:00 | 23 | 50.1 |
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| | 21:30:00 | 23 | 50.1 |
| | 22:00:00 | 23 | 50.1 |
| | 22:30:00 | 23 | 50 |
| | 23:00:00 | 23 | 50 |
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| | 1:00:00 | 23 | 50 |
| | 1:30:00 | 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 |
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| | 9:30:00 | 22.9 | 50 |
| | 10:00:00 | 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 |
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| | 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 |

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Ship Testing – 54 Samples

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11. APPENDIX I – SHIPPING TEST

Preconditioning:

Start Date: 7-20-2017 Chamber Number: 01268
Completion Date: 7-24-2017 Last Calibration: 5-23-2017
Signature/Date: Paul Valprede Calibration due: 5-31-2018
7-24-2017

Drop Test:

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

| Drop Sequence | Orientation | Specific face, edge or corner | Initials/Date |
|---------------|-------------|-------------------------------|---------------|
| 1 | Top | 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:

Signature: Paul Valprede Date: 7-26-17

Compression Test:

Catalog Number: 2525-10 Pounds Force: 100

Comments: No Failures.

Signature: Paul Valprede Date: 7-26-17

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

Vibration: N/A Vibration testing was performed at Rocky
~~Low Frequency, 40 minutes, Initials: _____~~ Mountain Testing Solutions
~~High frequency 10 minutes, Initials: _____~~ in Ogden, UT.

~~Completion Date: _____~~

~~Signature: _____~~ ~~Date: _____~~

Concentrated Impact Test:

Completion Date: 8-2-2017

Signature: Paul Valpreda Date: 8-2-2017

Second Drop Test:

Catalog Number: 2525-10 Weight: 3.5 lbs. Drop Height: 15" + 30"

| Drop Sequence | Orientation | Specific face, edge or corner | Initials/Date |
|---------------|-------------|---------------------------------------|---------------|
| 1 | Edge | Edge 4-6 | PV 8-2-17 |
| 2 | Face | Face 4 | PV 8-2-17 |
| 3 | Face | Face 6 | PV 8-2-17 |
| 4 | Corner | Corner 2-1-5 | PV 8-2-17 |
| 5 | Edge | Edge 2-1 | PV 8-2-17 |
| 6 | Bottom | Face 3, Increase height to 30 inches. | PV 8-2-17 |

Comments:

Signature: Paul Valpreda Date: 8-2-2017

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Vibration Testing – 54 Samples

ENVIRONMENTAL TEST REPORT

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

Megadyne Medical

July 28, 2017



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REPORT MEGA170404

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Megadyne Medical

ASTM 4169-14 Level II Testing

APPROVALS

Approved By: Aleisha Spent Date: 8/9/2017
Operations Assistant

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

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written consent of Rocky Mountain Testing Solutions, LLC*

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REPORT MEGA170404

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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 $73^{\circ} \pm 18^{\circ} \text{ F}$ ($23^{\circ} \pm 10^{\circ} \text{ C}$), 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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REPORT MEGA170404

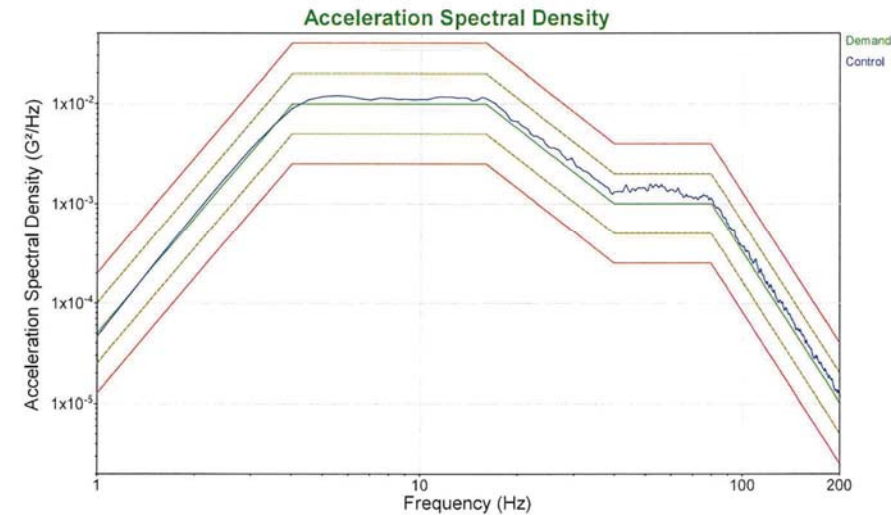
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Customer: Megadyne Medical
 Job#: MEGA170404

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 | G²/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 | | |
| ** 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

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Document: OPER-FRM-004 Rev: 002 Effective: 30 May 2017

| | | |
|---------------------------------|-----------------------------------|---------------------------------|
| Megadyne Medical Products, Inc. | FORM | Document Number OPER-FRM-004 |
| | PEEL POUCH – SEAL BURST TEST FORM | Revision: 002 |

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Appendix I
Multivac Test Samples

| Lot Number | Catalog Number | Description | Date Tested | Lot Size | Min. Burst Pressure (in H ₂ O) |
|------------|----------------|-------------|-------------|----------|---|
| 1507120 | 7525-10 | ZIP POUCH | 8-2-17 | N/A | 19 |

Burst Test Data

| B/M/E | C # | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
|-------|-------|------|------|------|------|------|------|------|------|------|----------|----------|----------|
| | Value | 27.8 | 25.5 | 28.3 | 27.7 | 27.3 | 27.4 | 24.6 | 26.6 | 37.8 | 26.9 | 29.3 | 26.3 |
| B/M/E | C # | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| | Value | 28.0 | 26.5 | 27.7 | 27.5 | 26.3 | 27.5 | 27.0 | 24.3 | 34.7 | 28.3 | 24.2 | 23.9 |
| B/M/E | C # | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 |
| | Value | 26.8 | 27.2 | 27.1 | 27.0 | 27.5 | 25.5 | 26.1 | 26.8 | 33.7 | 25.4 | 24.0 | 25.4 |
| B/M/E | C # | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | 48 |
| | Value | 32.7 | 23.4 | 27.0 | 26.5 | 26.2 | 27.4 | 26.0 | 26.5 | 27.2 | 24.1 | 27.1 | |
| B/M/E | C # | 49 | 50 | 51 | 52 | 53 | 54 | | | | | | |
| | Value | 27.6 | 25.6 | 27.1 | 16.3 | 25.2 | 34.0 | | | | | | |
| B/M/E | C # | | | | | | | | | | | | |
| | Value | | | | | | | | | | Sample 1 | Sample 2 | Sample 3 |
| | | | | | | | | | | | 17.6 | 17.9 | 24.7 |

Note: C= Cavity (MultiVac cavity location), B/M/E=Beginning/Middle/End, Value=Measured Burst Value

Burst Test Settings:
FLOW (#) 9 SENSIT (#) 1 PREFILL (Y/N) N

Burst Test Equipment:
Calibration Due Date 15-8-17 Equip. Id. # 01076 Tested by SHU11 - Manufacturing

Lot disposition: Quantity Tested 53 Accept Reject (NCMR #) N/A QAMfg initials & date: TS 8-2-17

Comments: 1 Failure due to improper testing. Investigated with 3 additional samples. See Sample 1, Sample 2, Sample 3. Failure was reproducible on Sample 1 & Sample 2.

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13. APPENDIX V – MINIMUM SEAL WIDTH TESTING

Package Seal Width Evaluation Data Collection Form

| 2525-10 LOT 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 | |
| 3 | 2525-10 - LOT 1507120 | 1 | | | 0.35 | |
| 4 | 2525-10 - LOT 1507120 | 2 | | | 0.32 | |
| 5 | 2525-10 - LOT 1507120 | 1 | | | 0.35 | |
| 6 | 2525-10 - LOT 1507120 | 2 | | | 0.32 | |
| 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 | | | 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 | |
| 35 | 2525-10 - LOT 1507120 | 2 | | | 0.32 | |

 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

 7-20-2017
Operator Signature Date

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14. APPENDIX VI – PRODUCT DAMAGE INSPECTION

| | | |
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| Megadyne Medical Products, Inc. | TEST PROTOCOL | Document Number XENG-PRT-425 |
| | ZIP ACE 6-Pack Ship Test Protocol | Revision: C |
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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 were observed.

Signature: Paul Valpudo

Date: 7-20-2017

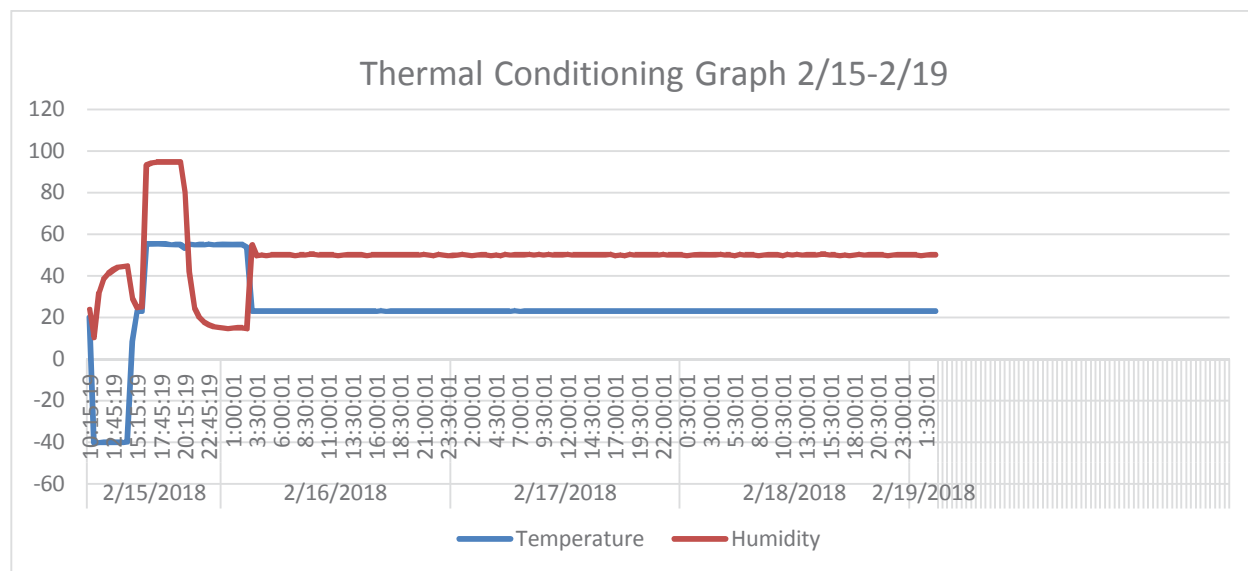
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15. APPENDIX VII – PRECONDITIONING AND SHIP TESTING WITH 210 LB VEHICLE STACKING (COMPRESSION TEST) LOAD



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 humidity control for a duration of 4 hours. | yes |
| Chamber condition held at 55 °C and 95%RH for a duration of 4 hours. | yes |
| Chamber condition held at 55 °C and 15%RH for a duration of 4 hours. | yes |
| Chamber condition held at 23 °C and 50%RH for a duration of 72 hours. | yes |

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

RAW DATA

| Date | Time | Air Temp | Humidity |
|-----------|----------|----------|----------|
| 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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| | | | |
|-----------|----------|------|------|
| | 6:00:01 | 23 | 49.9 |
| | 6:30:01 | 23 | 49.9 |
| | 7:00:01 | 23 | 50.1 |
| | 7:30:01 | 23 | 49.8 |
| | 8:00:01 | 23 | 49.9 |
| | 8:30:01 | 23 | 50 |
| | 9:00:01 | 23 | 50.3 |
| | 9:30:01 | 23 | 50.2 |
| | 10:00:01 | 23 | 49.9 |
| | 10:30:01 | 23 | 49.9 |
| | 11:00:01 | 22.9 | 50.1 |
| | 11:30:01 | 22.9 | 50.1 |
| | 12:00:01 | 23 | 49.8 |
| | 12:30:01 | 23 | 50.1 |
| | 13:00:01 | 23 | 50 |
| | 13:30:01 | 23 | 50 |
| | 14:00:01 | 23 | 50.1 |
| | 14:30:01 | 23 | 50.1 |
| | 15:00:01 | 23 | 49.8 |
| | 15:30:01 | 23 | 49.9 |
| | 16:00:01 | 23 | 49.9 |
| | 16:30:01 | 23.1 | 50 |
| | 17:00:01 | 23 | 50.1 |
| | 17:30:01 | 23 | 50 |
| | 18:00:01 | 23 | 50 |
| | 18:30:01 | 23 | 49.9 |
| | 19:00:01 | 23 | 50.1 |
| | 19:30:01 | 23 | 49.9 |
| | 20:00:01 | 22.9 | 50 |
| | 20:30:01 | 23 | 49.9 |
| | 21:00:01 | 23 | 50.2 |
| | 21:30:01 | 23 | 49.9 |
| | 22:00:01 | 23 | 49.7 |
| | 22:30:01 | 23 | 50.3 |
| | 23:00:01 | 23 | 50.1 |
| | 23:30:01 | 23 | 49.8 |
| 2/17/2018 | 0:00:01 | 23 | 49.8 |
| | 0:30:01 | 23 | 49.9 |

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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 |
| | 8:30:01 | 23 | 49.9 |
| | 9:00:01 | 23 | 50.2 |
| | 9:30:01 | 23 | 50 |
| | 10:00:01 | 23 | 50.3 |
| | 10:30:01 | 23 | 50 |
| | 11:00:01 | 23 | 50 |
| | 11:30:01 | 23 | 50 |
| | 12:00:01 | 23 | 50.2 |
| | 12:30:01 | 23 | 50 |
| | 13:00:01 | 23 | 50 |
| | 13:30:01 | 23 | 49.9 |
| | 14:00:01 | 23 | 50 |
| | 14:30:01 | 23 | 49.9 |
| | 15:00:01 | 23 | 50 |
| | 15:30:01 | 23 | 50.1 |
| | 16:00:01 | 22.9 | 49.9 |
| | 16:30:01 | 23 | 50.3 |
| | 17:00:01 | 23 | 49.7 |
| | 17:30:01 | 23 | 50.1 |
| | 18:00:01 | 23 | 49.8 |
| | 18:30:01 | 23 | 50.2 |
| | 19:00:01 | 23 | 50 |
| | 19:30:01 | 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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11. APPENDIX II – SHIPPING TEST

Preconditioning:

Start Date: 2-15-2018 Chamber Number: 01268
Completion Date: 2-19-2018 Last Calibration: 5-23-2017
Signature/Date: Paul Valpreda Calibration due: 5-31-2018
2-20-2018

Drop Test:

Catalog Number: ME7251C Weight: 3.51 lbs. Drop Height: 15"

| Drop Sequence | Orientation | Specific face, edge or corner | Initials/Date |
|---------------|-------------|-------------------------------|---------------|
| 1 | Top | 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 Valpreda Date: 2-20-2018

Compression Test:

Catalog Number: ME7251C Pounds Force: 210

Comments: All passed.

Signature: Paul Valpreda 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: 2-20-2018

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 2-20-18 |
| 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 2-20-18 |

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 | Pass | Fail |
| Damage | All passed - 36 pcs. | Ø |

Comments:

No failures were observed. -PV

Signature: Paul Valpreda

Date: 2-20-2018

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