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ISOS2 EO Compatibility Testing

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1. ABSTRACT

The single use electrosurgical pencil part numbers under ENG-DWG-656 (ND PN: PB252SM1 LOT# S140520) and ENG-DWG-657 (ND PN: PR252SM1 LOT# S150012) was evaluated for conformance to requirements of IEC 60601-1:2012, IEC 60601-2-2: 2009, and ENG-PS-010 per test protocol ENG-PRT-302 after exposure to the validated EO sterilization cycle specified in ENG-WI-001, Sterilization Chart. The electrosurgical pencil meets the requirements of these standards for all items tested in the protocol after exposure to the EO sterilization cycle, shipping conditions, and humidity and temperature extremes.

2. OBJECTIVE

This test report documents test results obtained while evaluating conformance to requirements of IEC 60601-1: 2012, IEC 60601-2-2: 2009, and ENG-PS-010 per test protocol ENG-PRT-302.

3. REFERENCES

XENG-PRT-306	ISOS2 EO Sterilization Product Design Verification
ENG-WI-003	Sterilization Chart
ENG-RPT-443	ISOS2 Limited Design Verification Aged (t=5year), Thermal Cycled, Ship and Vibration Cycle Product
ENG-PS-010	Product Specification Disposable Electrosurgical Pencil
ENG-DWG-1222	ESU Pencil, Cable
ENG-DWG-1227	PLUG, CLAMSHELL, TOP, ESU PENCIL
ENG-DWG-1228	PLUG, CLAMSHELL, BOTTOM, ESU PENCIL

4. APPENDICES

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5. RESULTS

5.1. PENCIL BUILD DOCUMENTATION, STERILIZATION

5.1.1. Pencil components were built at NewDeantronics under LOTs S150083 and S150084 on a certificate of compliance. Pencils were complete to finished product at Megadyne under work orders 151361, 151362, and 151363.

An additional LOT of ACE37H pencils for fluid ingress testing was built under Megadyne work order 160868.

Build documentation is included as attachments to the Info Card in MasterControl.

5.1.2. Final product under LOTs 151361 and 151363 was sterilized twice at Sterigenics on 4/21/2015 and 5/25/2015 using Cycle 115. Sterilization of product under LOT 160868 was completed at Nelson Labs on March 17, 2016 using exposure conditions equivalent to Sterigenics Cycle 115.

Sterilization documentation is included as an attachment to the Info Card in MasterControl.

5.2. SHIPPING AND STORAGE CYCLE PRECONDITIONING

5.2.1. Shipping and storage conditioning were completed as instructed in section 9.1 of XENG-PRT-315. See Appendix I.

5.3. SHIPPING TEST

5.3.1. All shipping test drops and compressions were completed for both 0036 and ACE37H according to Section 10 of XENG-PRT-302. See Appendix I.

5.4. HANDPIECE HF DIELECTRIC TEST

5.4.1. Continuity is checked at the beginning of testing. All samples of both button and rocker pencils had adequate continuity to perform testing.

5.4.2. For each sample of button and rocker pencils, the test voltage was maintained at 30 seconds without any observed breakdown. The lowest HF voltage applied was 6.60 kV. The highest activation resistance measured after the test was 24.6 Ω, well below the 50 Ω maximum. Raw data are included in Appendix II.

5.5. HANDPIECE MAINS DIELECTRIC TEST

5.5.1. No breakdown was observed for any sample of button and rocker pencils subjected to the 4,600 V_{RMS} condition for 30 seconds. Raw data is included in Appendix II.

5.6. CABLE LEAKAGE TEST

5.6.1. Continuity is checked at the beginning of testing. All samples of demonstrated adequate continuity to perform testing.

5.6.2. The allowable leakage was calculated to be 120.96 mA. The greatest leakage measured was 39.5, the lowest was 33.2 mA. See Appendix III for raw data.

5.7. CABLE HF DIELECTRIC TEST

5.7.1. For each sample of cable, the test voltage was maintained for 30 seconds. The lowest HF voltage applied was 6.60 kV. No sample

showed signs of breakdown during the test. Raw data are included in Appendix III.

5.8. CABLE MAINS DIELECTRIC TEST

5.8.1. A voltage of 4,596 V_{RMS} was applied to the cable samples for 5 minutes. No damage was observed, no sparks were observed, and the HI Pot alarm did not sound. All resistances were within established limits after testing. See Appendix III.

5.9. PLUG MAINS DIELECTRIC TEST

5.9.1. No visible signs of damage were observed and the HI Pot did not alarm when samples were subjected to 4,600 V_{RMS} for 30 seconds. See Appendix IV.

5.10. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

5.10.1. No change to component. NOT TESTED.

5.11. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

5.11.1. No change to component. NOT TESTED.

5.12. FLUID INGRESS

5.12.1. Button switch pencils: Switches on all test samples were successfully operated 10 times with current less than 2.5 mA for 0.5 seconds after released. All samples passed.

5.12.2. Rocker switch pencils: Switches on all test samples were successfully operated 10 times with current less than 2.5 mA for 0.5 seconds after released. All samples passed. One sample displayed self activation. Raw data is included in Appendix V.

5.13. IEC 60601-1 TEMPERATURE TEST

5.13.1. Pencil temperature remained below 41 °C for button and rocker pencils during activation. See Appendix V for raw data and analysis.

	Temperature		
Sample and Test Description	Before (°C)	After (°C)	Change (°C)
ISOS2, Rocker, 300 W CUT	22.9	24.4	1.5
ISOS2, Rocker, 120 W COAG	22.7	22.9	0.7

ISOS2, Button, 300 W CUT	22.2	24.9	2.7
ISOS2, Button, 120 W COAG	22.6	22.1	0.1

5.14. PLUG STRAIN RELIEF (ROTATIONAL) TEST

5.14.1. Testing was not performed.

5.15. HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

5.15.1. No sample, button or rocker pencil, showed any evidence that the cord had worked loose of the housing or showed any damage.

5.15.2. In all cases, the cable maintained acceptable continuity (less than 50Ω) between the CUT wire and the Active wire with the CUT button depressed. The greatest resistance measured was 21.0 Ω. Raw data is included in Appendix VII.

5.15.3. In all cases, the cable maintained acceptable continuity (less than 50Ω) between the COAG wire and the Active wire with the COAG button depressed. The greatest resistance measured was 33.4 Ω. Raw data is included in Appendix VII.

5.16. ACTIVATION FORCE TESTING

5.16.1. Rocker Pencil 0036: All button forces were well within the specifications. The values range from 527.75 grams force to 381.75 grams force. Cpk values for the button forces are well over the generally accepted minimum of 1.33.

Button Activation Force 0036 LOT 151363			
	SPEC	CUT	COAG
MAX	700	527.75	458.83
MIN	250	446.41	381.75
AVG	-	484.98	417.65
SD	-	19.57	20.67
Cpk	-	3.66	2.70

5.16.2. Button Pencil ACE37H: All button forces were well within the specifications. The values range from 434.72 grams force. to 343.39 grams force. Cpk values for the button forces are well over the generally accepted minimum of 1.33.

Button Activation Force ACE37H LOT 151361			
	SPEC	CUT	COAG
MAX	700	434.72	386.74
MIN	250	381.87	343.39
AVG	-	409.21	366.31
SD	-	13.93	10.95
Cpk	-	3.81	3.54

5.16.3. See Appendix VIII for raw data.

5.17. ACTIVATION OVER TIME

5.17.1. All pencils were activated 500 times. See Raw Data in Appendix IX.

5.17.2. Rocker Pencil 0036: All button forces were well within the specifications after 500 activations. The values range from 489.52 grams force to 364.58 grams force. Cpk values for the button forces are well over the generally accepted minimum of 1.33.

Button Activation Force 0036 LOT 151363			
	SPEC	CUT	COAG
MAX	700	489.52	448.60
MIN	250	414.14	364.58
AVG	-	448.34	398.34
SD	-	16.68	18.92
Cpk	-	3.96	2.61

5.17.3. Button Pencil ACE37H: All button forces were well within the specifications after 500 activations. The values range from 403.06 grams force. to 329.02 grams force. Cpk values for the button forces are well over the generally accepted minimum of 1.33.

Button Activation Force ACE37H LOT 151361			
	SPEC	CUT	COAG
MAX	700	403.06	367.99
MIN	250	356.79	329.02
AVG	-	379.60	349.84
SD	-	13.04	10.00
Cpk	-	3.31	3.33

5.18. ELECTRODE WOBBLE

5.18.1. Electrode wobble in ISOS2 pencils is slightly higher than ISOS1 pencils. See Appendix X.

Electrode Wobble			
	0036	ACE37H	Control (0035)
MAX	0.155	0.151	0.123
MIN	0.130	0.127	0.094
MEAN	0.141	0.139	0.116
SD	0.006	0.007	0.005

5.18.2. CORD LENGTH

5.18.3. Cord length was not tested in this protocol.

5.19. DURABILITY OF PRINT TO CHEMICAL IN USE ENVIRONMENT (ROCKER PENCIL ONLY)

5.19.1. 0036: The ink remained visible after applying both saline and lactated ringers on all samples. See Appendix XI.

5.20. RESISTANCE TO ISOPROPYL ALCOHOL

5.20.1. Not tested.

5.21. PENCIL BODY PEEL STRENGTH

5.21.1. All peel strength values were greater than 10 lbs. The lowest value observed is 22.07 lbs. and the greatest value observed is 49.96 lbs. See Appendix XII.

6. DISCUSSION

6.1. PENCIL BUILD DOCUMENTATION, STERILIZATION

6.1.1. Pencils are traceable and conform to the design.

6.1.2. Pencils were sterilized at an exposure between 50 and 55 kGy.

6.2. SHIPPING AND STORAGE CYCLE PRECONDITIONING

6.2.1. Shipping and storage conditions were completed on the equipment below.

Thermotron #1
Model number - SE-600-3-3
Megadyne number - 01095

Serial number - 28105
Calibration Date - 5/19/2015
Due Date - 5/31/2016
Shipping Weight - 1,680 lbs.

Sample preconditioning was performed to ensure that product was tested after being exposed to temperatures and humidity it would encounter in the field prior to testing.

6.3. SHIPPING TEST

6.3.1. Both catalog numbers 0036 and ACE37H were subjected to shipping conditions and storage conditions experienced by the product in the field.

6.3.2. Product was subjected to ship testing to ensure that product experienced the shock, vibration, and compression likely to occur in the field prior to testing, not to validate the packaging configuration. Packaging is not validated as part of this protocol.

6.4. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

6.4.1. There were no alarms or visible signs of damage to any hand piece during exposure to 120% of the rated accessory voltage. All samples satisfied the acceptance criteria.

6.5. HANDPIECE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

6.5.1. There were no alarms or visible signs of damage to any hand piece. All samples satisfied the acceptance criteria.

6.6. CABLE LEAKAGE TEST

6.6.1. Both pencils are manufactured with the same cable, ENG-DWG-1222.

6.6.2. Leakage current was much less than 120.96 mA for all test samples. All acceptance criteria for ENG-DWG-1222 were satisfied.

6.7. CABLE HF DIELECTRIC TEST

6.7.1. The cable samples were undamaged by 6.6 kV for 30 seconds. 6.6 kV corresponds to 120% of the Rated Accessory Voltage of 5.5kV. All acceptance criteria for ENG-DWG-1222 were satisfied.

6.8. CABLE MAINS DIELECTRIC TEST

6.8.1. All acceptance criteria for cable ENG-DWG-1222 were satisfied.

6.9. PLUG MAINS TEST

6.9.1. The plug is constructed from three (3) components; ENG-DWG-1222. ENG-DWG-1227, and ENG-DWG-1228; for both 0036 and ACE37H pencils, and all ISOS2 pencils.

6.9.2. All acceptance criteria for the plug design were satisfied.

6.10. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

6.10.1. The component was not available for testing. This component will not be qualified as part of this testing.

6.11. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

6.11.1. The component was not available for testing. This component will not be qualified as part of this testing.

6.12. FLUID INGRESS

6.12.1. Button switch pencils: All pencil buttons (ACE37H, Lot# 160868) operated correctly after exposure to saline. All samples satisfied the acceptance criteria.

6.12.2. Rocker switch pencils: All pencil buttons (0036, Lot# 151363) operated correctly after exposure to saline. All samples satisfied the acceptance criteria.

6.12.3. It should be noted that fluid ingress testing on rocker switch pencils was performed on two lots of button pencils. The second lot as indicated in section 5.1.1 above, passed. However, in the initial sample group (ACE37H, Lot# 151361), one pencil (sample #9 of ACE37H) self-activated during operation of the CUT button when connected to a generator. This failure was confirmed with a multimeter. The failure started in the CUT button and migrated to the COAG button over time.

The pencil was inspected under magnification. No obvious cause was found. The test method was examined and a discrepancy was found. In the case of this pencil, fluid ingress testing was the last of all tests performed. All pencils had been subjected to button force

testing and 500 button activations prior to fluid ingress. The 500 activations were performed using a new method, an Instron measurement system and fixtures. In all testing previously, 500 button activations had been performed by hand. The crosshead travel distance on the Instron was set to a distance that ensured that each button was pressed. Because button travel distance was controlled, instead of button force, wear may have been caused by buttons being over-depressed or due to poor alignment between the button and the pencil housing. Either of these cases could cause wear that would induce a fluid ingress failure not related to the design of the pencil, but to an unrelated test method.

This design adequately resists fluid ingress in conditions of normal use.

6.13. IEC 60601-1 TEMPERATURE TEST

6.13.1. The acceptance criteria were satisfied. The temperature on the pencil did not exceed 41°C on any pencil or in any image. In three cases, the temperature rose only slightly. All acceptance criteria were satisfied.

6.14. PLUG STRAIN RELIEF (ROTATIONAL) TEST

6.14.1. Because the design for retaining the cable in the plug and hand piece are similar, only the pencil hand piece strain relief test was performed. The hand piece test is more rigorous and is representative of plug performance as well. See ENG-PRT-306 section 10.5.2 for a complete discussion.

6.15. HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

6.15.1. As discussed in ENG-PRT-306, the pencil and plug use nearly identical means of holding the plug. The pencil strain relief test is more strenuous than the plug test because it applies more rotation cycles. Only the strain relief for the hand piece was tested, but results are also valid for the plug.

6.15.2. The strain relief adequately prevents the cable from wearing and exposing conductors or forming short circuits during use. The strain relief design meets the acceptance criteria.

6.16. ACTIVATION FORCE TESTING

6.16.1. All samples were within specification. The design satisfies the acceptance criteria of the protocol.

6.17. ACTIVATION OVER TIME

6.17.1. In previous testing, pencils had been activated 500 times by hand, each button was activated independently. Test samples used in this protocol were activated using the Instron Measurement System and a fixture. The test fixture allowed CUT and COAG buttons of five (5) pencils to activated simultaneously reducing the time required to activate all pencils. During testing, periodic continuity checks were made to ensure that pencils were being electrically activated during the test.

6.17.2. Button resistance is less than 50 Ω in the depressed condition and greater than 100,000 Ω after 500 activations in every case. Activation force is also within specification after 500 activations in every case. The design meets the acceptance criteria of the protocol after 500 activation cycles.

6.18. ELECTRODE WOBBLE

6.18.1. The protocol requirement for the electrode wobble as listed in section 31.18 of ENG-PRT-302 requires the wobble for the ISOS2 pencil to be less than that of current ISOS pencils. However, upon completion of the testing reported under XENG-RPT-452, it is noted that the ISOS2 pencil electrodes wobble (deviate) more than the LOT of current ISOS button pencils tested and do not meet the requirements of the protocol. The range difference in these means is 0.025”. This is deemed not significant.

6.18.2.

6.18.1.

6.19. CORD LENGTH

6.19.1. Cord length was tested previously as documented in Test Report ENG-RPT-433 for 15 foot cord pencils and Test Report ENG-RPT-438 for 10 ft. pencil.

6.20. DURABILITY OF PRINT (ROCKER PENCIL ONLY)

6.20.1. Both saline and lactated ringers are chemicals likely used to clean the pencil in the use environment. The ink was resistant to both solutions and did not smear or degrade during the test. The pencil design satisfies the acceptance criteria.

6.20.2. This alternative test for compliance with IEC 60601-1:2012 Clause 7.1.3 was used according to IEC 6060101-1:2012 Clause 4.5.

The risk associated with the button color is that the user will activate the CUT functionality instead of COAG if the ink is removed during manufacture or use. Button color is a redundant safety measure. Section 201.12.2 of IEC60601-2-2 requires that the CUT button be located closest to the electrode. As part of HF Dielectric testing, CUT and COAG functionality (i.e. the CUT button activates cut functionality, the COAG button activates coagulation functionality) is checked prior to the resistance measurement. See Appendix VIII.

6.21. RESISTANCE TO ISOPROPYL ALCOHOL

6.21.1. Isopropyl alcohol (70%) is used to clean pencils as needed in the manufacturing environment, prior to EO sterilization. The pencil will not be exposed to isopropyl alcohol under normal use. Resistance to isopropyl alcohol was completed as recorded in ENG-RPT-443.

6.22. PENCIL BODY PEEL STRENGTH

6.22.1. All test samples satisfy the acceptance criteria.

7. CONCLUSIONS

7.1. PENCIL BUILD DOCUMENTATION, STERILIZATION

7.1.1. Pencils represent the final product.

7.1.2. Pencils were correctly sterilized at Sterigenics using Cycle 115 per ENG-WI-003.

7.2. SHIPPING AND STORAGE CYCLE PRECONDITIONING

7.2.1. Both catalog numbers were subjected to temperature and humidity conditions conforming to ASTM D4169 prior to functional testing.

7.3. SHIPPING TEST

7.3.1. Both catalog numbers were subjected to shock, vibration, and compression conditions conforming to ASTM D4169 prior to functional testing.

7.4. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

7.4.1. The ISOS2 pencil hand piece is compliant with IEC 60601-2-2: 2009 Clause 201.8.8.3.103 after two exposures to the validated EO sterilization cycle.

7.5. HANDPIECE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

7.5.1. The ISOS2 pencil hand piece is compliant with IEC 60601-2-2: 2009 Clause 201.8.8.3.104 after two exposures to the validated EO sterilization cycle.

7.6. CABLE LEAKAGE TEST

7.6.1. The ISOS2 cable ENG-DWG-1222 is compliant with IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.102 after two exposures to the validated EO sterilization cycle.

7.7. CABLE HF DIELECTRIC WITHSTAND TEST

7.7.1. The ISOS2 cable is compliant with IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.103 after two exposures to the validated EO sterilization cycle.

7.8. CABLE MAINS DIELECTRIC WITHSTAND TEST

7.8.1. The ISOS2 pencil cable is compliant with IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.104 after two exposures to the validated EO sterilization cycle.

7.9. PLUG MAINS TEST

7.9.1. The plug is constructed from three (3) components; ENG-DWG-1222. ENG-DWG-1227, and ENG-DWG-1228; is compliant with IEC60601-2-2 Clause 201.8.8.3.101, and Clause 201.8.8.3.104.

7.10. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

7.10.1. No change to component. Not tested.

7.11. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

7.11.1. No change to component. Not tested.

7.12. FLUID INGRESS

7.12.1. CUT and COAG switches of button and rocker pencils conform to IEC 60601-2-2 Clause 201.11.6.5 b after two exposures to conditions of the validated EO sterilization cycle.

7.13. IEC 60601-1 TEMPERATURE TEST

7.13.1. Button and rocker switch pencils conform to IEC60601-1 Clause 11.1.2.2 after two exposures to the validated EO sterilization cycle.

7.14. PLUG STRAIN RELIEF (ROTATIONAL) TEST

7.14.1. The hand piece strain relief is functionally equivalent to the hand piece strain relief and meets the requirements of ICE60601-2-2 Clause 201.8.4.2 after two exposures to the validated EO sterilization cycle.

7.15. CABLE ANCHORAGE (HANDPIECE) TEST

7.15.1. The hand piece and plug strain relief designs meet the requirements of ICE60601-2-2 Clause 201.8.4.2 after two exposures to the validated EO sterilization cycle.

7.16. ACTIVATION FORCE TESTING

7.16.1. The button activation force is for CUT and COAG buttons on both 0036 and ACE37H is within the specification of ENG-PS-010 section 4.2.1 after two exposures to the validated EO sterilization cycle.

7.17. ACTIVATION OVER TIME

7.17.1. Button resistance and activation force demonstrate that the switch withstands 500 activations per switch after 500 activations and two exposures to the validated EO sterilization cycle.

7.18. ELECTRODE WOBBLE

7.18.1. The marketing department was consulted and a determination was made that the ISOS2 pencil wobble is acceptable though not meeting the intent of the protocol. It is determined that this wobble was not an issue in the field and the values are accepted as is. The pencil

wobble is acceptable after two exposures to the validated EO sterilization cycle.

7.19. CORD LENGTH

7.19.1. Cord length was verified previously and was not evaluated in this testing.

7.20. DURABILITY OF PRINT TO CHEMICAL IN USE ENVIRONMENT (ROCKER PENCIL ONLY)

7.20.1. The pencil design complies with IEC 60601-1:2012 Clause 7.1.3 after two exposures to the validated EO sterilization cycle. See also Clause 4.5.

7.21. RESISTANCE TO ISOPROPYL ALCOHOL

7.21.1. Not evaluated in this report. See ENG-RPT-443.

7.22. PENCIL BODY PEEL STRENGTH

7.22.1. ISOS2 pencils meet the requirement of product specification ENG-PS-010 requirement 4.2.9 after two exposures to the validated EO sterilization cycle.

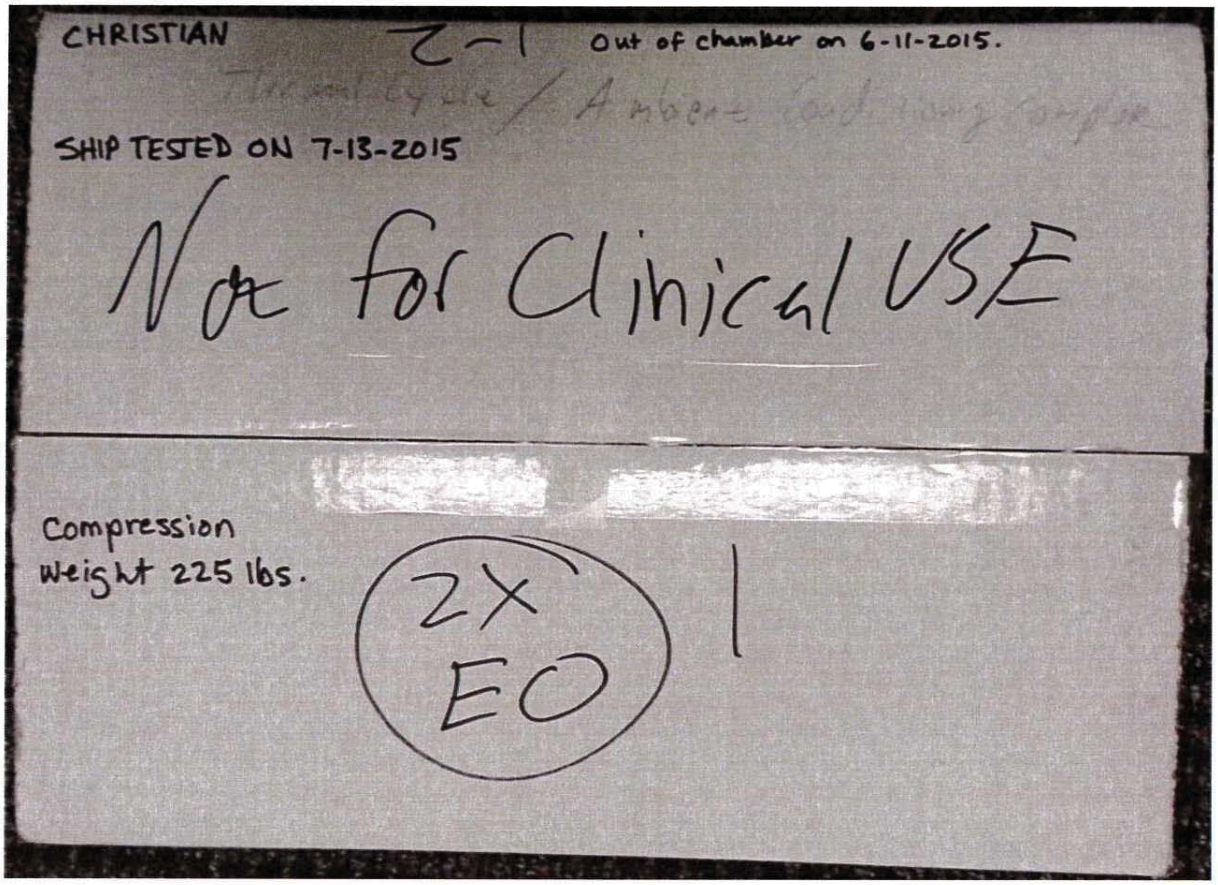
8. RECOMMENDATIONS

8.1. No further testing is required.

9. REVISION HISTORY

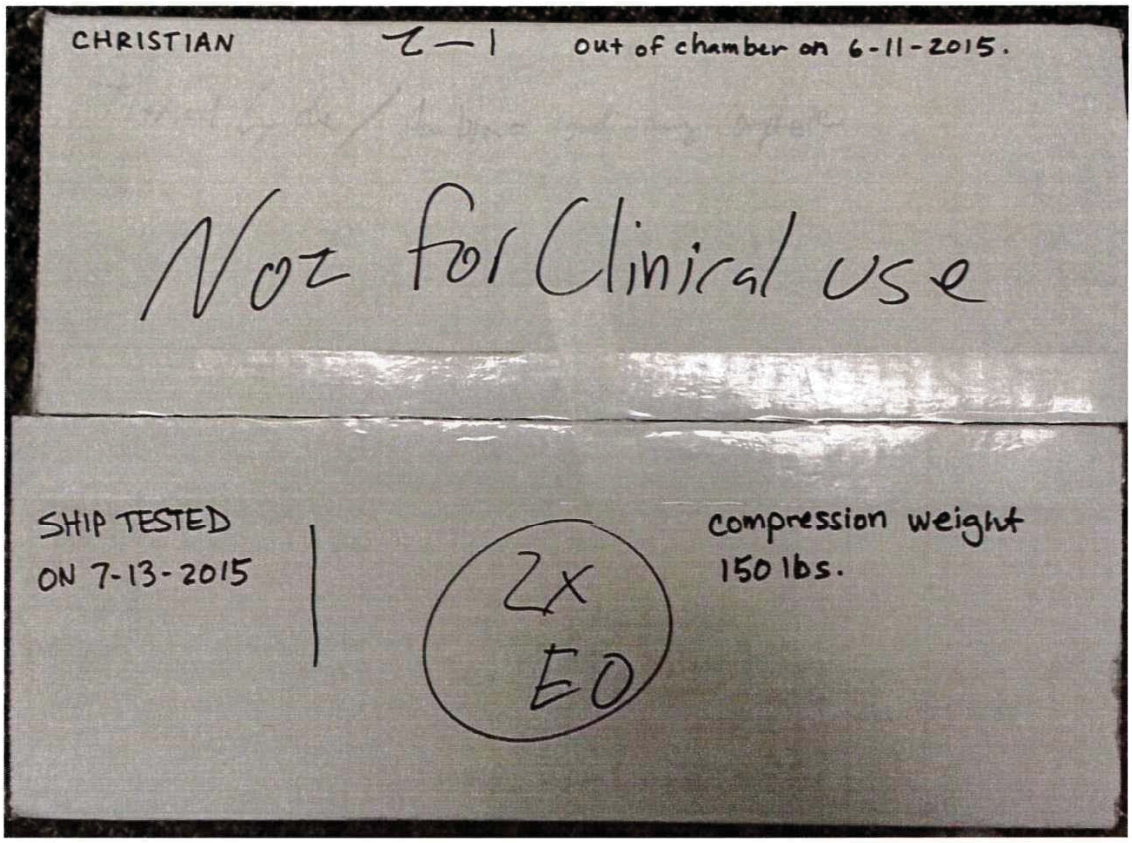
Revision	Document Change Order Number	Description Of Change	Effective Date
See Master Control for Revision History			

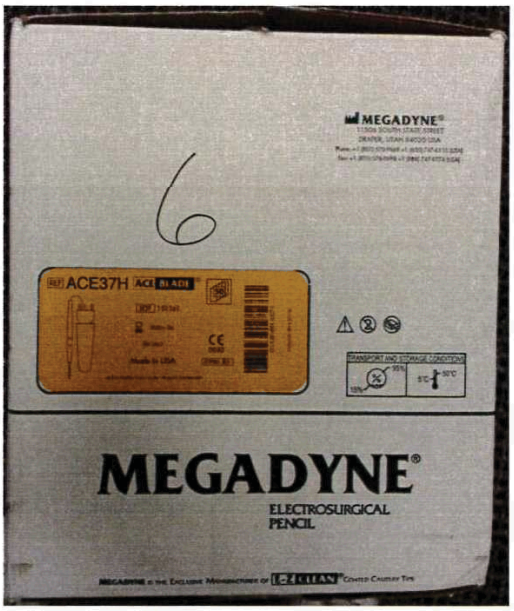
APPENDIX I – SHIPPING AND STORAGE CONDITIONING



2/8/16

Paul Valpreda 2-8-2016





2/8/2016

Paul Valpreda 2-8-2016

Conditioning Chamber Calibration Information	Chamber: 01268 Cal Due: Last Calibration: 5-19-2015 5-31-2016	Pass/Fail
Maximum Temperature (^{0}C):	70.2	
Minimum Temperature (^{0}C):	-40.6	
Maximum Humidity (%RH):	95.1	
Minimum Humidity (%RH):	2.5	
Chamber conditions held at -40°C with no humidity control for a duration of 4 hours:	9:57 AM TO 2:11 PM on 3-17-2016 Duration of 4 hrs. 14 minutes	Pass
Chamber conditions held at 70°C and 95% RH for a duration of 4 hours:	14:05 TO 18:40 on 3/21/2016 Duration of 4 hrs. 35 minutes	Pass
Chamber conditions held at 70°C and 15% RH for a duration of 4 hours:	19:45 TO 23:55 on 3/21/2016 Duration of 4 hrs. 10 minutes	Pass
Chamber conditions held at 23°C and 50% RH for a duration of 72 hours:	3/22/16 12:50 AM TO 3/25/16 12:50 AM Duration of 72 hrs.	Pass

Paul Valpreda — PAUL VALPREDA 3-25-2016
Test Technician Name — Signature Date

Christian Crook — 3/25/2016
Engineer Name — Signature Date

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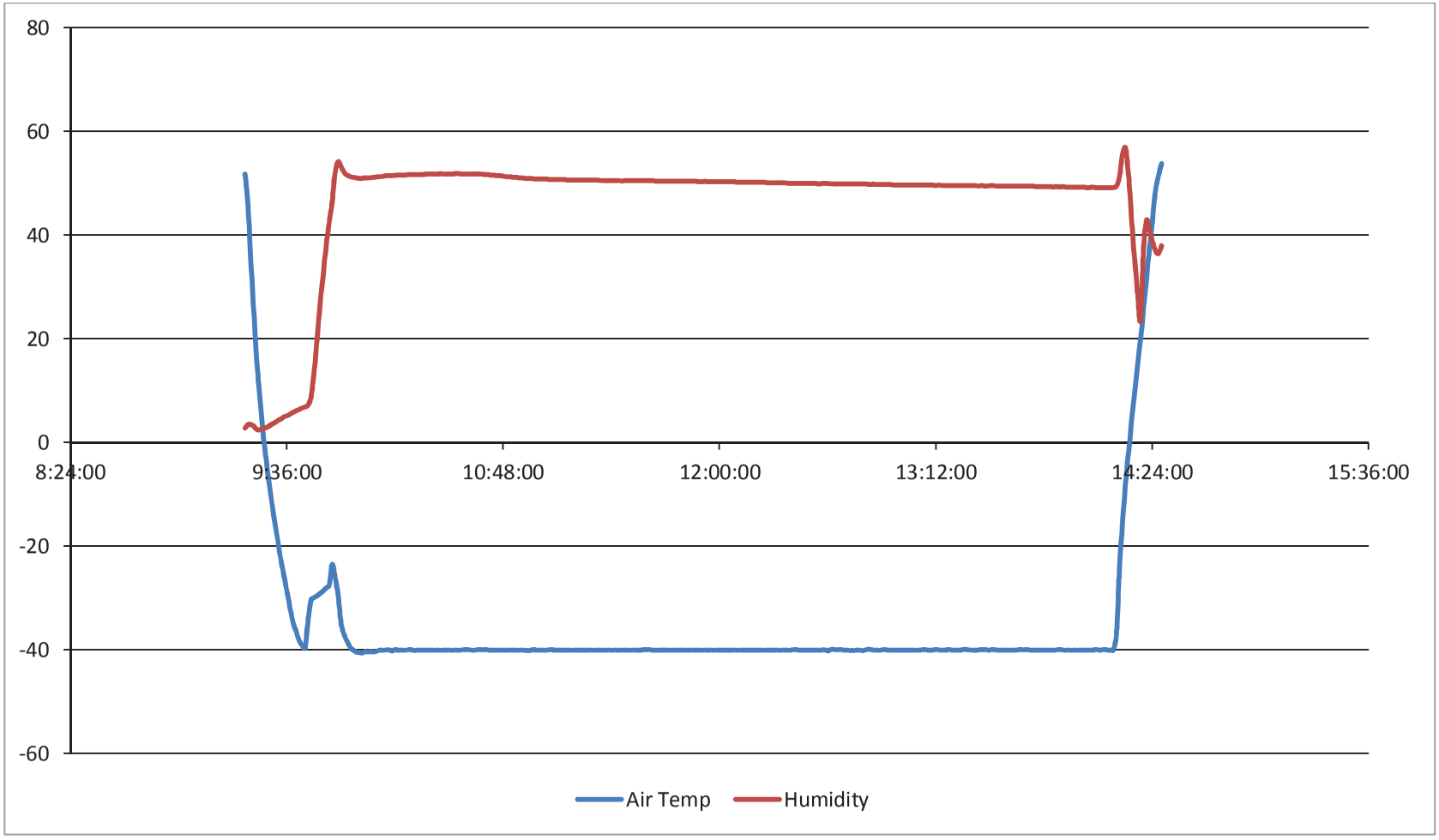
Low Temperature Conditioning.



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Low Temperature conditioning data.

Date	Time	Air Temp	Humidity
3/17/2016	9:22:05	51.8	2.8
3/17/2016	9:23:05	45.6	3.5
3/17/2016	9:24:05	34.1	3.5
3/17/2016	9:25:05	24.3	3.1
3/17/2016	9:26:05	14.9	2.5
3/17/2016	9:27:05	8.1	2.5
3/17/2016	9:28:05	2	2.7
3/17/2016	9:29:05	-3.3	2.9
3/17/2016	9:30:05	-7.8	3.2
3/17/2016	9:31:05	-12	3.6
3/17/2016	9:32:05	-15.8	3.9
3/17/2016	9:33:05	-19.4	4.3
3/17/2016	9:34:05	-22.9	4.6
3/17/2016	9:35:05	-25.8	5
3/17/2016	9:36:05	-29	5.2
3/17/2016	9:37:05	-32	5.5
3/17/2016	9:38:05	-34.8	5.8
3/17/2016	9:39:05	-36.4	6.1
3/17/2016	9:40:05	-38.2	6.4
3/17/2016	9:41:05	-39.1	6.7
3/17/2016	9:42:05	-39.6	6.9
3/17/2016	9:43:05	-34	7.3
3/17/2016	9:44:05	-30.3	8.9
3/17/2016	9:45:05	-29.9	13.9
3/17/2016	9:46:05	-29.5	20.3
3/17/2016	9:47:05	-29.1	26.8
3/17/2016	9:48:05	-28.6	32.6
3/17/2016	9:49:05	-28	37.9
3/17/2016	9:50:05	-27.5	42.5
3/17/2016	9:51:05	-23.5	46.5
3/17/2016	9:52:05	-26.1	52.3
3/17/2016	9:53:05	-29.7	54.2
3/17/2016	9:54:05	-35	53.2
3/17/2016	9:55:05	-37.1	52.1
3/17/2016	9:56:05	-38.4	51.6
3/17/2016	9:57:05	-39.5	51.3
3/17/2016	9:58:05	-40	51.2
3/17/2016	9:59:05	-40.4	51.1
3/17/2016	10:00:05	-40.5	51
3/17/2016	10:01:05	-40.6	51
3/17/2016	10:02:05	-40.3	51.1
3/17/2016	10:03:05	-40.4	51.1
3/17/2016	10:04:05	-40.3	51.1
3/17/2016	10:05:05	-40.4	51.2
3/17/2016	10:06:05	-40.2	51.3
3/17/2016	10:07:05	-40	51.3
3/17/2016	10:08:05	-40.1	51.4
3/17/2016	10:09:05	-40	51.5
3/17/2016	10:10:05	-40	51.5
3/17/2016	10:11:05	-40.2	51.5
3/17/2016	10:12:05	-39.9	51.6
3/17/2016	10:13:05	-40.1	51.6
3/17/2016	10:14:05	-40	51.6
3/17/2016	10:15:05	-40.1	51.6
3/17/2016	10:16:05	-40	51.7
3/17/2016	10:17:05	-39.9	51.7
3/17/2016	10:18:05	-40.1	51.7
3/17/2016	10:19:05	-40.1	51.7
3/17/2016	10:20:05	-40	51.7
3/17/2016	10:21:05	-40	51.7
3/17/2016	10:22:05	-40	51.8
3/17/2016	10:23:05	-40	51.8
3/17/2016	10:24:05	-40	51.8
3/17/2016	10:25:05	-40.1	51.8
3/17/2016	10:26:05	-40	51.8
3/17/2016	10:27:05	-40.1	51.9
3/17/2016	10:28:05	-40	51.8
3/17/2016	10:29:05	-40	51.8
3/17/2016	10:30:05	-40	51.8
3/17/2016	10:31:05	-40.1	51.8
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3/17/2016	10:33:05	-40.1	51.9
3/17/2016	10:34:05	-40	51.8
3/17/2016	10:35:05	-39.9	51.8
3/17/2016	10:36:05	-39.9	51.8
3/17/2016	10:37:05	-40	51.8
3/17/2016	10:38:05	-40.1	51.8
3/17/2016	10:39:05	-40	51.8
3/17/2016	10:40:05	-39.9	51.8
3/17/2016	10:41:05	-40	51.8
3/17/2016	10:42:05	-39.9	51.7
3/17/2016	10:43:05	-40	51.7
3/17/2016	10:44:05	-40	51.6
3/17/2016	10:45:05	-40	51.6
3/17/2016	10:46:05	-40	51.5
3/17/2016	10:47:05	-40	51.5
3/17/2016	10:48:05	-40.1	51.4
3/17/2016	10:49:05	-40.1	51.3
3/17/2016	10:50:05	-40	51.3
3/17/2016	10:51:05	-40	51.2
3/17/2016	10:52:05	-40	51.2
3/17/2016	10:53:05	-40.1	51.1
3/17/2016	10:54:05	-40	51.1
3/17/2016	10:55:05	-40.1	51
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3/17/2016	10:57:05	-40.1	51
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3/17/2016	10:59:05	-40.1	50.9
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3/17/2016	11:01:05	-40	50.9
3/17/2016	11:02:05	-40.1	50.9
3/17/2016	11:03:05	-40	50.8
3/17/2016	11:04:05	-39.9	50.8
3/17/2016	11:05:05	-40.1	50.8
3/17/2016	11:06:05	-40	50.8
3/17/2016	11:07:05	-40	50.8
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3/17/2016	12:12:05	-40	50.2
3/17/2016	12:13:05	-40	50.2
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3/17/2016	12:15:05	-40.1	50.2
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3/17/2016	12:17:05	-40	50.1
3/17/2016	12:18:05	-40	50.1
3/17/2016	12:19:05	-40	50.1
3/17/2016	12:20:05	-40.1	50.1
3/17/2016	12:21:05	-40	50.1
3/17/2016	12:22:05	-40	50.1
3/17/2016	12:23:05	-40.1	50
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3/17/2016	12:31:05	-40	50
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3/17/2016	12:52:05	-40	49.8
3/17/2016	12:53:05	-40.1	49.8
3/17/2016	12:54:05	-40	49.8
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3/17/2016	12:56:05	-40.1	49.8
3/17/2016	12:57:05	-40	49.8
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3/17/2016	13:00:05	-40	49.7
3/17/2016	13:01:05	-40	49.7
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3/17/2016	13:04:05	-40	49.7
3/17/2016	13:05:05	-40.1	49.7
3/17/2016	13:06:05	-40	49.7
3/17/2016	13:07:05	-40	49.7
3/17/2016	13:08:05	-39.9	49.7
3/17/2016	13:09:05	-40	49.7
3/17/2016	13:10:05	-40	49.7
3/17/2016	13:11:05	-40	49.7
3/17/2016	13:12:05	-39.9	49.6
3/17/2016	13:13:05	-40	49.7
3/17/2016	13:14:05	-40	49.6
3/17/2016	13:15:05	-40.1	49.6
3/17/2016	13:16:05	-39.9	49.6
3/17/2016	13:17:05	-40	49.6
3/17/2016	13:18:05	-40	49.6
3/17/2016	13:19:05	-40	49.6
3/17/2016	13:20:05	-40.1	49.6
3/17/2016	13:21:05	-39.9	49.6
3/17/2016	13:22:05	-39.9	49.6
3/17/2016	13:23:05	-40	49.6
3/17/2016	13:24:05	-40	49.6

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
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3/17/2016	13:25:05	-40	49.6
3/17/2016	13:26:05	-40	49.5
3/17/2016	13:30:05	-40	49.6
3/17/2016	13:31:05	-39.9	49.6
3/17/2016	13:32:05	-40	49.5
3/17/2016	13:33:05	-40	49.5
3/17/2016	13:34:05	-40	49.5
3/17/2016	13:35:05	-40	49.5
3/17/2016	13:36:05	-40.1	49.5
3/17/2016	13:37:05	-40	49.5
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3/17/2016	13:39:05	-40	49.5
3/17/2016	13:40:05	-39.9	49.5
3/17/2016	13:41:05	-40	49.5
3/17/2016	13:42:05	-39.9	49.5
3/17/2016	13:43:05	-40	49.5
3/17/2016	13:44:05	-40	49.5
3/17/2016	13:45:05	-40	49.4
3/17/2016	13:46:05	-40	49.4
3/17/2016	13:47:05	-40	49.4
3/17/2016	13:48:05	-40	49.4
3/17/2016	13:49:05	-40	49.4
3/17/2016	13:50:05	-40.1	49.4
3/17/2016	13:51:05	-40.1	49.3
3/17/2016	13:52:05	-40	49.4
3/17/2016	13:53:05	-39.9	49.3
3/17/2016	13:54:05	-40	49.4
3/17/2016	13:55:05	-40.1	49.3
3/17/2016	13:56:05	-40	49.3
3/17/2016	13:57:05	-40.1	49.3
3/17/2016	13:58:05	-40	49.3
3/17/2016	13:59:05	-40.1	49.3
3/17/2016	14:00:05	-40	49.3
3/17/2016	14:01:05	-40	49.3
3/17/2016	14:02:05	-40	49.2
3/17/2016	14:03:05	-40	49.2
3/17/2016	14:04:05	-40.1	49.3
3/17/2016	14:05:05	-39.9	49.2
3/17/2016	14:06:05	-40	49.2
3/17/2016	14:07:05	-40	49.2
3/17/2016	14:08:05	-39.9	49.2
3/17/2016	14:09:05	-40	49.2
3/17/2016	14:10:05	-40	49.2
3/17/2016	14:11:05	-40	49.2
3/17/2016	14:12:05	-36.9	49.5
3/17/2016	14:13:05	-24.3	51.3
3/17/2016	14:14:05	-15.4	55.7
3/17/2016	14:15:05	-8.1	56.9
3/17/2016	14:16:05	-1.9	51.6
3/17/2016	14:17:05	4	43.2
3/17/2016	14:18:05	9.6	35.7
3/17/2016	14:19:05	14.9	28.9
3/17/2016	14:20:05	20.2	23.6
3/17/2016	14:21:05	25.8	37.7
3/17/2016	14:22:05	31.7	42.9
3/17/2016	14:23:05	37.6	41
3/17/2016	14:24:05	43.1	38.8
3/17/2016	14:25:05	48.7	36.9
3/17/2016	14:26:05	51.5	36.5
3/17/2016	14:27:05	53.8	38
3/17/2016	13:27:05	-39.9	49.6
3/17/2016	13:28:05	-39.9	49.5
3/17/2016	13:29:05	-40	49.5

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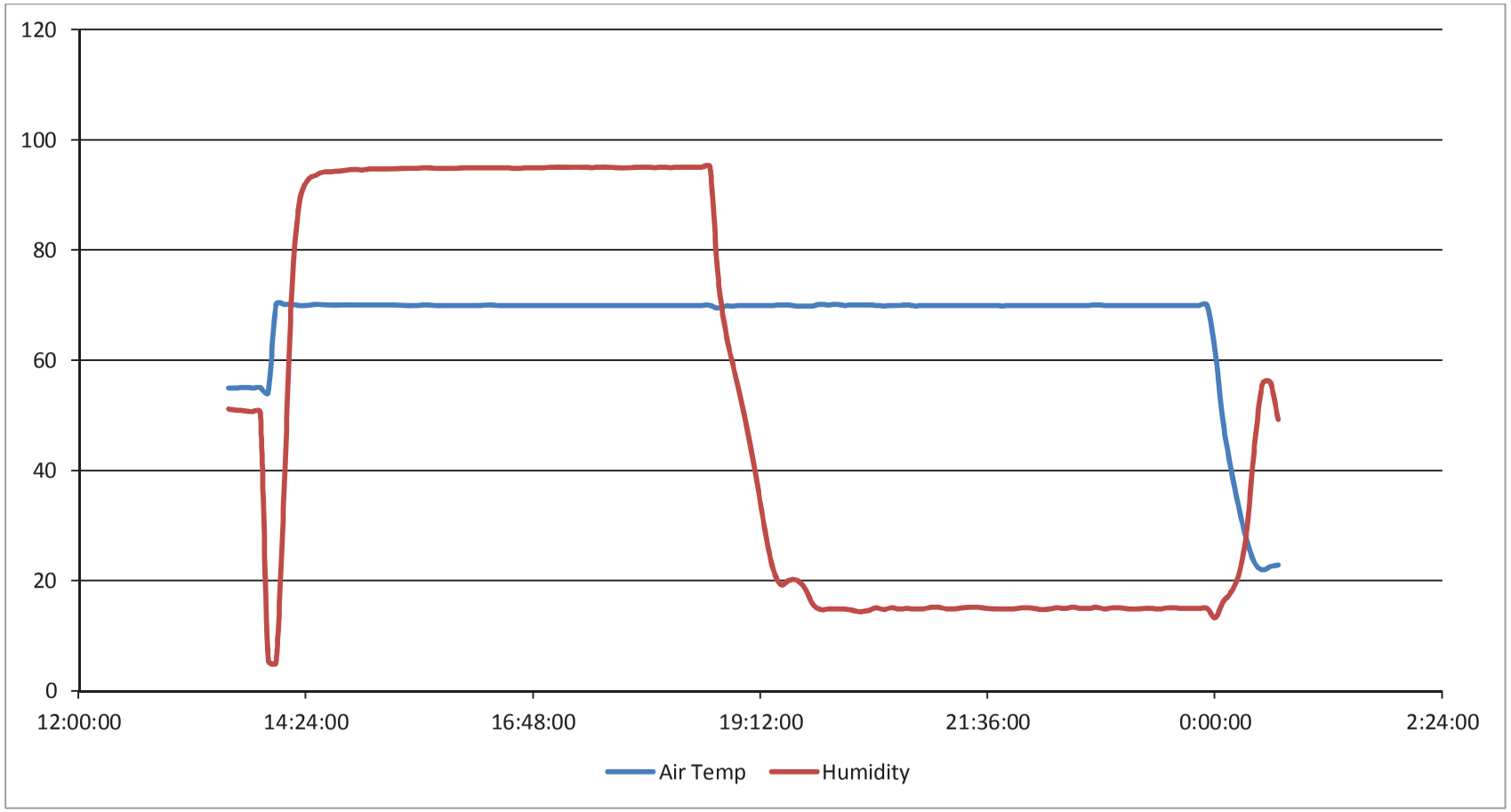
High Temperature Conditioning.



Date	Time	Air Temp	Humidity
3/21/2016	13:35:05	55	51.2
3/21/2016	13:40:05	55	51
3/21/2016	13:45:05	55.1	50.9
3/21/2016	13:50:05	55	50.7
3/21/2016	13:55:05	55.1	50.6
3/21/2016	14:00:05	54.2	5.6
3/21/2016	14:05:05	70.2	5.1
3/21/2016	14:10:05	70.2	35.4
3/21/2016	14:15:05	70.2	72.8
3/21/2016	14:20:05	70	89.1
3/21/2016	14:25:05	70	92.7
3/21/2016	14:30:05	70.2	93.6
3/21/2016	14:35:05	70.1	94.2
3/21/2016	14:40:05	70.1	94.3
3/21/2016	14:45:05	70.1	94.4
3/21/2016	14:50:05	70.1	94.6
3/21/2016	14:55:05	70.1	94.7
3/21/2016	15:00:05	70.1	94.6
3/21/2016	15:05:05	70.1	94.8
3/21/2016	15:10:05	70.1	94.8
3/21/2016	15:15:05	70.1	94.8
3/21/2016	15:20:05	70.1	94.8
3/21/2016	15:25:05	70	94.9
3/21/2016	15:30:05	70	94.9
3/21/2016	15:35:05	70	94.9
3/21/2016	15:40:05	70.1	95
3/21/2016	15:45:05	70	94.9
3/21/2016	15:50:05	70	94.9
3/21/2016	15:55:05	70	94.9
3/21/2016	16:00:05	70	94.9
3/21/2016	16:05:05	70	95
3/21/2016	16:10:05	70	95
3/21/2016	16:15:05	70	95
3/21/2016	16:20:05	70.1	95
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3/21/2016	16:35:05	70	94.9
3/21/2016	16:40:05	70	94.9
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3/21/2016	17:30:05	70	95.1
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3/21/2016	18:10:05	70	95.1
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3/21/2016	18:25:05	70	95.1
3/21/2016	18:30:05	70	95.1
3/21/2016	18:35:05	70	95.1
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3/21/2016	18:50:05	69.9	65.1
3/21/2016	18:55:05	69.9	58.6
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3/21/2016	19:05:05	70	45.4
3/21/2016	19:10:05	70	37.4
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3/21/2016	19:40:05	69.9	18.7
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3/21/2016	21:05:05	70	15.2
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3/22/2016	0:15:05	33.4	21.1
3/22/2016	0:20:05	27.5	28.7
3/22/2016	0:25:05	23.3	44.4
3/22/2016	0:30:05	22	55.7
3/22/2016	0:35:05	22.6	56.1
3/22/2016	0:40:05	22.9	49.3

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
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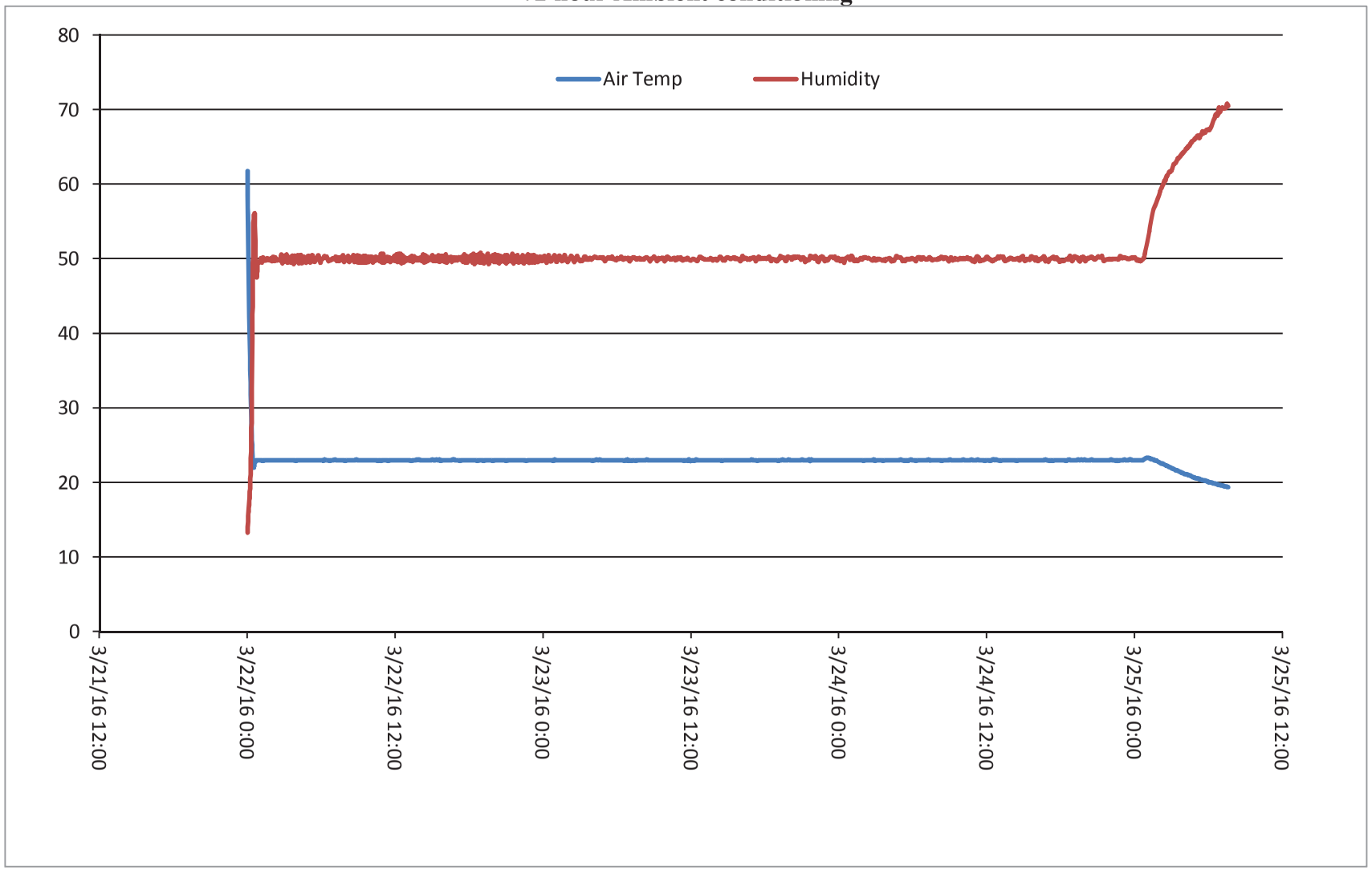
72 hour Ambient conditioning



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3/22/2016	0:15:05	33.4	21.1
3/22/2016	0:20:05	27.5	28.7
3/22/2016	0:25:05	23.3	44.4
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3/22/2016	0:35:05	22.6	56.1
3/22/2016	0:40:05	22.9	49.3
3/22/2016	0:45:05	23	47.5
3/22/2016	0:50:05	23	49.4
3/22/2016	0:55:05	23	49.5
3/22/2016	1:00:05	23	49.6
3/22/2016	1:05:05	23	50.1
3/22/2016	1:10:05	23	49.5
3/22/2016	1:15:05	22.9	50.2
3/22/2016	1:20:05	23	49.8
3/22/2016	1:25:05	23	49.9
3/22/2016	1:30:05	23	49.8
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3/22/2016	1:45:05	23	49.9
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3/24/2016	17:25:05	23	50.3
3/24/2016	17:30:05	23	50
3/24/2016	17:35:05	23	50.1
3/24/2016	17:40:05	23	50.2
3/24/2016	17:45:05	23	49.9
3/24/2016	17:50:05	23	49.9
3/24/2016	17:55:05	23	49.6
3/24/2016	18:00:05	23	49.8
3/24/2016	18:05:05	23	49.8
3/24/2016	18:10:05	23	49.7
3/24/2016	18:15:05	23	49.8
3/24/2016	18:20:05	23	49.8
3/24/2016	18:25:05	22.9	49.9
3/24/2016	18:30:05	23	50
3/24/2016	18:35:05	23	49.9
3/24/2016	18:40:05	23.1	50.1
3/24/2016	18:45:05	23	50.4
3/24/2016	18:50:05	23	50
3/24/2016	18:55:05	23	49.7
3/24/2016	19:00:05	23	49.9
3/24/2016	19:05:05	23	50.3
3/24/2016	19:10:05	23	50.3
3/24/2016	19:15:05	23	50.2
3/24/2016	19:20:05	23	50.2
3/24/2016	19:25:05	23.1	49.9
3/24/2016	19:30:05	23	49.7
3/24/2016	19:35:05	23	49.7
3/24/2016	19:40:05	23.1	50.2
3/24/2016	19:45:05	23	50.2
3/24/2016	19:50:05	23	50.3
3/24/2016	19:55:05	23.1	49.9
3/24/2016	20:00:05	23	49.7
3/24/2016	20:05:05	23	49.9
3/24/2016	20:10:05	23	50.1
3/24/2016	20:15:05	23	50.1
3/24/2016	20:20:05	23	50.1
3/24/2016	20:25:05	23	50.2
3/24/2016	20:30:05	23.1	50.3
3/24/2016	20:35:05	23	50.1
3/24/2016	20:40:05	23	50.1
3/24/2016	20:45:05	23	49.9
3/24/2016	20:50:05	23	50
3/24/2016	20:55:05	23	50.1
3/24/2016	21:00:05	23	50.3
3/24/2016	21:05:05	23	50.3
3/24/2016	21:10:05	23	50.2
3/24/2016	21:15:05	23	50.2
3/24/2016	21:20:05	23	50.4
3/24/2016	21:25:05	23	50
3/24/2016	21:30:05	23	49.7
3/24/2016	21:35:05	23	49.8
3/24/2016	21:40:05	23	49.9
3/24/2016	21:45:05	23	49.9
3/24/2016	21:50:05	23	49.9
3/24/2016	21:55:05	23	50
3/24/2016	22:00:05	23	50
3/24/2016	22:05:05	23.1	49.9
3/24/2016	22:10:05	23	50
3/24/2016	22:15:05	23	50
3/24/2016	22:20:05	23	50
3/24/2016	22:25:05	23	50
3/24/2016	22:30:05	22.9	50
3/24/2016	22:35:05	23	50
3/24/2016	22:40:05	22.9	49.9
3/24/2016	22:45:05	23	50.1
3/24/2016	22:50:05	23	50.4
3/24/2016	22:55:05	23	50.2
3/24/2016	23:00:05	23	50.1
3/24/2016	23:05:05	23	50.2
3/24/2016	23:10:05	23.1	50.2
3/24/2016	23:15:05	23	50.1
3/24/2016	23:20:05	23	50.1
3/24/2016	23:25:05	23	50
3/24/2016	23:30:05	23	50
3/24/2016	23:35:05	23.1	50
3/24/2016	23:40:05	23.1	50.1
3/24/2016	23:45:05	23	50.2
3/24/2016	23:50:05	23	50.1
3/24/2016	23:55:05	23	50.2
3/25/2016	0:00:05	23	50.2
3/25/2016	0:05:05	23	50.1
3/25/2016	0:10:05	23	49.8
3/25/2016	0:15:05	23	49.8
3/25/2016	0:20:05	23	49.9
3/25/2016	0:25:05	23	49.7
3/25/2016	0:30:05	23	49.7
3/25/2016	0:35:05	23	49.9
3/25/2016	0:40:05	23	50
3/25/2016	0:45:05	23.1	50.1
3/25/2016	0:50:05	23.2	50.8
3/25/2016	0:55:05	23.3	51.5
3/25/2016	1:00:05	23.3	52.1
3/25/2016	1:05:05	23.3	52.8
3/25/2016	1:10:05	23.3	53.5
3/25/2016	1:15:05	23.2	54.4
3/25/2016	1:20:05	23.2	55.2
3/25/2016	1:25:05	23.1	55.9
3/25/2016	1:30:05	23.1	56.5
3/25/2016	1:35:05	23	56.9
3/25/2016	1:40:05	23	57.2
3/25/2016	1:45:05	22.9	57.6
3/25/2016	1:50:05	22.9	57.9
3/25/2016	1:55:05	22.8	58.3
3/25/2016	2:00:05	22.7	58.7
3/25/2016	2:05:05	22.6	59.2
3/25/2016	2:10:05	22.6	59.5
3/25/2016	2:15:05	22.5	59.8
3/25/2016	2:20:05	22.5	60.1
3/25/2016	2:25:05	22.4	60.5
3/25/2016	2:30:05	22.3	60.5
3/25/2016	2:35:05	22.3	61.1
3/25/2016	2:40:05	22.2	61.2
3/25/2016	2:45:05	22.1	61.5
3/25/2016	2:50:05	22.1	61.7
3/25/2016	2:55:05	22	61.7
3/25/2016	3:00:05	21.9	61.9
3/25/2016	3:05:05	21.9	62.3
3/25/2016	3:10:05	21.8	62.7
3/25/2016	3:15:05	21.7	62.8
3/25/2016	3:20:05	21.7	62.9
3/25/2016	3:25:05	21.6	63.2
3/25/2016	3:30:05	21.6	63.5
3/25/2016	3:35:05	21.5	63.5
3/25/2016	3:40:05	21.4	63.7
3/25/2016	3:45:05	21.4	63.9
3/25/2016	3:50:05	21.3	64.1

Appendix I
Shipping Test Log Sheet

Preconditioning:

Start Date: 3-21-2016 Chamber Number: 01268

Completion Date: 3-25-2016 Last Calibration: 5-19-2015

Signature/Date: Paul Valpreda 3-25-16 Calibration due: 5-31-2016

Drop Test:

Catalog ACE37H Weight 12 lbs. Drop Height: 15 inches

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 3-25-2016
2	Edge	Edge 5-3	PV 3-25-2016
3	Edge	Edge 6-3	PV 3-25-2016
4	Corner	Corner 2-3-5	PV 3-25-2016
5	Corner	Corner 4-3-6	PV 3-25-2016
6	Bottom	Face 3	PV 3-25-2016

Comments:

Signature: Paul Valpreda Date: 3-25-2016

Compression Test:

Catalog ACE37H Pounds Force 2201bs.

Comments: LOT # 160868

Signature: Paul Valpreda Date: 3-25-2016

3-28-2016

Appendix I Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials PV High frequency 10 minutes, Initials PV

Completion Date: 3-25-2016

Signature: Paul Valpreda Date: 3-25-2016

Second Drop Test:

Catalog AE3714 Weight 12lbs. Drop Height: 15 & 30 inches.

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 3-25-2016
2	Face	Face 4	PV 3-25-2016
3	Face	Face 6	PV 3-25-2016
4	Corner	Corner 2-1-5	PV 3-25.2016
5	Edge	Edge 2-1	PV 3-25-2016
6	Bottom	Face 3, Increase height to 2 times specified height.	PV 3-25-2016

Comments: _____

Signature: Paul Valpreda Date: 3-25-2016.

APPENDIX II – HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

High Frequency Dielectric Withstand Testing
ISOS2 0036 - LOT 151363 EOx2
Data Collection Form

Sample	Configuration	High Frequency Max V_{peak} (kV)	High Frequency P/F	Mains P/F	Button Activation Ω P/F
1	0036 - 151363	6.68	PASS	PASS	1.5, 1.6 - PASS
2	0036 - 151363	6.60	PASS	PASS	1.6, 1.5 - PASS
3	0036 - 151363	6.72	PASS	PASS	1.6, 1.8 - PASS
4	0036 - 151363	6.76	PASS	PASS	8.6, 2.7 - PASS
5	0036 - 151363	6.60	PASS	PASS	1.7, 1.5 - PASS
6	0036 - 151363	6.60	PASS	PASS	2.3, 4.6 - PASS
7	0036 - 151363	6.60	PASS	PASS	1.9, 1.5 - PASS
8	0036 - 151363	6.68	PASS	PASS	1.7, 3.7 - PASS
9	0036 - 151363	6.72	PASS	PASS	1.7, 1.9 - PASS
10	0036 - 151363	6.72	PASS	PASS	4.5, 4.5 - PASS
11	0036 - 151363	6.60	PASS	PASS	10.5, 3.1 - PASS
12	0036 - 151363	6.68	PASS	PASS	13.4, 6.9 - PASS
13	0036 - 151363	6.60	PASS	PASS	2.0, 1.5 - PASS
14	0036 - 151363	6.60	PASS	PASS	1.6, 1.4 - PASS
15	0036 - 151363	6.60	PASS	PASS	4.5, 4.2 - PASS
16	0036 - 151363	6.68	PASS	PASS	1.6, 1.5 - PASS
17	0036 - 151363	6.72	PASS	PASS	1.5, 1.6 - PASS
18	0036 - 151363	6.60	PASS	PASS	3.2, 5.5 - PASS
19	0036 - 151363	6.68	PASS	PASS	1.7, 1.5 - PASS
20	0036 - 151363	6.64	PASS	PASS	1.7, 3.6 - PASS
21	0036 - 151363	6.60	PASS	PASS	1.6, 1.5 - PASS
22	0036 - 151363	6.72	PASS	PASS	1.6, 1.9 - PASS
23	0036 - 151363	6.60	PASS	PASS	13.7, 18.5 - PASS
24	0036 - 151363	6.64	PASS	PASS	14.0, 24.6 - PASS
25	0036 - 151363	6.64	PASS	PASS	1.6, 8.1 - PASS
26	0036 - 151363	6.60	PASS	PASS	1.5, 1.4 - PASS
27	0036 - 151363	6.64	PASS	PASS	2.0, 11.4 - PASS
28	0036 - 151363	6.76	PASS	PASS	5.6, 1.9 - PASS
29	0036 - 151363	6.72	PASS	PASS	5.8, 4.3 - PASS
30	0036 - 151363	6.80	PASS	PASS	1.6, 22.2 - PASS
			7/16/2015 PV	7/17/2015 PV	7/20/2015 PV

Rated Accessory V_{peak}	5.500	V_{peak}
Minimum Mains Test Value	4.596	V_{RMS}
Actual Mains Test Value	4.600	V_{RMS}
Mains Test Value Calculation:	(Rated Accessory V_{peak} +1000V_{peak}) / √2	

CALIBRATION INFORMATION	
Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/16/2014
Calibration Due:	10/31/2015
Hitpot Test Generator	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/26/2014
Calibration Due:	8/31/2015
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	8/6/2014
Calibration Due:	8/31/2015
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/16/2014
Calibration Due:	10/16/2015

Paul Valpreda
Operator(s) Name

7/20/2015
Date

Operator(s) Signature

11/17/2015
Date

High Frequency Dielectric Withstand Testing
ISOS2 ACE37H - LOT 151361 EOx2
Data Collection Form

Sample	Configuration	High Frequency		Mains	Button Activation	
		Max V_{peak} (kV)	P/ F	P/ F	Ω P/F	
1	ACE37H - 151361	6.68	PASS	PASS	1.6, 2.1 - PASS	
2	ACE37H - 151361	6.72	PASS	PASS	1.6, 1.4 - PASS	
3	ACE37H - 151361	6.76	PASS	PASS	1.8, 2.0 - PASS	
4	ACE37H - 151361	6.76	PASS	PASS	1.6, 1.9 - PASS	
5	ACE37H - 151361	6.68	PASS	PASS	1.8, 1.4 - PASS	
6	ACE37H - 151361	6.76	PASS	PASS	2.0, 1.4 - PASS	
7	ACE37H - 151361	6.68	PASS	PASS	2.9, 1.4 - PASS	
8	ACE37H - 151361	6.72	PASS	PASS	1.9, 1.4 - PASS	
9	ACE37H - 151361	6.72	PASS	PASS	1.6, 1.5 - PASS	
10	ACE37H - 151361	6.80	PASS	PASS	1.8, 1.5 - PASS	
11	ACE37H - 151361	6.76	PASS	PASS	1.7, 1.5 - PASS	
12	ACE37H - 151361	6.72	PASS	PASS	1.7, 1.6 - PASS	
13	ACE37H - 151361	6.68	PASS	PASS	3.4, 1.5 - PASS	
14	ACE37H - 151361	6.64	PASS	PASS	2.0, 1.5 - PASS	
15	ACE37H - 151361	6.76	PASS	PASS	1.8, 1.5 - PASS	
16	ACE37H - 151361	6.76	PASS	PASS	1.6, 1.4 - PASS	
17	ACE37H - 151361	6.68	PASS	PASS	1.6, 2.1 - PASS	
18	ACE37H - 151361	6.64	PASS	PASS	1.6, 1.4 - PASS	
19	ACE37H - 151361	6.72	PASS	PASS	1.7, 1.9 - PASS	
20	ACE37H - 151361	6.76	PASS	PASS	1.7, 1.6 - PASS	
21	ACE37H - 151361	6.76	PASS	PASS	1.8, 1.5 - PASS	
22	ACE37H - 151361	6.72	PASS	PASS	1.6, 1.4 - PASS	
23	ACE37H - 151361	6.60	PASS	PASS	1.5, 1.5 - PASS	
24	ACE37H - 151361	6.72	PASS	PASS	1.8, 1.6 - PASS	
25	ACE37H - 151361	6.80	PASS	PASS	1.8, 1.4 - PASS	
26	ACE37H - 151361	6.68	PASS	PASS	1.8, 1.5 - PASS	
27	ACE37H - 151361	6.84	PASS	PASS	1.6, 1.4 - PASS	
28	ACE37H - 151361	6.60	PASS	PASS	2.4, 1.4 - PASS	
29	ACE37H - 151361	6.68	PASS	PASS	1.7, 1.5 - PASS	
30	ACE37H - 151361	6.68	PASS	PASS	1.5, 1.4 - PASS	
			9/1/2015 PV	9/2/2015 PV	9/4/2015 PV	

Rated Accessory V_{peak}	5.500	V_{peak}
Minimum Mains Test Value	4.596	V_{RMS}
Actual Mains Test Value	4.600	V_{RMS}
Mains Test Value Calculation:	(Rated Accessory V_{peak} + 1000V_{peak}) / √2	

CALIBRATION INFORMATION	
Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/16/2014
Calibration Due:	10/31/2015
Hitpot Test Generator	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/25/2015
Calibration Due:	8/31/2016
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	8/6/2014
Calibration Due:	8/31/2015
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/16/2014
Calibration Due:	10/16/2015

Paul Valpreda
Operator(s) Name

9/4/2015
Date

Operator(s) Signature

11/17/2015
Date

APPENDIX II – CABLE LEAKAGE TEST

Cable Dielectric Withstand Testing

Cable with new inner jacket EOx2 on 0036 pencils LOT 151363

Data Collection Form

Sample	Configuration	d (mm)	L (cm)	ftest (kHz)	Upeak (Vp-p)/2	LEAKAGE Measured Leakage	Calculated Acceptable Leakage	P/F	Power (W)
1	New Inner Jacket Cable EOx2	2.8	30	400	400	35.1	120.96	PASS	14
2	New Inner Jacket Cable EOx2	2.8	30	400	400	35.3	120.96	PASS	14
3	New Inner Jacket Cable EOx2	2.8	30	400	400	37.1	120.96	PASS	14
4	New Inner Jacket Cable EOx2	2.8	30	400	400	38.6	120.96	PASS	15
5	New Inner Jacket Cable EOx2	2.8	30	400	400	35.5	120.96	PASS	14
6	New Inner Jacket Cable EOx2	2.8	30	400	400	34.7	120.96	PASS	14
7	New Inner Jacket Cable EOx2	2.8	30	400	400	37.7	120.96	PASS	15
8	New Inner Jacket Cable EOx2	2.8	30	400	400	33.8	120.96	PASS	14
9	New Inner Jacket Cable EOx2	2.8	30	400	400	33.5	120.96	PASS	14
10	New Inner Jacket Cable EOx2	2.8	30	400	400	39.5	120.96	PASS	16
11	New Inner Jacket Cable EOx2	2.8	30	400	400	33.8	120.96	PASS	14
12	New Inner Jacket Cable EOx2	2.8	30	400	400	36.5	120.96	PASS	14
13	New Inner Jacket Cable EOx2	2.8	30	400	400	33.3	120.96	PASS	14
14	New Inner Jacket Cable EOx2	2.8	30	400	400	35.8	120.96	PASS	14
15	New Inner Jacket Cable EOx2	2.8	30	400	400	34.6	120.96	PASS	15
16	New Inner Jacket Cable EOx2	2.8	30	400	400	35.9	120.96	PASS	15
17	New Inner Jacket Cable EOx2	2.8	30	400	400	34.5	120.96	PASS	14
18	New Inner Jacket Cable EOx2	2.8	30	400	400	34.6	120.96	PASS	14
19	New Inner Jacket Cable EOx2	2.8	30	400	400	38.8	120.96	PASS	15
20	New Inner Jacket Cable EOx2	2.8	30	400	400	34.5	120.96	PASS	14
21	New Inner Jacket Cable EOx2	2.8	30	400	400	33.4	120.96	PASS	14
22	New Inner Jacket Cable EOx2	2.8	30	400	400	33.2	120.96	PASS	14
23	New Inner Jacket Cable EOx2	2.8	30	400	400	35.6	120.96	PASS	15
24	New Inner Jacket Cable EOx2	2.8	30	400	400	34.3	120.96	PASS	14
25	New Inner Jacket Cable EOx2	2.8	30	400	400	37.2	120.96	PASS	15
26	New Inner Jacket Cable EOx2	2.8	30	400	400	37.7	120.96	PASS	15
27	New Inner Jacket Cable EOx2	2.8	30	400	400	37.8	120.96	PASS	15
28	New Inner Jacket Cable EOx2	2.8	30	400	400	33.7	120.96	PASS	14
29	New Inner Jacket Cable EOx2	2.8	30	400	400	37.9	120.96	PASS	15
30	New Inner Jacket Cable EOx2	2.8	30	400	400	39.2	120.96	PASS	16
								7/22/2015	
								PV	

d = smallest measured outer dimension of cable insulation
L = length of cable insulation up to a max. of 300 mm
ftest = frequency of the pure cut signal
Upeak = Oscilloscope test p-p voltage

Leakage Calculation - $I_{leakage} = 9.0*10^{-6}*d*L*f_{test}*U_{peak}\,(mA)$

Sample	Configuration	HIGH FREQUENCY Max Vpk (kV)	HIGH FREQUENCY P/ F	MAINS P/ F
1	New Inner Jacket Cable EOx2	6.72	PASS	PASS
2	New Inner Jacket Cable EOx2	6.68	PASS	PASS
3	New Inner Jacket Cable EOx2	6.72	PASS	PASS
4	New Inner Jacket Cable EOx2	6.76	PASS	PASS
5	New Inner Jacket Cable EOx2	6.72	PASS	PASS
6	New Inner Jacket Cable EOx2	6.72	PASS	PASS
7	New Inner Jacket Cable EOx2	6.68	PASS	PASS
8	New Inner Jacket Cable EOx2	6.76	PASS	PASS
9	New Inner Jacket Cable EOx2	6.72	PASS	PASS
10	New Inner Jacket Cable EOx2	6.68	PASS	PASS
11	New Inner Jacket Cable EOx2	6.64	PASS	PASS
12	New Inner Jacket Cable EOx2	6.60	PASS	PASS
13	New Inner Jacket Cable EOx2	6.68	PASS	PASS
14	New Inner Jacket Cable EOx2	6.68	PASS	PASS
15	New Inner Jacket Cable EOx2	6.76	PASS	PASS
16	New Inner Jacket Cable EOx2	6.68	PASS	PASS
17	New Inner Jacket Cable EOx2	6.64	PASS	PASS
18	New Inner Jacket Cable EOx2	6.68	PASS	PASS
19	New Inner Jacket Cable EOx2	6.72	PASS	PASS
20	New Inner Jacket Cable EOx2	6.72	PASS	PASS
21	New Inner Jacket Cable EOx2	6.68	PASS	PASS
22	New Inner Jacket Cable EOx2	6.68	PASS	PASS
23	New Inner Jacket Cable EOx2	6.60	PASS	PASS
24	New Inner Jacket Cable EOx2	6.72	PASS	PASS
25	New Inner Jacket Cable EOx2	6.68	PASS	PASS
26	New Inner Jacket Cable EOx2	6.64	PASS	PASS
27	New Inner Jacket Cable EOx2	6.72	PASS	PASS
28	New Inner Jacket Cable EOx2	6.76	PASS	PASS
29	New Inner Jacket Cable EOx2	6.72	PASS	PASS
30	New Inner Jacket Cable EOx2	6.64	PASS	PASS
			7/23/2015	9/3/2015
			PV	PV

Mains Test Value Calculation: (Rated Accessory V_{peak} +1000V_{peak}) / √2		
Rated Accessory V_{peak}	5,500	V_{peak}
Minimum Mains Test Value	4,596	V_{RMS}
Actual Mains Test Value	4,600	V_{RMS}

CALIBRATION INFORMATION	
Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/16/2014
Calibration Due:	10/31/2015
Hitpot Test Generator	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/26/2014
Calibration Due:	8/31/2015
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	8/6/2014
Calibration Due:	8/31/2015
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/16/2014
Calibration Due:	10/16/2015

Paul Valpreda — 9/4/2015
Operator Name — Date

Operator Signature — 11/16/15 Date

APPENDIX III – PLUG MAINS DIELECTRIC

Plug Dielectric
Data collection Form

Sample	Configuration	MAINS P/ F
1	0036 - 151363 Rocker EOx2	PASS
2	0036 - 151363 Rocker EOx2	PASS
3	0036 - 151363 Rocker EOx2	PASS
4	0036 - 151363 Rocker EOx2	PASS
5	0036 - 151363 Rocker EOx2	PASS
6	0036 - 151363 Rocker EOx2	PASS
7	0036 - 151363 Rocker EOx2	PASS
8	0036 - 151363 Rocker EOx2	PASS
9	0036 - 151363 Rocker EOx2	PASS
10	0036 - 151363 Rocker EOx2	PASS
11	0036 - 151363 Rocker EOx2	PASS
12	0036 - 151363 Rocker EOx2	PASS
13	0036 - 151363 Rocker EOx2	PASS
14	0036 - 151363 Rocker EOx2	PASS
15	0036 - 151363 Rocker EOx2	PASS
16	0036 - 151363 Rocker EOx2	PASS
17	0036 - 151363 Rocker EOx2	PASS
18	0036 - 151363 Rocker EOx2	PASS
19	0036 - 151363 Rocker EOx2	PASS
20	0036 - 151363 Rocker EOx2	PASS
21	0036 - 151363 Rocker EOx2	PASS
22	0036 - 151363 Rocker EOx2	PASS
23	0036 - 151363 Rocker EOx2	PASS
24	0036 - 151363 Rocker EOx2	PASS
25	0036 - 151363 Rocker EOx2	PASS
26	0036 - 151363 Rocker EOx2	PASS
27	0036 - 151363 Rocker EOx2	PASS
28	0036 - 151363 Rocker EOx2	PASS
29	0036 - 151363 Rocker EOx2	PASS
30	0036 - 151363 Rocker EOx2	PASS
		9/18/2015
		PV

CALIBRATION INFORMATION	
Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/16/2014
Calibration Due:	10/31/2015
Hitpot Test Generator	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/25/2015
Calibration Due:	8/31/2016
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	8/6/2014
Calibration Due:	8/31/2015
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/16/2014
Calibration Due:	10/16/2015

Mains Test Value Calculation:		
(Rated Accessory V_{peak} +1000V_{peak}) / √2		
Rated Accessory V_{peak}	5,500	V_{peak}
Minimum Mains Test Value	4,596	V_{RMS}
Actual Mains Test Value	4,600	V_{RMS}

Paul Valpreda — 9/18/2015
Operator Name — Date

11/16/15
Operator Signature — Date

APPENDIX IV – FLUID INGRESS

Ingress of Fluids

Data Collection Form

Product Tested - 0036 LOT 151363 EOx2

Sample	Configuration	INITIAL CONTINUITY CUT, COAG (Ω)	FLUID INGRESS CUT & COAG - P/F
1	0036 - 151363	6.0, 2.3	PASS
2	0036 - 151363	11.4, 19.2	PASS
3	0036 - 151363	3.5, 9.7	PASS
4	0036 - 151363	1.5, 4.1	PASS
5	0036 - 151363	11.2, 8.4	PASS
6	0036 - 151363	7.3, 8.3	PASS
7	0036 - 151363	3.4, 8.7	PASS
8	0036 - 151363	4.3, 13.7	PASS
9	0036 - 151363	5.7, 8.1	PASS
10	0036 - 151363	17.1, 15.4	PASS
11	0036 - 151363	3.3, 9.6	PASS
12	0036 - 151363	3.0, 2.6	PASS
13	0036 - 151363	3.5, 2.8	PASS
14	0036 - 151363	4.9, 12.0	PASS
15	0036 - 151363	3.9, 5.3	PASS
16	0036 - 151363	7.7, 5.4	PASS
17	0036 - 151363	2.1, 2.2	PASS
18	0036 - 151363	3.7, 2.8	PASS
19	0036 - 151363	3.7, 13.9	PASS
20	0036 - 151363	7.1, 6.4	PASS
21	0036 - 151363	1.6, 29.8	PASS
22	0036 - 151363	2.5, 1.5	PASS
23	0036 - 151363	5.9, 2.6	PASS
24	0036 - 151363	5.8, 3.6	PASS
25	0036 - 151363	3.2, 16.9	PASS
26	0036 - 151363	5.4, 8.2	PASS
27	0036 - 151363	2.1, 10.9	PASS
28	0036 - 151363	2.5, 6.3	PASS
29	0036 - 151363	5.3, 24.3	PASS
30	0036 - 151363	2.5, 7.9	PASS

10/19/2015
PV

CALIBRATION INFORMATION	
Multimeter *Fluke 79 Series II Multimeter*	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Oscilloscope *Tektronix TDS 3012B*	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/12/2015
Calibration Due:	10/31/2016
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/20/2015
Calibration Due:	10/20/2016
Waveform/Function Generator *BK Precision 4084AWG*	
Serial Number:	40849136407060000
Megadyne Number:	01458
Calibration Date:	10/6/2015
Calibration Due:	10/6/2016

Paul Valpreda	10/19/2015
Operator Name(s)	Date Completed
Operator Signature	11/16/15 Date Completed

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Ingress of Fluids

Data Collection Form

Product Tested - ACE37H - 160868 EOx2

Sample	Configuration	INITIAL CONTINUITY CUT, COAG (Ω)	FLUID INGRESS CUT & COAG - P/F
1	ACE37H - 160868	1.6, 1.6	PASS
2	ACE37H - 160868	1.6, 1.4	PASS
3	ACE37H - 160868	1.7, 1.7	PASS
4	ACE37H - 160868	1.6, 1.5	PASS
5	ACE37H - 160868	1.8, 1.6	PASS
6	ACE37H - 160868	1.8, 1.6	PASS
7	ACE37H - 160868	1.8, 2.8	PASS
8	ACE37H - 160868	1.5, 1.7	PASS
9	ACE37H - 160868	6.2, 2.2	PASS
10	ACE37H - 160868	2.0, 2.0	PASS
11	ACE37H - 160868	1.9, 2.1	PASS
12	ACE37H - 160868	3.2, 1.8	PASS
13	ACE37H - 160868	3.1, 10.0	PASS
14	ACE37H - 160868	4.0, 3.8	PASS
15	ACE37H - 160868	2.7, 6.3	PASS
16	ACE37H - 160868	1.8, 1.8	PASS
17	ACE37H - 160868	1.9, 2.3	PASS
18	ACE37H - 160868	1.6, 1.6	PASS
19	ACE37H - 160868	2.9, 1.6	PASS
20	ACE37H - 160868	1.8, 6.7	PASS
21	ACE37H - 160868	1.9, 7.4	PASS
22	ACE37H - 160868	1.7, 2.3	PASS
23	ACE37H - 160868	7.7, 3.0	PASS
24	ACE37H - 160868	2.4, 2.4	PASS
25	ACE37H - 160868	1.5, 1.6	PASS
26	ACE37H - 160868	1.4, 1.4	PASS
27	ACE37H - 160868	1.5, 2.6	PASS
28	ACE37H - 160868	3.2, 2.0	PASS
29	ACE37H - 160868	2.2, 1.6	PASS
30	ACE37H - 160868	2.0, 1.5	PASS

No failures were observed - PV

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True RMS Multimeter	
Serial Number:	33660168
Megadyne Number:	01507
Calibration Date:	1/29/2016
Calibration Due:	1/31/2017
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/12/2015
Calibration Due:	10/31/2016
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/25/2016
Calibration Due:	1/31/2017
Waveform/Function Generator	
BK Precision 4084AWG	
Serial Number:	40849136407060000
Megadyne Number:	01458
Calibration Date:	10/20/2015
Calibration Due:	10/20/2016

Paul Valpreda – PV
Operator Name(s)

3/28/2016
Date Completed

Engineer Signature

3/28/2016
Date

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Ingress of Fluids

Data Collection Form

Product Tested - ACE37H - 151361 EOx2

Sample	Configuration	INITIAL CONTINUITY CUT, COAG (Ω)	FLUID INGRESS CUT & COAG - P/F
1	ACE37H - 151361	3.8, 15.5	PASS
2	ACE37H - 151361	15.5, 6.5	PASS
3	ACE37H - 151361	2.7, 16.5	PASS
4	ACE37H - 151361	2.0, 19.5	PASS
5	ACE37H - 151361	5.5, 12.6	PASS
6	ACE37H - 151361	8.5, 7.5	PASS
7	ACE37H - 151361	5.5, 1.5	PASS
8	ACE37H - 151361	20.4, 30.9	PASS
9	ACE37H - 151361	2.5, 2.6	FAIL
10	ACE37H - 151361	8.1, 6.2	PASS
11	ACE37H - 151361	6.4, 1.3	PASS
12	ACE37H - 151361	10.1, 6.9	PASS
13	ACE37H - 151361	3.5, 6.5	PASS
14	ACE37H - 151361	12.5, 21.5	PASS
15	ACE37H - 151361	3.4, 12.9	PASS
16	ACE37H - 151361	9.4, 6.8	PASS
17	ACE37H - 151361	2.3, 4.2	PASS
18	ACE37H - 151361	3.3, 2.4	PASS
19	ACE37H - 151361	7.7, 2.4	PASS
20	ACE37H - 151361	20.4, 3.1	PASS
21	ACE37H - 151361	2.5, 20.6	PASS
22	ACE37H - 151361	2.3, 4.4	PASS
23	ACE37H - 151361	1.6, 1.5	PASS
24	ACE37H - 151361	2.5, 2.9	PASS
25	ACE37H - 151361	26.0, 2.7	PASS
26	ACE37H - 151361	4.7, 5.6	PASS
27	ACE37H - 151361	4.9, 6.1	PASS
28	ACE37H - 151361	1.2, 4.4	PASS
29	ACE37H - 151361	27.3, 21.4	PASS
30	ACE37H - 151361	4.9, 1.2	PASS

10/21/2015
PV

CALIBRATION INFORMATION	
Multimeter *Fluke 79 Series II Multimeter*	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016
Oscilloscope *Tektronix TDS 3012B*	
Serial Number:	B010635
Megadyne Number:	01142
Calibration Date:	10/12/2015
Calibration Due:	10/31/2016
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/14/2015
Calibration Due:	1/14/2016
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	10/20/2015
Calibration Due:	10/20/2016
Waveform/Function Generator *BK Precision 4084AWG*	
Serial Number:	40849136407060000
Megadyne Number:	01458
Calibration Date:	10/6/2015
Calibration Due:	10/6/2016

Paul Valpreda	10/21/2015
Operator Name(s)	Date Completed
	11/16/15
Operator Signature	Date Completed

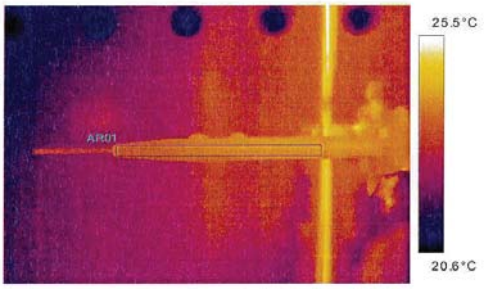
APPENDIX V – IEC 60601-1 TEMPERATURE TEST

2016-01-28

Button - Cut 300W - Pre

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	20.7	25.5	4.8		
AR01	22.2	22.8	0.7	22.5	0.2

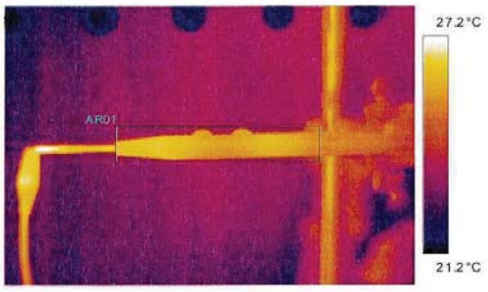
Image	
Name	Value
Date	10/7/2015
Time	12:44:02 PM
File name	3a-b-pure cut-300 w.jpg



Button - Cut 300W - Post

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21.2	27.2	6		
AR01	22.3	24.9	2.6	23.5	0.8

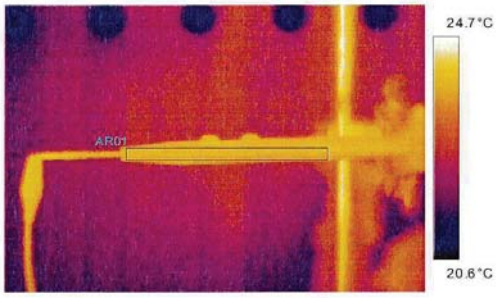
Image	
Name	Value
Date	10/7/2015
Time	1:45:58 PM
File name	3b-b-pure cut-300 w.jpg



Button - Coag 120W - Pre

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21.2	24.2	2.9		
AR01	22.6	23.2	0.6	23	0.1

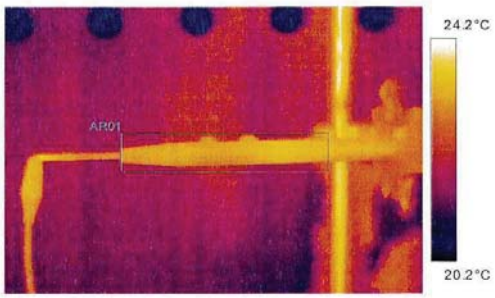
Image	
Name	Value
Date	10/8/2015
Time	5:25:17 AM
File name	4a-b-std coag-120 w.jpg



Button - Coag 120W - Post

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	20.8	23.7	3		
AR01	21.6	22.7	1.1	22.1	0.3

Image	
Name	Value
Date	10/8/2015
Time	6:30:20 AM
File name	4b-b-std coag-120 w.jpg



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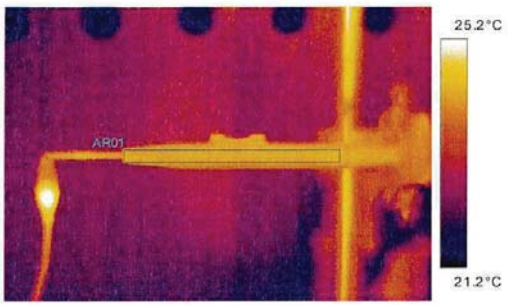
2016-01-28

Rocker - Cut 300W - Pre

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21.5	25	3.5		
AR01	22.9	23.3	0.4	23.2	0.1

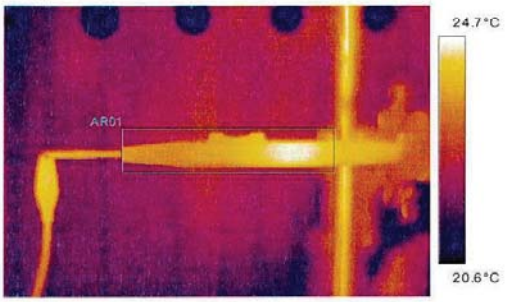
Image	
Name	Value
Date	10/7/2015
Time	9:42:43 AM
File name	1a-r-pure cut-300 w.jpg



Rocker - Cut 300W - Post

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21	24.4	3.4		
AR01	21.9	24.4	2.5	22.8	0.7

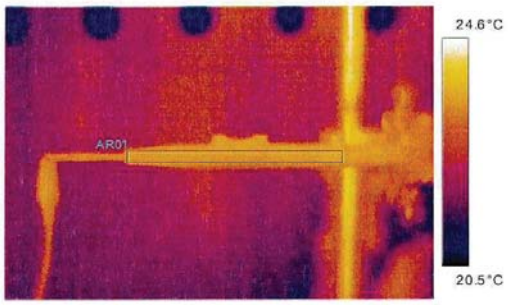
Image	
Name	Value
Date	10/7/2015
Time	10:51:04 AM
File name	1b-r-pure cut-300 w.jpg



Rocker - coag 120W - Pre

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21.1	24	2.9		
AR01	22.2	22.7	0.5	22.5	0.1

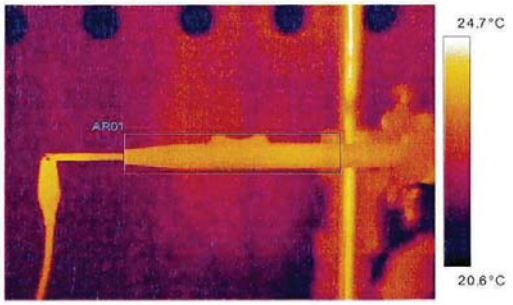
Image	
Name	Value
Date	10/7/2015
Time	11:27:26 AM
File name	2a-r-std coag-120 w.jpg



Rocker - coag 120W - Post

Analysis Label	Min	Max	Max - Min	Avg	Stdev
Image	21.1	24.4	3.4		
AR01	21.8	22.9	1.2	22.4	0.3

Image	
Name	Value
Date	10/7/2015
Time	12:28:43 PM
File name	2b-r-std coag-120 w.jpg



APPENDIX VI – HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

PENCIL		
ROTATION ON 0036 - 151363, ISOS2 - 200 CYCLES		
Sample Number	Rotation CUT, COAG Ω P/F	Configuration
1	1.9, 4.6 - PASS	0036 - 151363
2	3.5, 2.5 - PASS	0036 - 151363
3	1.6, 5.9 - PASS	0036 - 151363
4	2.1, 5.9 - PASS	0036 - 151363
5	1.5, 8.7 - PASS	0036 - 151363
6	3.5, 3.9 - PASS	0036 - 151363
7	8.9, 2.6 - PASS	0036 - 151363
8	6.0, 1.8 - PASS	0036 - 151363
9	2.7, 21.0 - PASS	0036 - 151363
10	1.8, 2.0 - PASS	0036 - 151363
11	3.1, 18.6 - PASS	0036 - 151363
12	2.2, 2.6 - PASS	0036 - 151363
13	3.6, 6.1 - PASS	0036 - 151363
14	3.0, 3.5 - PASS	0036 - 151363
15	6.1, 4.3 - PASS	0036 - 151363
16	2.3, 1.9 - PASS	0036 - 151363
17	1.6, 1.9 - PASS	0036 - 151363
18	2.6, 9.1 - PASS	0036 - 151363
19	2.4, 1.8 - PASS	0036 - 151363
20	1.9, 9.0 - PASS	0036 - 151363
21	1.4, 7.1 - PASS	0036 - 151363
22	1.7, 1.5 - PASS	0036 - 151363
23	5.1, 2.2 - PASS	0036 - 151363
24	2.5, 13.6 - PASS	0036 - 151363
25	2.8, 6.1 - PASS	0036 - 151363
26	1.4, 4.0 - PASS	0036 - 151363
27	2.2, 2.7 - PASS	0036 - 151363
28	2.2, 2.2 - PASS	0036 - 151363
29	4.6, 6.9 - PASS	0036 - 151363
30	1.4, 1.8 - PASS	0036 - 151363
Mass: 80 g		Date: 10/6/2015
Resistance Pass Value (Ω): <50		

CALIBRATION INFORMATION	
Brass Weights	
N/A	
Serial Number	56206
Megadyne Number	1085
Calibration Date	1/30/2012
Calibration Due	1/31/2022

Paul Valpreda — 10/6/2015
OPERATOR NAME — DATE

11/16/15
OPERATOR SIGNATURE — DATE

PENCIL		
ROTATION ON ACE37H - 151361, ISOS2 - 200 CYCLES		
Sample Number	Rotation CUT, COAG Ω P/F	Configuration
1	7.8, 3.3 - PASS	ACE37H - 151361
2	2.4, 1.5 - PASS	ACE37H - 151361
3	4.1, 1.2 - PASS	ACE37H - 151361
4	1.8, 5.5 - PASS	ACE37H - 151361
5	1.7, 1.5 - PASS	ACE37H - 151361
6	2.9, 1.4 - PASS	ACE37H - 151361
7	2.3, 1.5 - PASS	ACE37H - 151361
8	6.5, 16.7 - PASS	ACE37H - 151361
9	5.0, 2.3 - PASS	ACE37H - 151361
10	1.7, 4.9 - PASS	ACE37H - 151361
11	1.2, 1.1 - PASS	ACE37H - 151361
12	1.2, 9.2 - PASS	ACE37H - 151361
13	2.0, 1.9 - PASS	ACE37H - 151361
14	2.9, 6.4 - PASS	ACE37H - 151361
15	2.7, 3.2 - PASS	ACE37H - 151361
16	1.4, 1.4 - PASS	ACE37H - 151361
17	1.9, 6.3 - PASS	ACE37H - 151361
18	3.9, 2.2 - PASS	ACE37H - 151361
19	1.7, 1.0 - PASS	ACE37H - 151361
20	1.6, 4.2 - PASS	ACE37H - 151361
21	1.6, 1.7 - PASS	ACE37H - 151361
22	2.9, 1.9 - PASS	ACE37H - 151361
23	1.4, 4.5 - PASS	ACE37H - 151361
24	10.8, 1.6 - PASS	ACE37H - 151361
25	2.4, 6.9 - PASS	ACE37H - 151361
26	3.9, 1.5 - PASS	ACE37H - 151361
27	2.0, 2.1 - PASS	ACE37H - 151361
28	2.0, 2.7 - PASS	ACE37H - 151361
29	2.1, 2.0 - PASS	ACE37H - 151361
30	1.5, 1.2 - PASS	ACE37H - 151361
Mass: 80 g		Date: 10/2/2015
Resistance Pass Value (Ω): <50		

CALIBRATION INFORMATION	
Brass Weights	
N/A	
Serial Number	56206
Megadyne Number	1085
Calibration Date	1/30/2012
Calibration Due	1/31/2022

Paul Valpreda — 10/2/2015
OPERATOR NAME — DATE

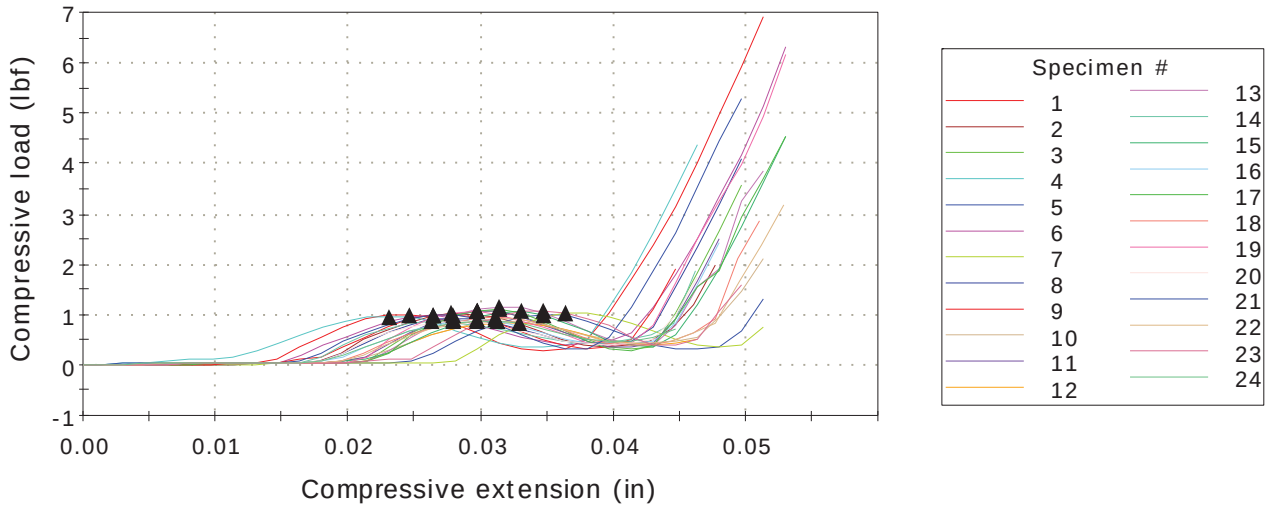
11/15/16
OPERATOR SIGNATURE — DATE

APPENDIX VII – ACTIVATION FORCE TESTING

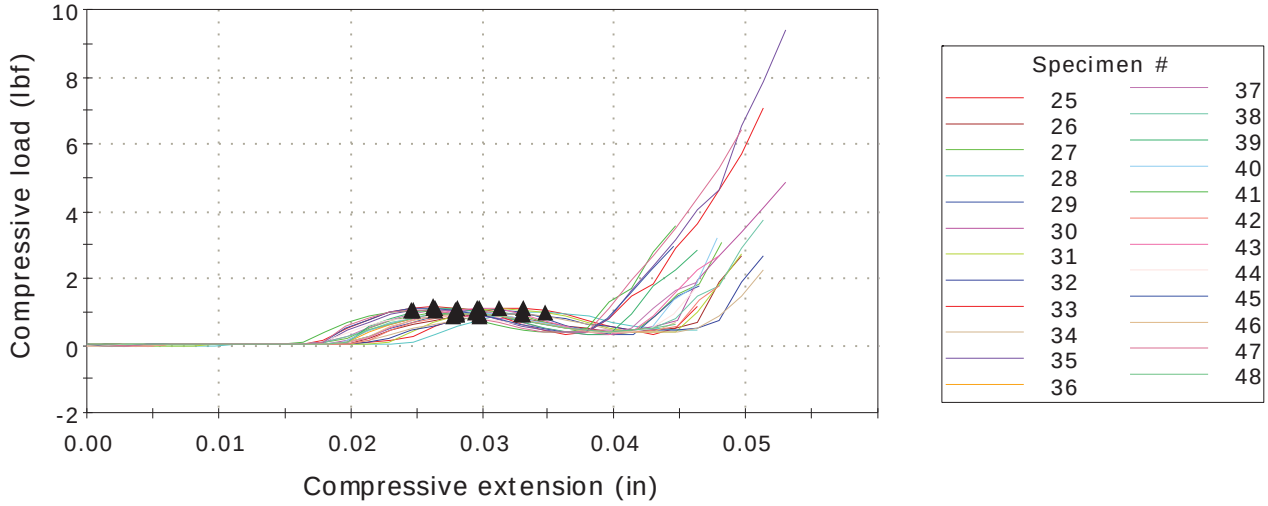
Wednesday, October 07, 2015

Button Force on ISOS2 0036 - 151363.is_comp

Specimen 1 to 24



Specimen 25 to 48



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
	ISOS2 Functional Verification After EO Exposure	Revision: 001
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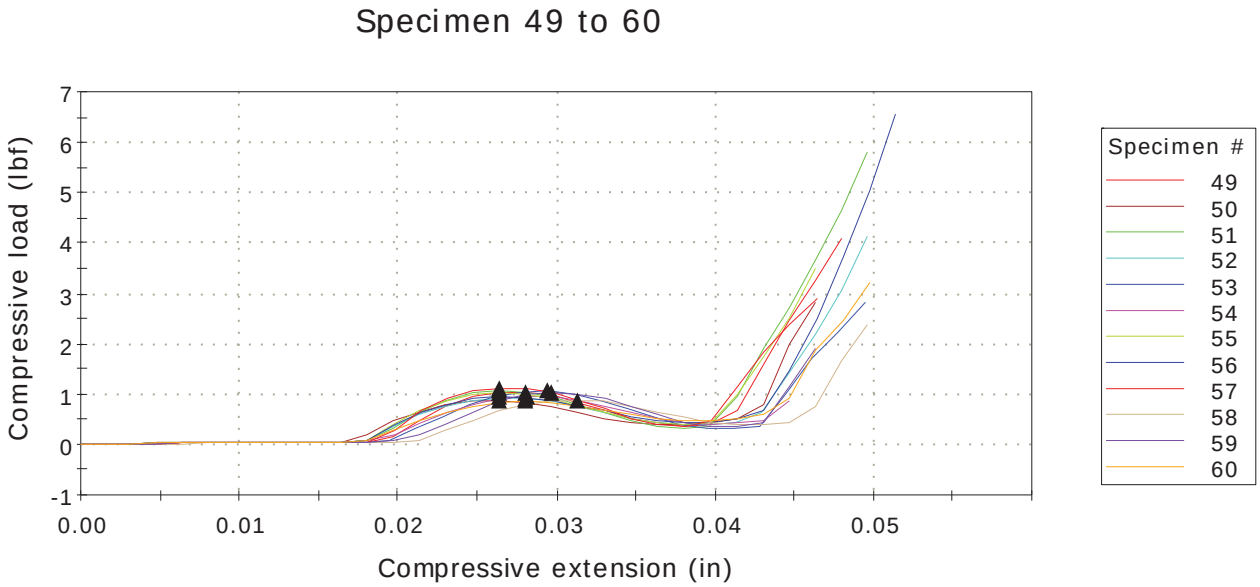

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
1	1.00349	CUT	Sample 1
2	1.01155	COAG	Sample 1
3	1.07061	CUT	Sample 2
4	0.95786	COAG	Sample 2
5	1.00618	CUT	Sample 3
6	0.97719	COAG	Sample 3
7	1.02605	CUT	Sample 4
8	0.92108	COAG	Sample 4
9	0.99974	CUT	Sample 5
10	0.86980	COAG	Sample 5
11	1.06470	CUT	Sample 6
12	0.84162	COAG	Sample 6
13	1.16349	CUT	Sample 7
14	0.85370	COAG	Sample 7
15	1.05772	CUT	Sample 8
16	0.90282	COAG	Sample 8
17	1.10121	CUT	Sample 9
18	0.94175	COAG	Sample 9

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
19	1.07168	CUT	Sample 10
20	0.87329	COAG	Sample 10
21	0.98417	CUT	Sample 11
22	0.92162	COAG	Sample 11
23	1.07544	CUT	Sample 12
24	0.87947	COAG	Sample 12
25	1.11571	CUT	Sample 13
26	0.88860	COAG	Sample 13
27	1.07544	CUT	Sample 14
28	0.99813	COAG	Sample 14
29	1.08242	CUT	Sample 15
30	0.90121	COAG	Sample 15
31	1.08672	CUT	Sample 16
32	0.91652	COAG	Sample 16
33	1.15544	CUT	Sample 17
34	0.91759	COAG	Sample 17
35	1.06417	CUT	Sample 18
36	0.95303	COAG	Sample 18
37	1.06524	CUT	Sample 19
38	0.95813	COAG	Sample 19
39	1.07652	CUT	Sample 20
40	1.00833	COAG	Sample 20
41	1.04860	CUT	Sample 21
42	0.93209	COAG	Sample 21
43	1.11732	CUT	Sample 22
44	0.88457	COAG	Sample 22
45	1.12806	CUT	Sample 23
46	0.92698	COAG	Sample 23
47	1.05504	CUT	Sample 24
48	0.94631	COAG	Sample 24
49	1.04162	CUT	Sample 25
50	0.87437	COAG	Sample 25
51	1.07598	CUT	Sample 26
52	0.92027	COAG	Sample 26
53	1.06739	CUT	Sample 27
54	0.95410	COAG	Sample 27
55	1.04430	CUT	Sample 28

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
56	0.94927	COAG	Sample 28
57	1.11786	CUT	Sample 29
58	0.88860	COAG	Sample 29
59	1.03356	CUT	Sample 30
60	0.85316	COAG	Sample 30
Maximum	1.16349		
Minimum	0.84162		
Mean	0.99498		
Standard Deviation	0.09		

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
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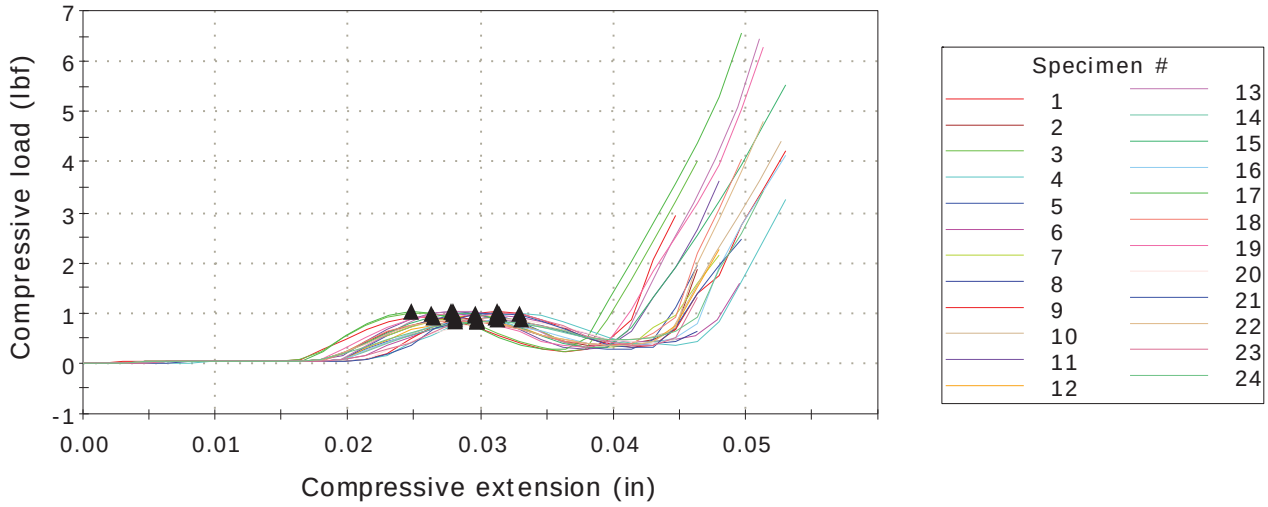
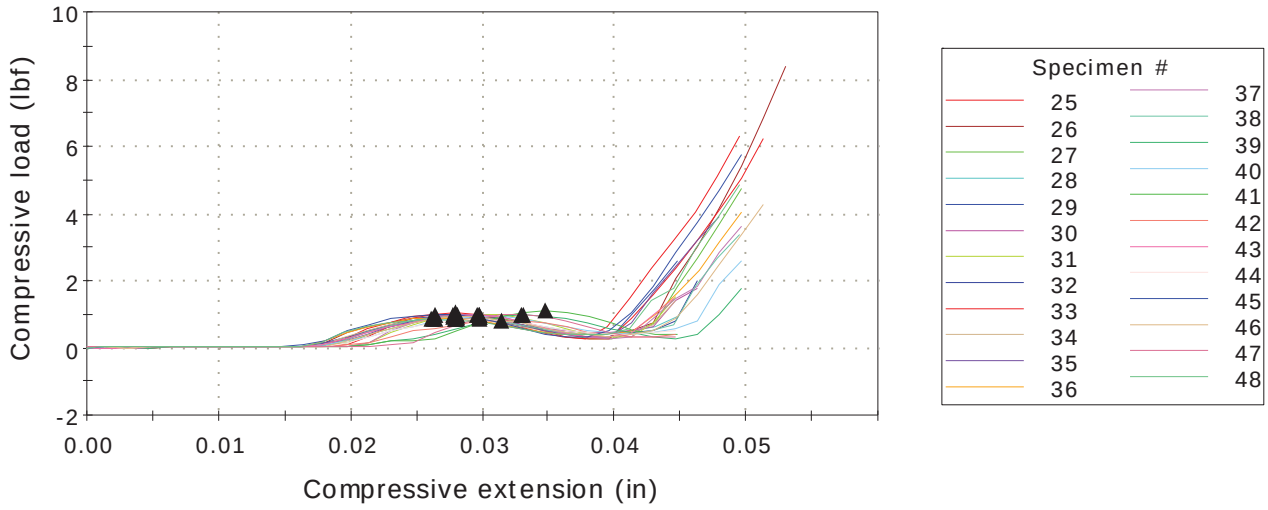
Wednesday, October 14, 2015 Button Force on ISOS2 0036 - 151363 post 500.is_comp

Specimen 1 to 24



Specimen 25 to 48



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	ISOS2 Functional Verification After EO Exposure	Revision: 001
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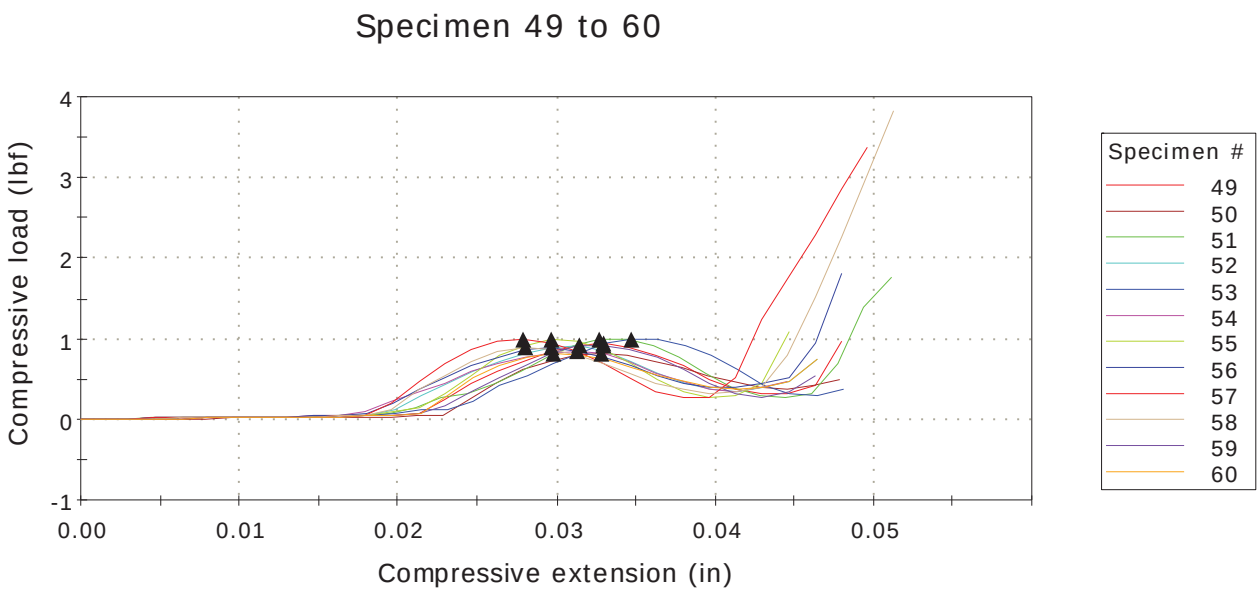

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
1	0.91303	CUT	Sample 1, post activation
2	0.89584	COAG	Sample 1, post activation
3	0.99490	CUT	Sample 2, post activation
4	0.98900	COAG	Sample 2, post activation
5	0.98631	CUT	Sample 3, post activation
6	0.93987	COAG	Sample 3, post activation
7	0.93396	CUT	Sample 4, post activation
8	0.86900	COAG	Sample 4, post activation
9	1.02443	CUT	Sample 5, post activation
10	0.89450	COAG	Sample 5, post activation
11	1.02014	CUT	Sample 6, post activation
12	0.84698	COAG	Sample 6, post activation
13	1.04860	CUT	Sample 7, post activation
14	0.81772	COAG	Sample 7, post activation
15	0.98148	CUT	Sample 8, post activation
16	0.86819	COAG	Sample 8, post activation
17	1.01692	CUT	Sample 9, post activation
18	0.84376	COAG	Sample 9, post activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
19	0.98524	CUT	Sample 10, post activation
20	0.86766	COAG	Sample 10, post activation
21	0.98954	CUT	Sample 11, post activation
22	0.87141	COAG	Sample 11, post activation
23	0.98578	CUT	Sample 12, post activation
24	0.84430	COAG	Sample 12, post activation
25	1.00242	CUT	Sample 13, post activation
26	0.89450	COAG	Sample 13, post activation
27	0.93745	CUT	Sample 14, post activation
28	0.93558	COAG	Sample 14, post activation
29	0.96645	CUT	Sample 15, post activation
30	0.88725	COAG	Sample 15, post activation
31	1.01477	CUT	Sample 16, post activation
32	0.87517	COAG	Sample 16, post activation
33	1.03303	CUT	Sample 17, post activation
34	0.87652	COAG	Sample 17, post activation
35	1.00618	CUT	Sample 18, post activation
36	0.87571	COAG	Sample 18, post activation
37	0.99974	CUT	Sample 19, post activation
38	0.93101	COAG	Sample 19, post activation
39	0.95678	CUT	Sample 20, post activation
40	0.94229	COAG	Sample 20, post activation
41	1.07920	CUT	Sample 21, post activation
42	0.83007	COAG	Sample 21, post activation
43	0.96430	CUT	Sample 22, post activation
44	0.84967	COAG	Sample 22, post activation
45	0.98524	CUT	Sample 23, post activation
46	0.90443	COAG	Sample 23, post activation
47	0.99813	CUT	Sample 24, post activation
48	0.84752	COAG	Sample 24, post activation
49	0.93182	CUT	Sample 25, post activation
50	0.82202	COAG	Sample 25, post activation
51	0.99383	CUT	Sample 26, post activation
52	0.90309	COAG	Sample 26, post activation
53	1.00188	CUT	Sample 27, post activation
54	0.83947	COAG	Sample 27, post activation
55	0.98685	CUT	Sample 28, post activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
56	0.88349	COAG	Sample 28, post activation
57	0.98900	CUT	Sample 29, post activation
58	0.89611	COAG	Sample 29, post activation
59	0.92537	CUT	Sample 30, post activation
60	0.80376	COAG	Sample 30, post activation
Maximum	1.07920		
Minimum	0.80376		
Mean	0.93331		
Standard Deviation	0.07		

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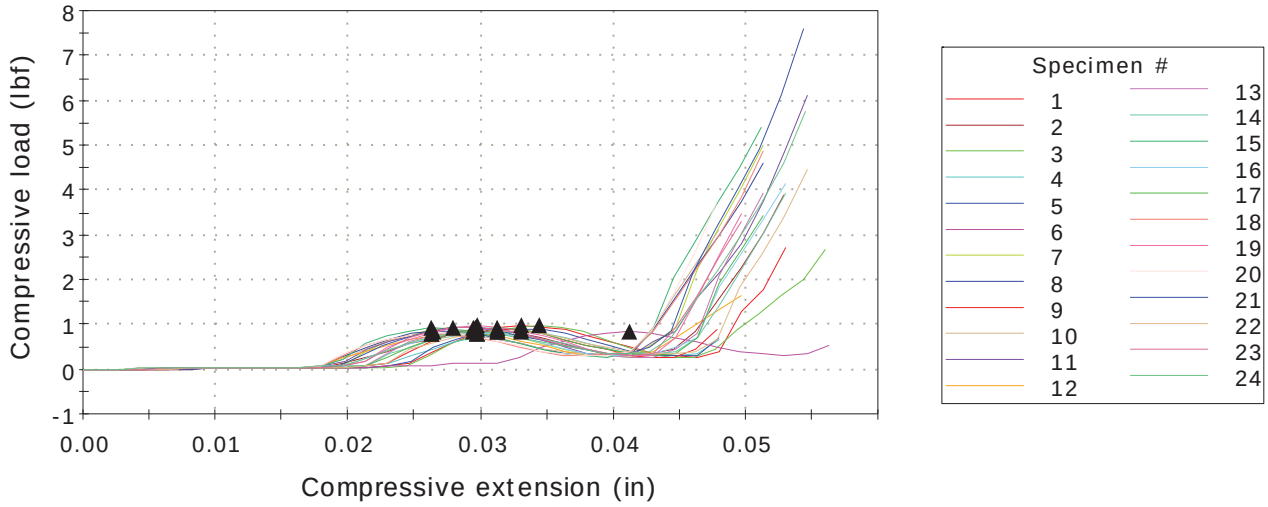
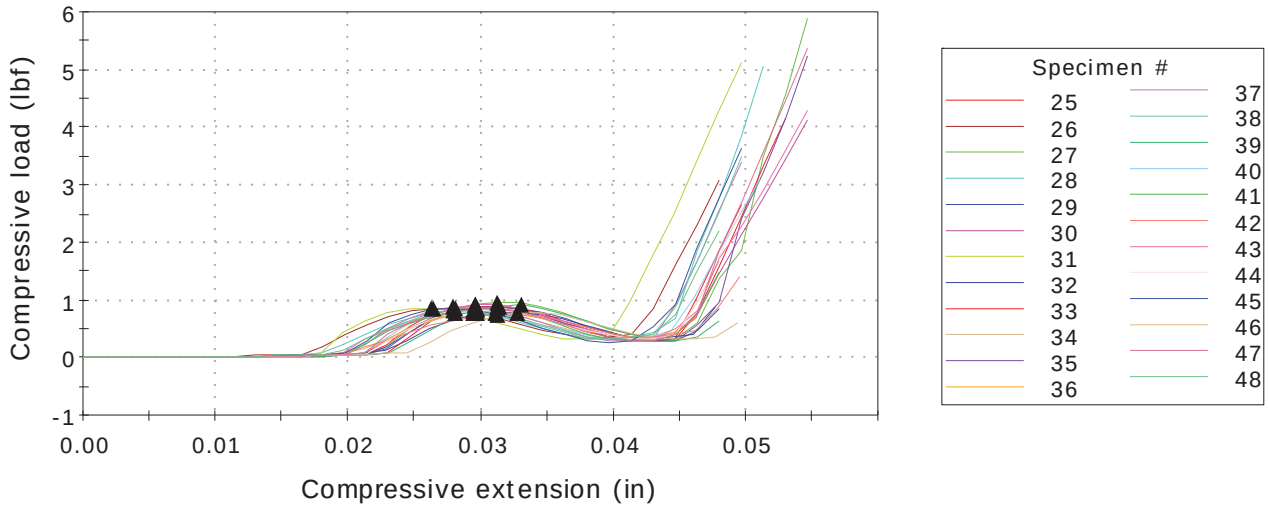
Thursday, October 08, 2015

Button Force on ISOS2 ACE37H - 151361.is_comp

Specimen 1 to 24



Specimen 25 to 48



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
	ISOS2 Functional Verification After EO Exposure	Revision: 001
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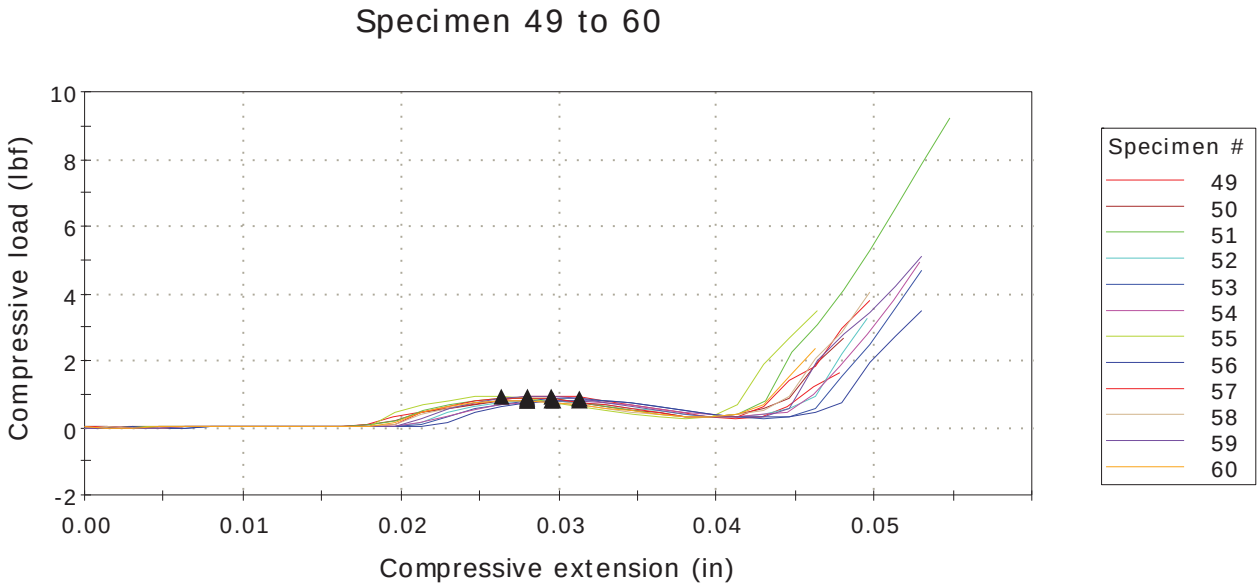

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
1	0.95383	CUT	Sample 1, pre-activation
2	0.83893	COAG	Sample 1, pre-activation
3	0.94900	CUT	Sample 2, pre-activation
4	0.82121	COAG	Sample 2, pre-activation
5	0.89692	CUT	Sample 3, pre-activation
6	0.83222	COAG	Sample 3, pre-activation
7	0.91947	CUT	Sample 4, pre-activation
8	0.82846	COAG	Sample 4, pre-activation
9	0.89719	CUT	Sample 5, pre-activation
10	0.78121	COAG	Sample 5, pre-activation
11	0.93692	CUT	Sample 6, pre-activation
12	0.78256	COAG	Sample 6, pre-activation
13	0.87974	CUT	Sample 7, pre-activation
14	0.79678	COAG	Sample 7, pre-activation
15	0.91517	CUT	Sample 8, pre-activation
16	0.81155	COAG	Sample 8, pre-activation
17	0.90605	CUT	Sample 9, pre-activation
18	0.78658	COAG	Sample 9, pre-activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
19	0.95490	CUT	Sample 10, pre-activation
20	0.80215	COAG	Sample 10, pre-activation
21	0.91759	CUT	Sample 11, pre-activation
22	0.84027	COAG	Sample 11, pre-activation
23	0.92349	CUT	Sample 12, pre-activation
24	0.81799	COAG	Sample 12, pre-activation
25	0.90927	CUT	Sample 13, pre-activation
26	0.85262	COAG	Sample 13, pre-activation
27	0.95839	CUT	Sample 14, pre-activation
28	0.80215	COAG	Sample 14, pre-activation
29	0.89584	CUT	Sample 15, pre-activation
30	0.84564	COAG	Sample 15, pre-activation
31	0.85504	CUT	Sample 16, pre-activation
32	0.78631	COAG	Sample 16, pre-activation
33	0.89155	CUT	Sample 17, pre-activation
34	0.77074	COAG	Sample 17, pre-activation
35	0.88296	CUT	Sample 18, pre-activation
36	0.79490	COAG	Sample 18, pre-activation
37	0.86954	CUT	Sample 19, pre-activation
38	0.79088	COAG	Sample 19, pre-activation
39	0.90202	CUT	Sample 20, pre-activation
40	0.79303	COAG	Sample 20, pre-activation
41	0.84188	CUT	Sample 21, pre-activation
42	0.75705	COAG	Sample 21, pre-activation
43	0.90792	CUT	Sample 22, pre-activation
44	0.82417	COAG	Sample 22, pre-activation
45	0.85692	CUT	Sample 23, pre-activation
46	0.77235	COAG	Sample 23, pre-activation
47	0.85987	COAG	Sample 24, pre-activation
48	0.81799	COAG	Sample 24, pre-activation
49	0.92886	CUT	Sample 25, pre-activation
50	0.83303	COAG	Sample 25, pre-activation
51	0.88349	CUT	Sample 26, pre-activation
52	0.80537	COAG	Sample 26, pre-activation
53	0.88000	CUT	Sample 27, pre-activation
54	0.80886	COAG	Sample 27, pre-activation
55	0.90551	CUT	Sample 28, pre-activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
56	0.83329	COAG	Sample 28, pre-activation
57	0.87705	CUT	Sample 29, pre-activation
58	0.80054	COAG	Sample 29, pre-activation
59	0.90792	CUT	Sample 30, pre-activation
60	0.79839	COAG	Sample 30, pre-activation
Maximum	0.95839		
Minimum	0.75705		
Mean	0.85486		
Standard Deviation	0.05		

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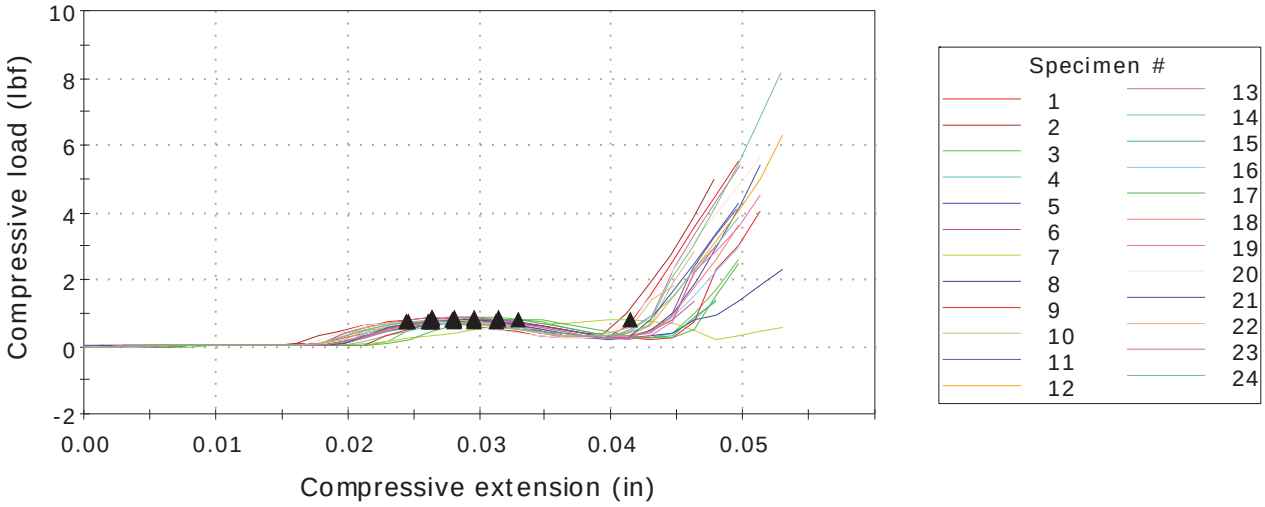
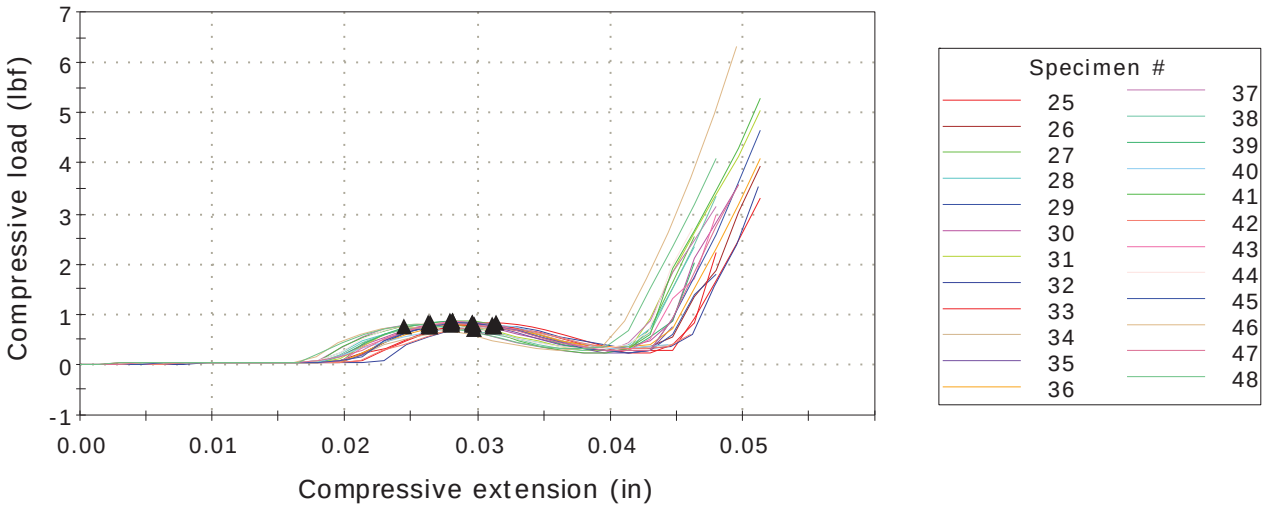
Wednesday, October 14, 2015 Button Force on ISOS2 ACE37H - 151361
post 500.is_comp

Specimen 1 to 24



Specimen 25 to 48



Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
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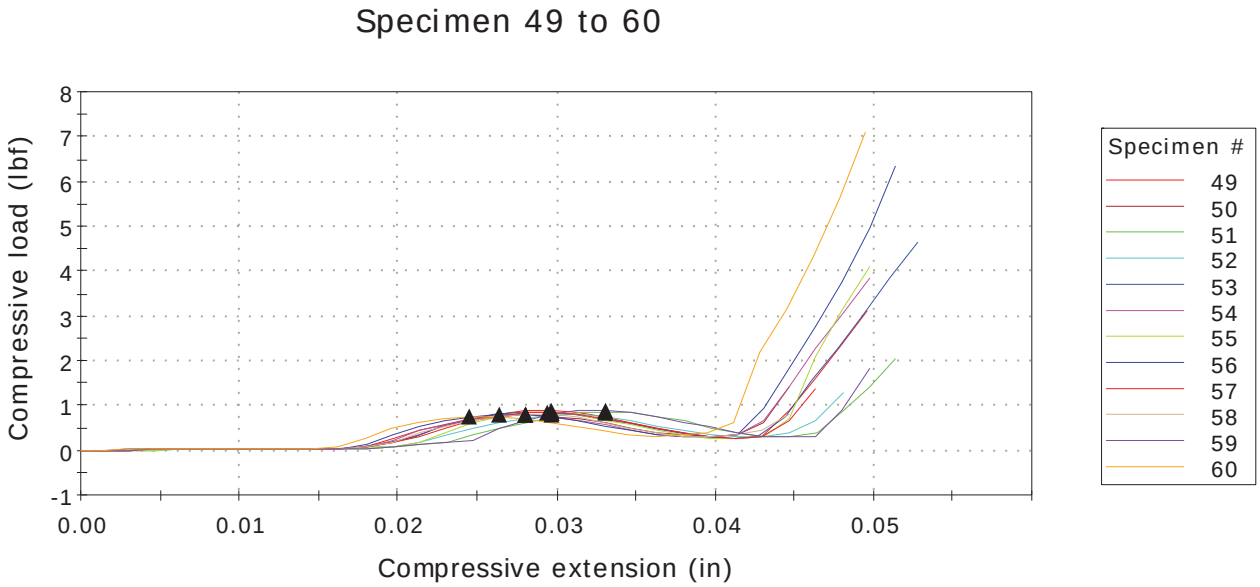

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
1	0.85235	CUT	Sample 1, post activation
2	0.76940	COAG	Sample 1, post activation
3	0.87705	CUT	Sample 2, post activation
4	0.75195	COAG	Sample 2, post activation
5	0.80242	CUT	Sample 3, post activation
6	0.76484	COAG	Sample 3, post activation
7	0.80081	CUT	Sample 4, post activation
8	0.76430	COAG	Sample 4, post activation
9	0.82658	CUT	Sample 5, post activation
10	0.72537	COAG	Sample 5, post activation
11	0.86470	CUT	Sample 6, post activation
12	0.75974	COAG	Sample 6, post activation
13	0.84457	CUT	Sample 7, post activation
14	0.75410	COAG	Sample 7, post activation
15	0.82524	CUT	Sample 8, post activation
16	0.77799	COAG	Sample 8, post activation
17	0.82658	CUT	Sample 9, post activation
18	0.77933	COAG	Sample 9, post activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
19	0.82363	CUT	Sample 10, post activation
20	0.75652	COAG	Sample 10, post activation
21	0.80698	CUT	Sample 11, post activation
22	0.80913	COAG	Sample 11, post activation
23	0.85209	CUT	Sample 12, post activation
24	0.77209	COAG	Sample 12, post activation
25	0.83141	CUT	Sample 13, post activation
26	0.80806	COAG	Sample 13, post activation
27	0.88484	CUT	Sample 14, post activation
28	0.76162	COAG	Sample 14, post activation
29	0.83490	CUT	Sample 15, post activation
30	0.80081	COAG	Sample 15, post activation
31	0.78658	CUT	Sample 16, post activation
32	0.76913	COAG	Sample 16, post activation
33	0.80564	CUT	Sample 17, post activation
34	0.72886	COAG	Sample 17, post activation
35	0.81826	CUT	Sample 18, post activation
36	0.79437	COAG	Sample 18, post activation
37	0.79195	CUT	Sample 19, post activation
38	0.74954	COAG	Sample 19, post activation
39	0.88484	CUT	Sample 20, post activation
40	0.77584	COAG	Sample 20, post activation
41	0.82309	CUT	Sample 21, post activation
42	0.75544	COAG	Sample 21, post activation
43	0.85316	CUT	Sample 22, post activation
44	0.81128	COAG	Sample 22, post activation
45	0.82470	CUT	Sample 23, post activation
46	0.74148	COAG	Sample 23, post activation
47	0.81933	CUT	Sample 24, post activation
48	0.77504	COAG	Sample 24, post activation
49	0.88860	CUT	Sample 25, post activation
50	0.78792	COAG	Sample 25, post activation
51	0.84135	CUT	Sample 26, post activation
52	0.77182	COAG	Sample 26, post activation
53	0.85370	CUT	Sample 27, post activation
54	0.77209	COAG	Sample 27, post activation
55	0.82631	CUT	Sample 28, post activation

	Compressive load at Preset Point (Cursor) (lbf)	Button Type	Note
56	0.80108	COAG	Sample 28, post activation
57	0.84752	CUT	Sample 29, post activation
58	0.78578	COAG	Sample 29, post activation
59	0.88698	CUT	Sample 30, post activation
60	0.76323	COAG	Sample 30, post activation
Maximum	0.88860		
Minimum	0.72537		
Mean	0.80407		
Standard Deviation	0.04		

APPENDIX VIII – ACTIVATION OVER TIME

Pencil Dome Switch Activation Force Test

Product Tested - 0036 - 151363

Data Collection Form

Sample Number	Initial Continuity (Ω) CUT, COAG	Initial Force CUT	Initial Force COAG	Final Force CUT	Final Force COAG	Final Continuity (Ω) CUT, COAG
1	1.9, 4.6	455.17541	458.83136	414.14344	406.34619	6.0, 2.3 - PASS
2	3.5, 2.5	485.62053	434.47799	451.27905	448.60285	11.4, 19.2 - PASS
3	1.6, 5.9	456.39557	443.24593	447.38269	426.31786	3.5, 9.7 - PASS
4	2.1, 5.9	465.40845	417.79486	423.63713	394.17177	1.5, 4.1 - PASS
5	1.5, 8.7	453.47443	394.53464	464.67363	405.73837	11.2, 8.4 - PASS
6	3.5, 3.9	482.93979	381.75241	462.72772	384.18366	7.3, 8.3 - PASS
7	8.9, 2.6	527.75018	387.23180	475.63696	370.91155	3.4, 8.7 - PASS
8	6.0, 1.8	479.77372	409.51226	445.19184	393.80436	4.3, 13.7 - PASS
9	2.7, 21.0	499.50045	427.17061	461.26715	382.72310	5.7, 8.1 - PASS
10	1.8, 2.0	486.10587	396.11768	446.89735	393.56395	17.1, 15.4 - PASS
11	3.1, 18.6	446.41200	418.03980	448.84779	395.26493	3.3, 9.6 - PASS
12	2.2, 2.6	487.81138	398.92088	447.14228	382.96804	3.0, 2.6 - PASS
13	3.6, 6.1	506.07754	403.06218	454.69006	405.73837	3.5, 2.8 - PASS
14	3.0, 3.5	487.81138	452.74415	425.22017	424.37195	4.9, 12.0 - PASS
15	6.1, 4.3	490.97745	408.78198	438.37434	402.44983	3.9, 5.3 - PASS
16	2.3, 1.9	492.92790	415.72648	460.29193	396.97043	7.7, 5.4 - PASS
17	1.6, 1.9	524.09877	416.21182	468.57452	397.58278	2.1, 2.2 - PASS
18	2.6, 9.1	482.69939	432.28713	456.39557	397.21537	3.7, 2.8 - PASS
19	2.4, 1.8	483.18473	434.60046	453.47443	422.29903	3.7, 13.9 - PASS
20	1.9, 9.0	488.30126	457.37079	433.98811	427.41555	7.1, 6.4 - PASS
21	1.4, 7.1	475.63696	422.78891	489.51688	376.51342	1.6, 29.8 - PASS
22	1.7, 1.5	506.80783	401.23420	437.39912	385.40383	2.5, 1.5 - PASS
23	5.1, 2.2	511.67941	420.47105	446.89735	410.24255	5.9, 2.6 - PASS
24	2.5, 13.6	478.55809	429.23899	452.74415	384.42860	5.8, 3.6 - PASS
25	2.8, 6.1	472.47088	396.60756	422.66644	372.86200	3.2, 16.9 - PASS
26	1.4, 4.0	488.05632	417.42745	450.79370	409.63473	5.4, 8.2 - PASS
27	2.2, 2.7	484.15996	432.77248	454.44512	380.77719	2.1, 10.9 - PASS
28	2.2, 2.2	473.68651	430.58163	447.62763	400.74432	2.5, 6.3 - PASS
29	4.6, 6.9	507.05276	403.06218	448.60285	406.46866	5.3, 24.3 - PASS
30	1.4, 1.8	468.81493	386.98687	419.74077	364.57940	2.5, 7.9 - PASS
	MAX	527.75018	458.83136	489.51688	448.60285	
	MIN	446.41200	381.75241	414.14344	364.57940	
	AVG	484.97899	417.65288	448.34234	398.34315	
	SD	19.57490327	20.67146154	16.68182837	18.91835671	
	Cpk	3.661508178	2.703451551	3.963241414	2.613742781	

Calibration Information:

Instron	
System ID Number	4464C2820
Megadyne Number	01028
Calibration Date	5/1/2015
Calibration Due	5/1/2016

Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016

PAUL VALPREDA — Operator Name
Paul Valpreda — Operator Signature
1-26-2016 — Date

Christy Crook — Engineer Name
Operator Signature
1/25/2016 — Date

Pencil Dome Switch Activation Force Test

Product Tested - ACE37H - 151361

Data Collection Form

Sample Number	Initial Continuity (Ω) CUT, COAG	Initial Force CUT	Initial Force COAG	Final Force CUT	Final Force COAG	Final Continuity (Ω) CUT, COAG
1	7.8, 3.3	432.65001	380.53225	386.61946	348.99397	3.8, 15.5 - PASS
2	2.4, 1.5	430.45916	372.49459	397.82319	341.07878	15.5, 6.5 - PASS
3	4.1, 1.2	406.83607	377.48864	363.97159	346.92559	2.7, 16.5 - PASS
4	1.8, 5.5	417.06458	375.78313	363.24130	346.68065	2.0, 19.5 - PASS
5	1.7, 1.5	406.95854	354.35089	374.93038	329.02230	5.5, 12.6 - PASS
6	2.9, 1.4	424.97976	354.96324	392.22132	344.61227	8.5, 7.5 - PASS
7	2.3, 1.5	399.04335	361.41333	383.09051	342.05401	5.5, 1.5 - PASS
8	6.5, 16.7	415.11413	368.11289	374.32257	352.89033	20.4, 30.9 - PASS
9	5.0, 2.3	410.97737	356.78669	374.93038	353.49814	2.5, 2.6 - PASS
10	1.7, 4.9	433.13535	363.84912	373.59228	343.15170	8.1, 6.2 - PASS
11	1.2, 1.1	416.21182	381.14006	366.03997	367.01519	6.4, 1.3 - PASS
12	1.2, 9.2	418.88802	371.03402	386.50152	350.21413	10.1, 6.9 - PASS
13	2.0, 1.9	412.43793	386.74193	377.12123	366.52985	3.5, 6.5 - PASS
14	2.9, 6.4	434.71839	363.84912	401.35667	345.46502	12.5, 21.5 - PASS
15	2.7, 3.2	406.34619	383.57585	378.70427	363.24130	3.4, 12.9 - PASS
16	1.4, 1.4	387.83962	356.66422	356.78669	348.87150	9.4. 6.8 - PASS
17	1.9, 6.3	404.40028	349.60178	365.43216	330.60533	2.3, 4.2 - PASS
18	3.9, 2.2	400.50392	360.56057	371.15649	360.32017	3.3, 2.4 - PASS
19	1.7, 1.0	394.41671	358.73713	359.22248	339.98562	7.7, 2.4 - PASS
20	1.6, 4.2	409.14939	359.71236	401.35667	351.91510	20.4, 3.1 - PASS
21	1.6, 1.7	381.87034	343.39210	373.34734	342.66182	2.5, 20.6 - PASS
22	2.9, 1.9	411.82558	373.83722	386.98687	367.99042	2.3, 4.4 - PASS
23	1.4, 4.5	388.69237	350.33207	374.07763	336.32967	1.6, 1.5 - PASS
24	10.8, 1.6	390.03047	371.03402	371.64184	351.55223	2.5, 2.9 - PASS
25	2.4, 6.9	421.32381	377.85605	403.06218	357.39450	26.0, 2.7 - PASS
26	3.9, 1.5	400.74432	365.30969	381.62994	350.09166	4.7, 5.6 - PASS
27	2.0, 2.1	399.16128	366.89272	387.23180	350.21413	4.9, 6.1 - PASS
28	2.0, 2.7	410.73243	377.97398	374.80791	363.36377	1.2, 4.4 - PASS
29	2.1, 2.0	397.82319	363.11883	384.42860	356.42381	27.3, 21.4 - PASS
30	1.5, 1.2	411.82558	362.14361	402.32736	346.19530	4.9, 1.2 - PASS
	MAX	434.71839	386.74193	403.06218	367.99042	
	MIN	381.87034	343.39210	356.78669	329.02230	
	AVG	409.20533	366.30940	379.59875	349.84294	
	SD	13.9254158	10.95244773	13.03610145	10.00429473	
	Cpk	3.810905506	3.539829825	3.313842283	3.32666935	

Calibration Information:

Instron	
System ID Number	4464C2820
Megadyne Number	01028
Calibration Date	5/1/2015
Calibration Due	5/1/2016

Multimeter	
Fluke 79 Series II Multimeter	
Serial Number:	57040475
Megadyne Number:	01010
Calibration Date:	4/10/2015
Calibration Due:	4/30/2016

PAUL VALPREDA — Paul Valprede — 1-26-2016
Operator Name — Operator Signature — Date

Christian Crook — Christian Crook — 1/25/2016
Engineer Name — Engineer Signature — Date

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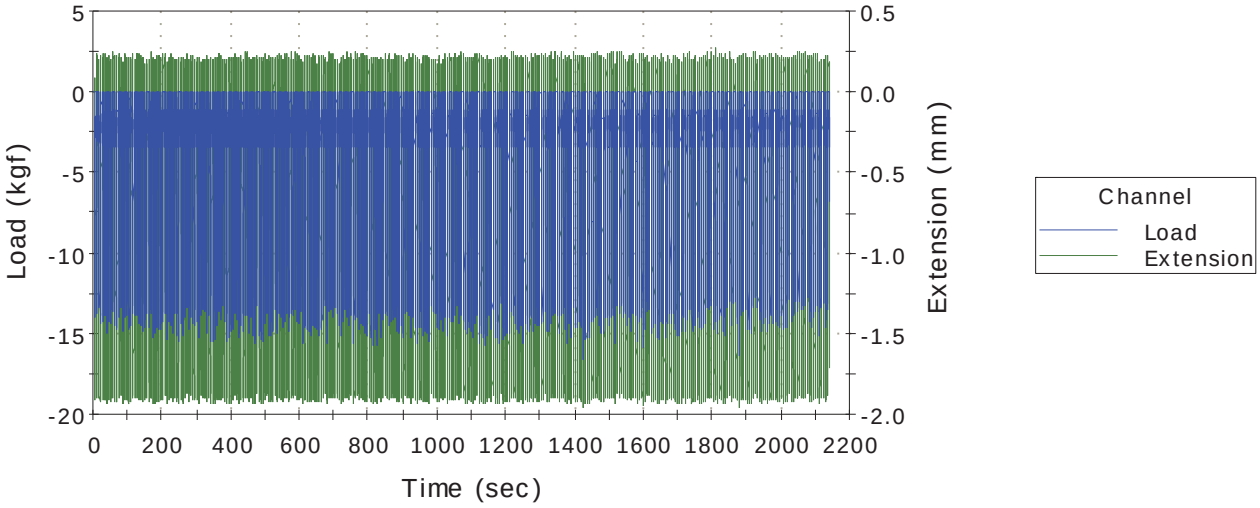
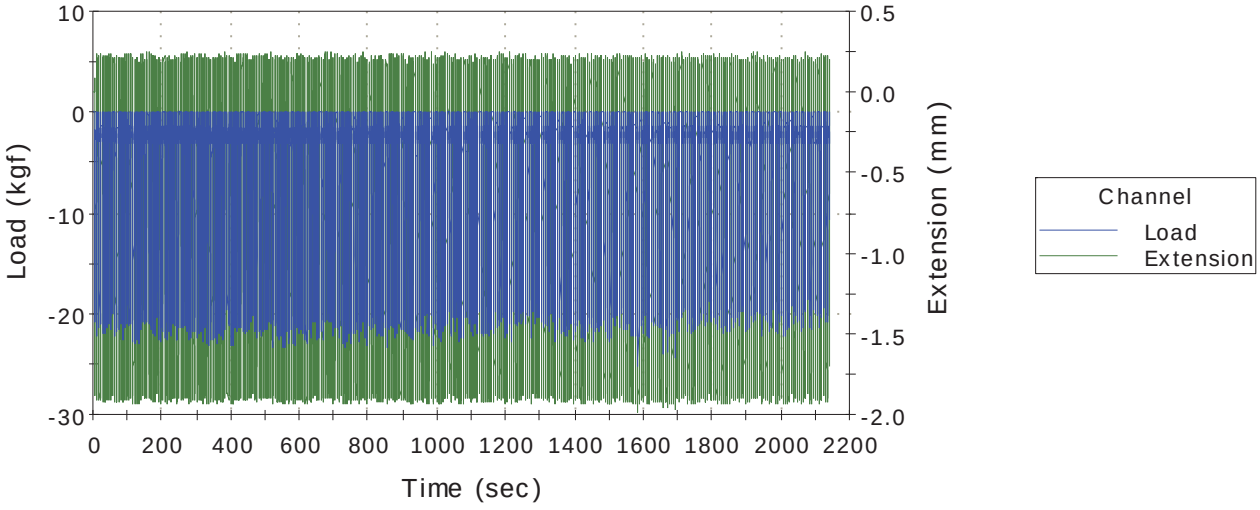
500 Cycles on 0036 Pencils

Text Inputs: Method Author	P. Valpreda
Text Inputs: Test Operator	P. Valpreda

Specimen 1



Specimen 2



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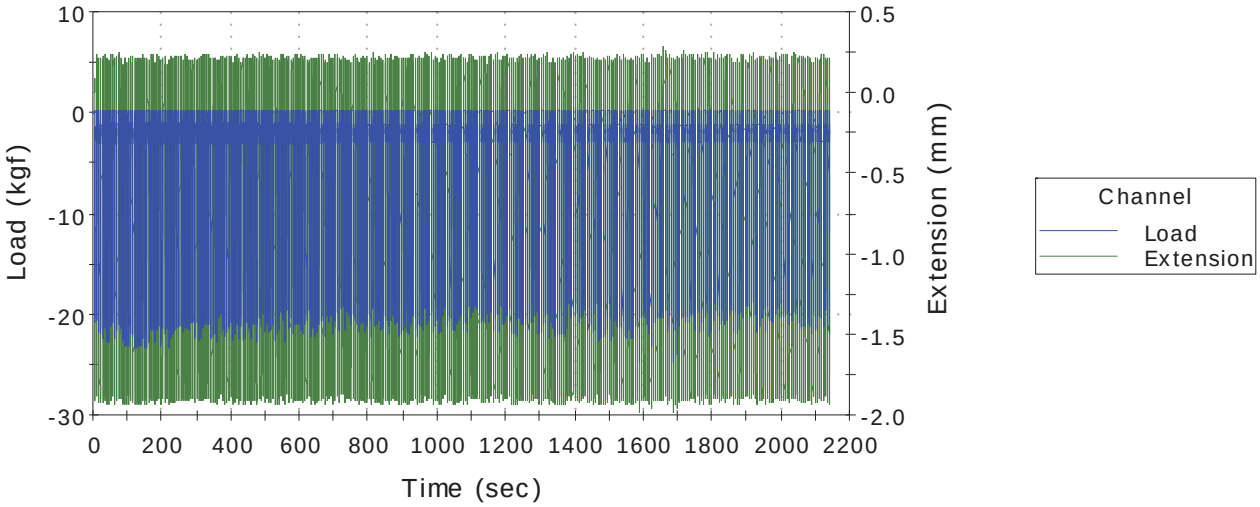

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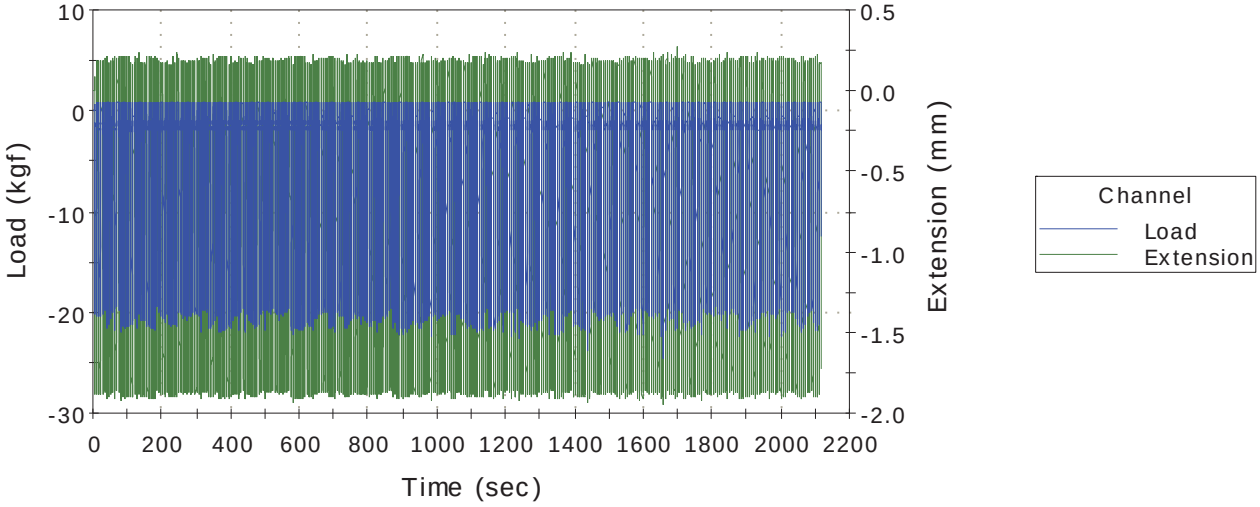

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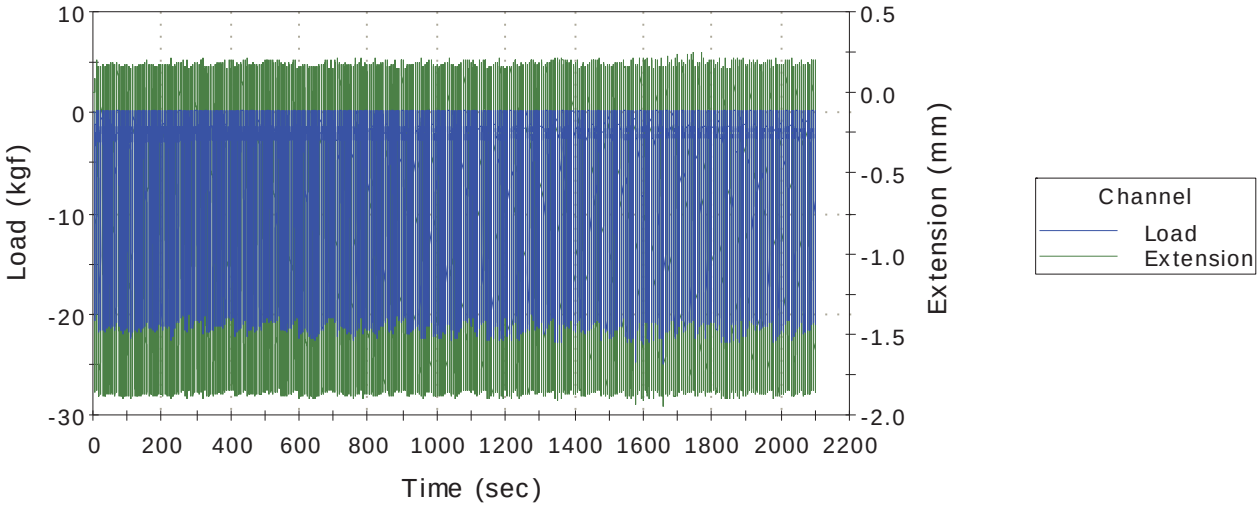
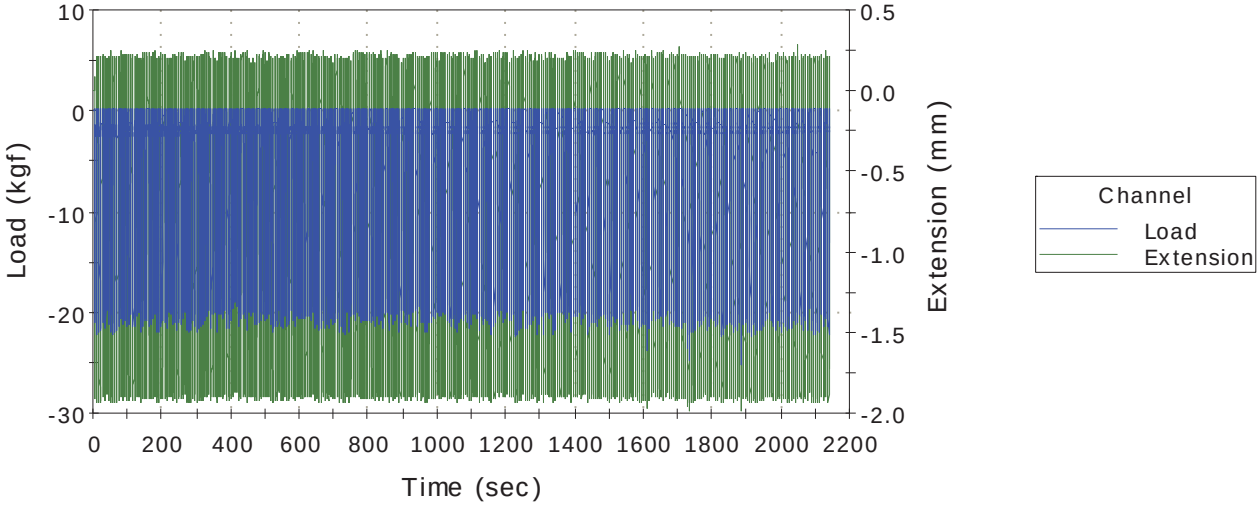


Specimen 6



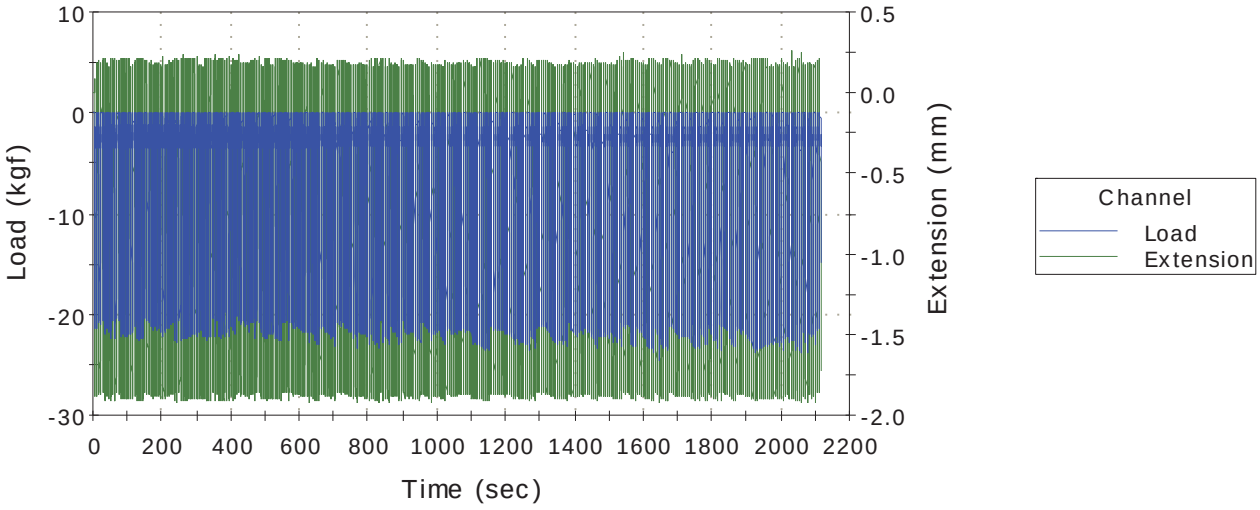
	Specimen note	Load at Machine Peak Load (kgf)	Notes
1	0036 - 151363	-16.58334	Samples 1, 2, 3, 4, 5 - 500 Cycles
2	0036 - 151363	-25.24242	Samples 6, 7, 8, 9, 10 - 500 Cycles
3	0036 - 151363	-24.91583	Samples 11, 12, 13, 14, 15 - 500 Cycles
4	0036 - 151363	-24.67089	Samples 16, 17, 18, 19, 20 - 500 Cycles
5	0036 - 151363	-25.11088	Samples 21, 22, 23, 24, 25 - 500 Cycles
6	0036 - 151363	-25.15624	Samples 26, 27, 28, 29, 30 - 500 Cycles
Maximum		-16.58334	
Minimum		-25.24242	
Mean		-23.61326	
Standard Deviation		3.45001	

500 Cycles on ACE37H Pencils

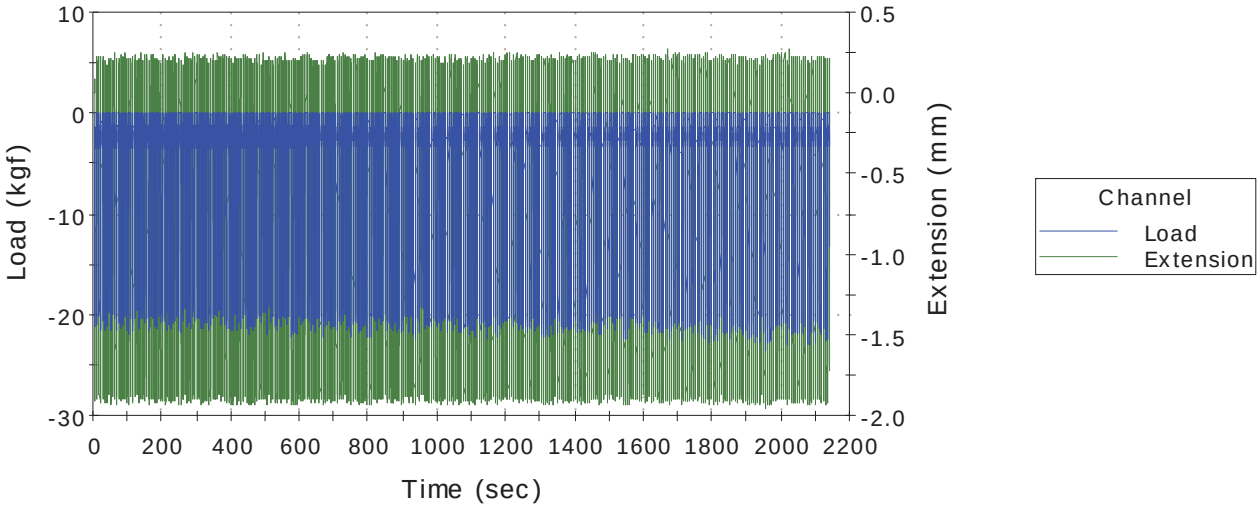
Monday, October 12, 2015 ACE37H - 151361.is_tcyclic

Text Inputs: Method Author	P. Valpreda
Text Inputs: Test Operator	P. Valpreda

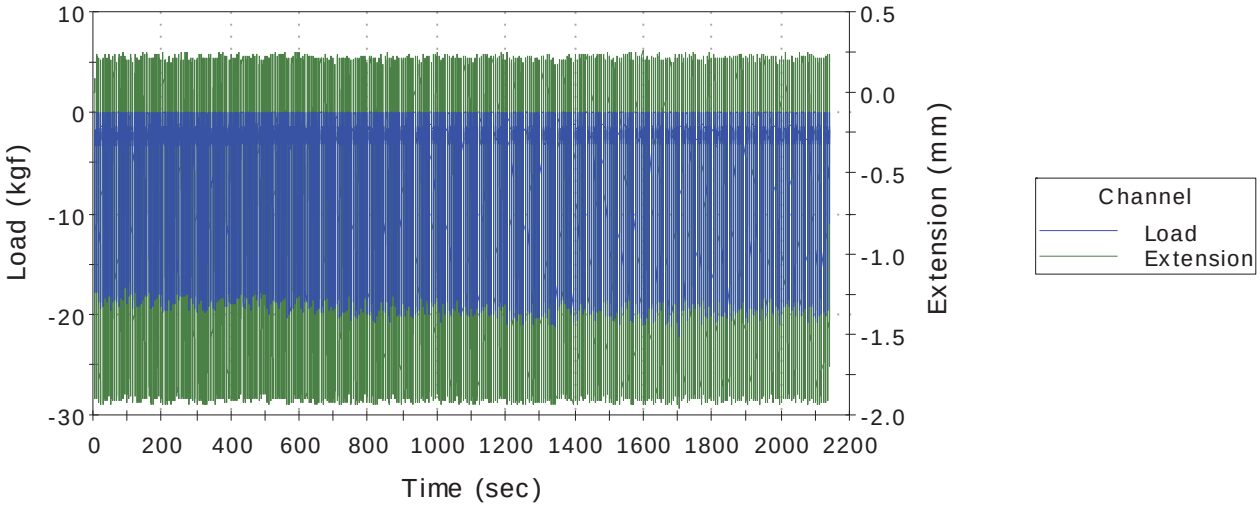
Specimen 1



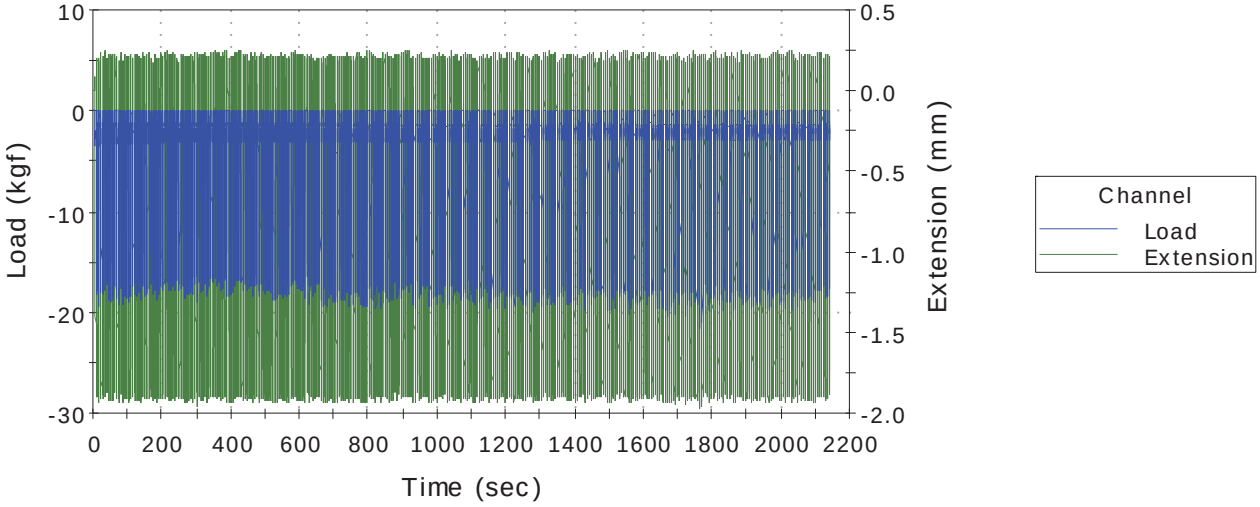
Specimen 2



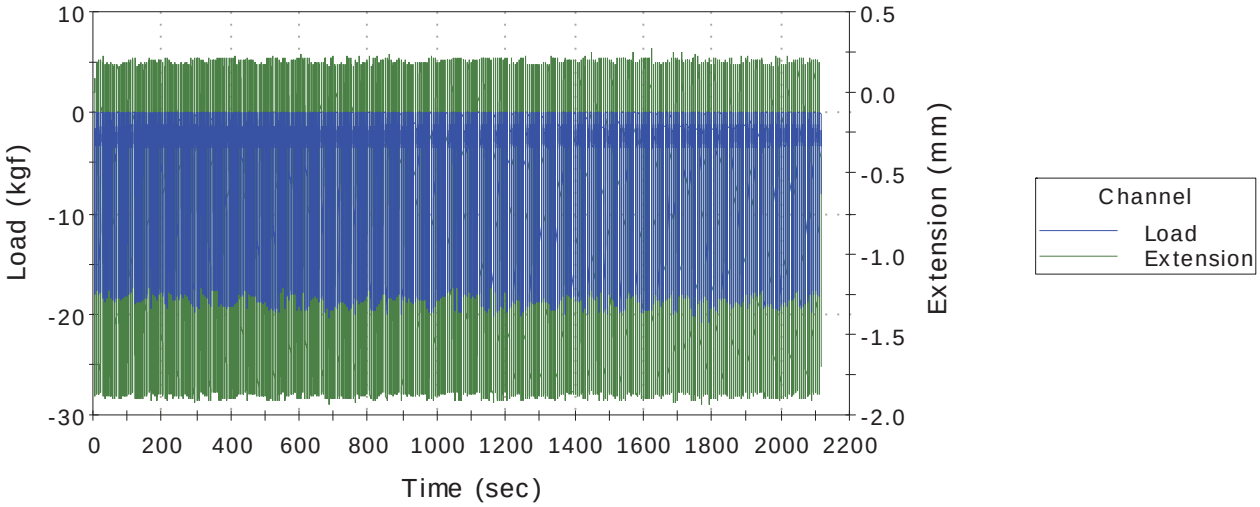
Specimen 3



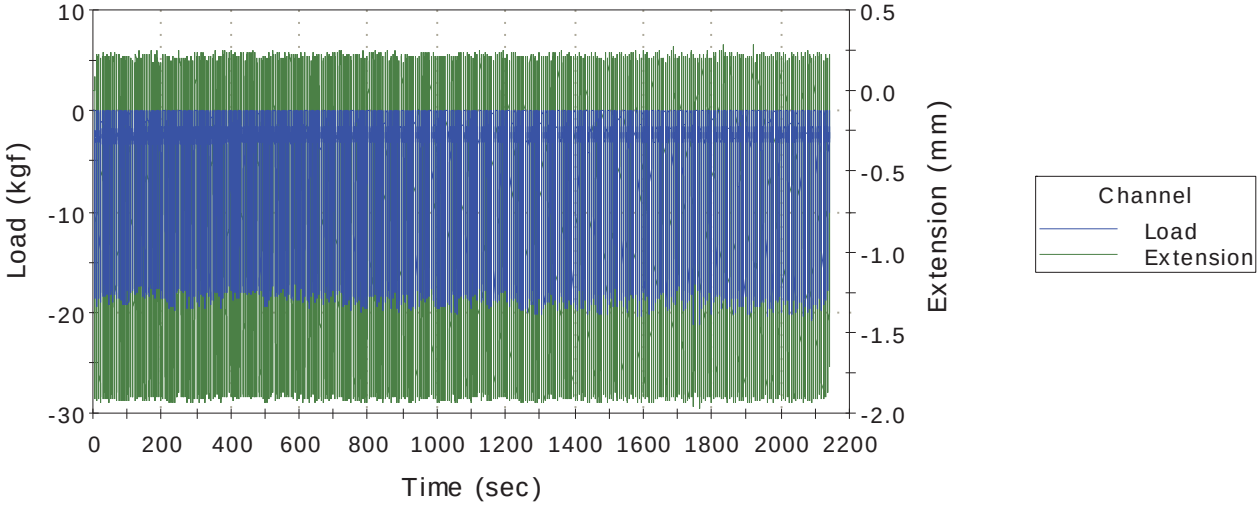
Specimen 4



Specimen 5



Specimen 6



	Specimen note 1	Load at Machine Peak Load (kgf)	Specimen label
1	ACE37H - 151361	-24.65728	Samples 1, 2, 3, 4, 5 - 500 Cycles
2	ACE37H - 151361	-23.69567	Samples 6, 7, 8, 9, 10 - 500 Cycles
3	ACE37H - 151361	-22.33035	Samples 11, 12, 13, 14, 15 - 500 Cycles
4	ACE37H - 151361	-21.59553	Samples 16, 17, 18, 19, 20 - 500 Cycles
5	ACE37H - 151361	-20.90607	Samples 21, 22, 23, 24, 25 - 500 Cycles
6	ACE37H - 151361	-21.27348	Samples 26, 27, 28, 29, 30 - 500 Cycles
Maximum		-20.90607	
Minimum		-24.65728	
Mean		-22.40973	
Standard Deviation		1.47827	

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APPENDIX IX – ELECTRODE WOBBLE

ELECTRODE DEVIATION WOBBLE ON E0x2 SAMPLES

ND PN: ACE37H	LOT# 151361	ND PN: 0036	LOT# 151363
Sample #	Wobble	Sample #	Wobble
1	0.143	1	0.145
2	0.128	2	0.132
3	0.149	3	0.146
4	0.127	4	0.140
5	0.131	5	0.140
6	0.128	6	0.147
7	0.145	7	0.149
8	0.142	8	0.135
9	0.132	9	0.136
10	0.133	10	0.140
11	0.131	11	0.132
12	0.133	12	0.143
13	0.145	13	0.143
14	0.143	14	0.147
15	0.147	15	0.146
16	0.144	16	0.135
17	0.136	17	0.137
18	0.147	18	0.155
19	0.143	19	0.149
20	0.145	20	0.131
21	0.143	21	0.137
22	0.130	22	0.144
23	0.145	23	0.132
24	0.144	24	0.130
25	0.135	25	0.138
26	0.143	26	0.143
27	0.151	27	0.141
28	0.131	28	0.146
29	0.143	29	0.138
30	0.142	30	0.144
	Button		Rocker

Paul Valpreda — Operator Name — 9/30/2015 — Date

Engineer Signature — 1/26/2016 — Date

Megadyne Medical Products, Inc.	TEST REPORT	Document Number ENG-RPT-452
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ELECTRODE DEVIATION

ND PN: 0035	LOT# 1410115
Sample #	Wobble
1	0.118
2	0.117
3	0.111
4	0.121
5	0.121
6	0.111
7	0.114
8	0.119
9	0.117
10	0.120
11	0.119
12	0.112
13	0.115
14	0.115
15	0.112
16	0.113
17	0.121
18	0.119
19	0.118
20	0.094
21	0.122
22	0.118
23	0.123
24	0.115
25	0.117
26	0.114
27	0.118
28	0.116
29	0.120
30	0.116
	Button

10/1/2015
PV

Paul Valpreda — Operator Name — 10/1/2015 — Date

Operator Signature — 1/26/2016 — Date

APPENDIX X – DURABILITY OF PRINT TO CHEMICAL IN USE ENVIRONMENT (ROCKER PENCIL ONLY)

PRINT DURABILITY EVALUATION			
MEGADYNE PN: 0036			
ND PN:			LOT # 151363
Sample #	Saline	Lactated Ringer's	Notes
1	Visible	Visible	
2	Visible	Visible	
3	Visible	Visible	
4	Visible	Visible	
5	Visible	Visible	
6	Visible	Visible	
7	Visible	Visible	
8	Visible	Visible	
9	Visible	Visible	
10	Visible	Visible	
11	Visible	Visible	
12	Visible	Visible	
13	Visible	Visible	
14	Visible	Visible	
15	Visible	Visible	
16	Visible	Visible	
17	Visible	Visible	
18	Visible	Visible	
19	Visible	Visible	
20	Visible	Visible	
21	Visible	Visible	
22	Visible	Visible	
23	Visible	Visible	
24	Visible	Visible	
25	Visible	Visible	
26	Visible	Visible	
27	Visible	Visible	
28	Visible	Visible	
29	Visible	Visible	
30	Visible	Visible	
Saline: Hospira, Part # NDC 0409-7983-09, LOT # 36-049-JT, EXP 1 DEC 2015			
Lactated Ringer's: Hospira, Part # NDC 0409-7953-09, LOT # 52-089-JT, EXP 1 APR 2017			

Paul Valpreda — Operator Name — 10/29/2015 — Date

Engineer Signature — 11/18/15 — Date

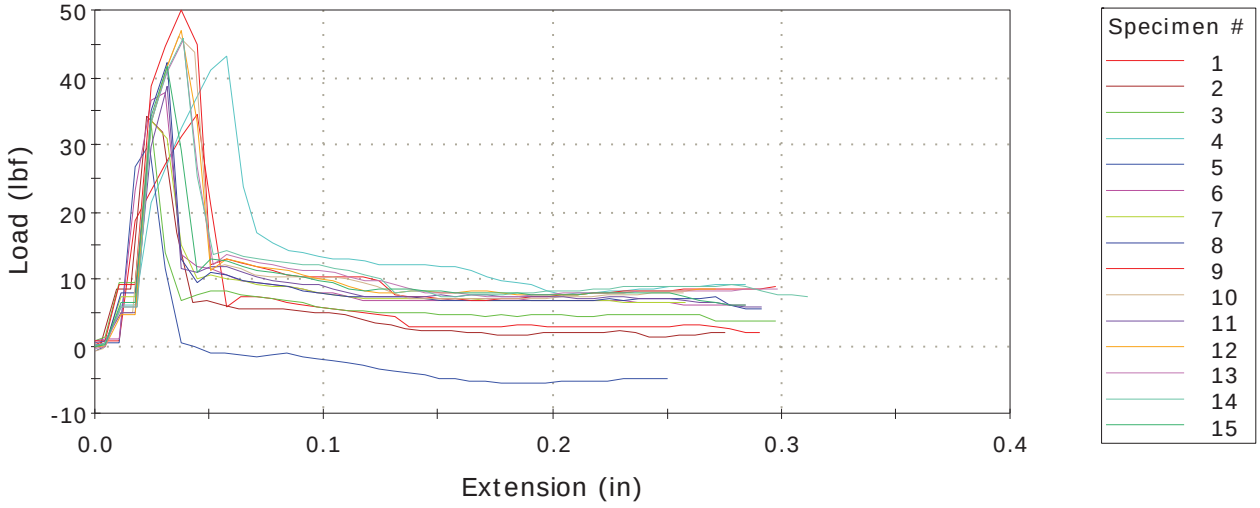
APPENDIX XI – PENCIL BODY PEEL STRENGTH

Friday, October 23, 2015

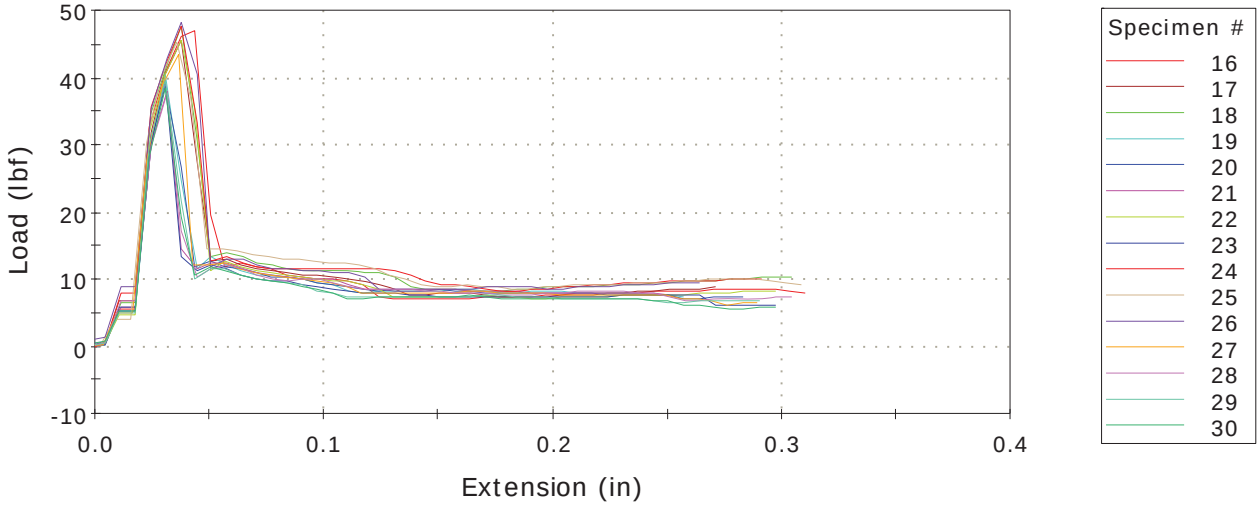
Weld Strength on ISOS2 0036 - 151363.is_tens

Specimen label	0036 LOT 151363

Specimen 1 to 15



Specimen 16 to 30



	Specimen label	Maximum Load (lbf)	Specimen note 1
1	0036 LOT 151363	34.42	Proximal End
2	0036 LOT 151363	34.07	Proximal End
3	0036 LOT 151363	33.13	Proximal End
4	0036 LOT 151363	43.27	Proximal End
5	0036 LOT 151363	30.01	Proximal End
6	0036 LOT 151363	37.80	Proximal End
7	0036 LOT 151363	33.72	Proximal End
8	0036 LOT 151363	42.09	Proximal End
9	0036 LOT 151363	49.96	Proximal End
10	0036 LOT 151363	46.01	Proximal End
11	0036 LOT 151363	38.79	Proximal End
12	0036 LOT 151363	46.93	Proximal End
13	0036 LOT 151363	45.64	Proximal End
14	0036 LOT 151363	45.82	Proximal End
15	0036 LOT 151363	41.56	Proximal End
16	0036 LOT 151363	47.06	Proximal End
17	0036 LOT 151363	45.53	Proximal End
18	0036 LOT 151363	47.76	Proximal End
19	0036 LOT 151363	40.32	Proximal End
20	0036 LOT 151363	38.58	Proximal End
21	0036 LOT 151363	38.12	Proximal End
22	0036 LOT 151363	45.50	Proximal End
23	0036 LOT 151363	39.65	Proximal End
24	0036 LOT 151363	47.68	Proximal End
25	0036 LOT 151363	45.21	Proximal End
26	0036 LOT 151363	48.27	Proximal End
27	0036 LOT 151363	43.46	Proximal End
28	0036 LOT 151363	37.77	Proximal End
29	0036 LOT 151363	39.62	Proximal End
30	0036 LOT 151363	38.50	Proximal End
Maximum		49.96	
Mean		41.54	
Minimum		30.01	
Standard Deviation		5.26815	

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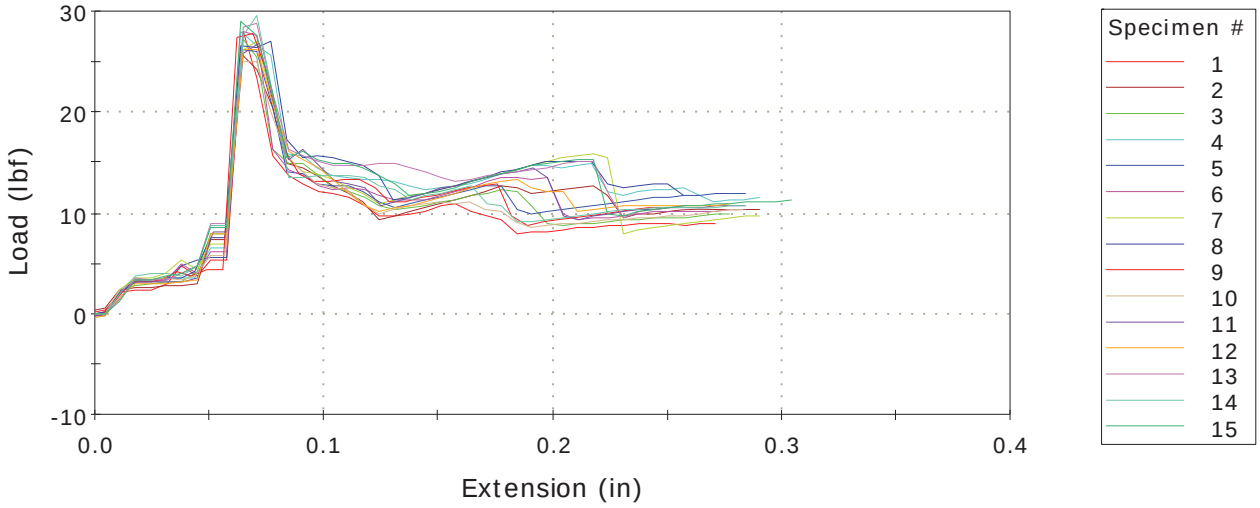
Friday, October 23, 2015

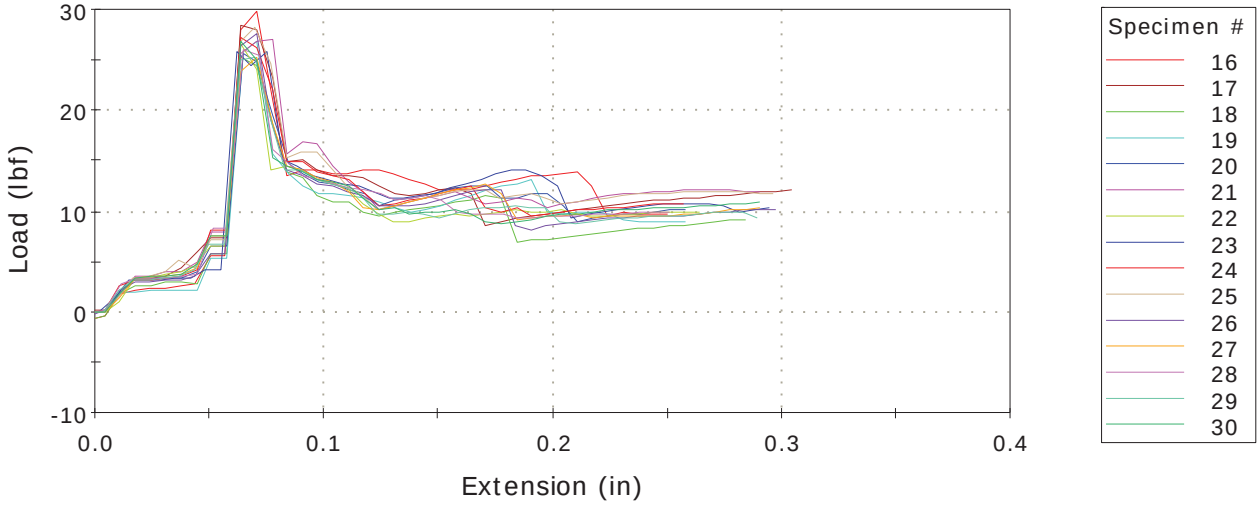
Weld Strength on ISOS2 0036 - 151363_Distal.is_tens

Specimen label	0036 LOT 151363

Specimen 1 to 15



Specimen 16 to 30



	Specimen label	Maximum Load (lbf)	Specimen note 1
1	0036 LOT 151363	28.11	Distal End
2	0036 LOT 151363	25.88	Distal End
3	0036 LOT 151363	27.17	Distal End
4	0036 LOT 151363	28.03	Distal End
5	0036 LOT 151363	26.25	Distal End
6	0036 LOT 151363	28.05	Distal End
7	0036 LOT 151363	27.09	Distal End
8	0036 LOT 151363	27.03	Distal End
9	0036 LOT 151363	27.87	Distal End
10	0036 LOT 151363	25.10	Distal End
11	0036 LOT 151363	26.74	Distal End
12	0036 LOT 151363	26.28	Distal End
13	0036 LOT 151363	28.78	Distal End
14	0036 LOT 151363	29.66	Distal End
15	0036 LOT 151363	29.10	Distal End
16	0036 LOT 151363	29.83	Distal End
17	0036 LOT 151363	28.48	Distal End
18	0036 LOT 151363	25.13	Distal End
19	0036 LOT 151363	26.87	Distal End
20	0036 LOT 151363	25.72	Distal End
21	0036 LOT 151363	27.01	Distal End
22	0036 LOT 151363	26.55	Distal End
23	0036 LOT 151363	25.85	Distal End
24	0036 LOT 151363	27.22	Distal End
25	0036 LOT 151363	28.27	Distal End
26	0036 LOT 151363	27.70	Distal End
27	0036 LOT 151363	25.15	Distal End
28	0036 LOT 151363	26.07	Distal End
29	0036 LOT 151363	25.18	Distal End
30	0036 LOT 151363	26.87	Distal End
Maximum		29.83	
Mean		27.10	
Minimum		25.10	
Standard Deviation		1.32832	

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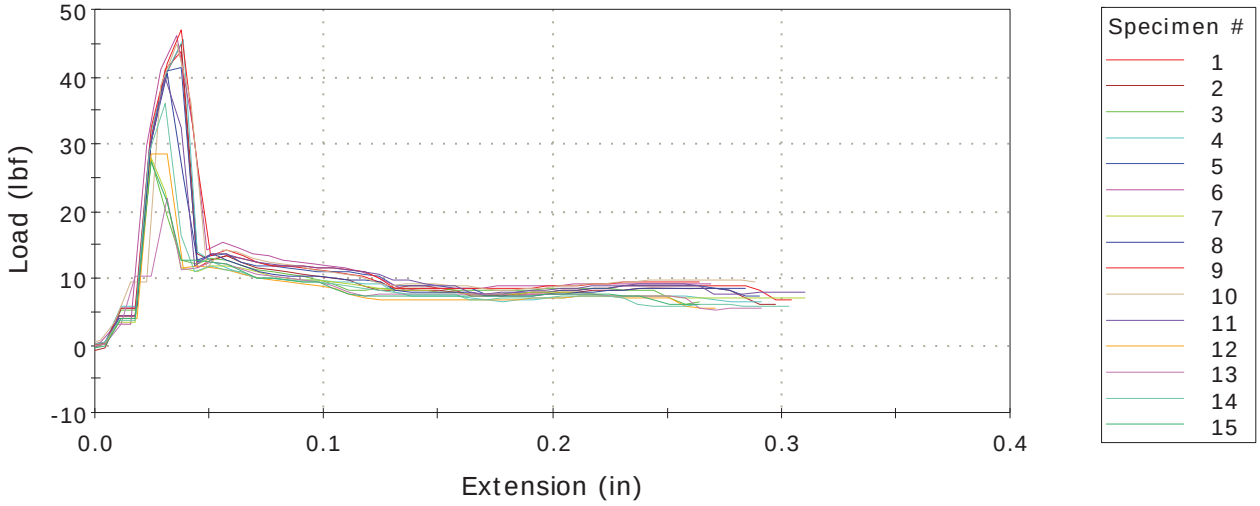
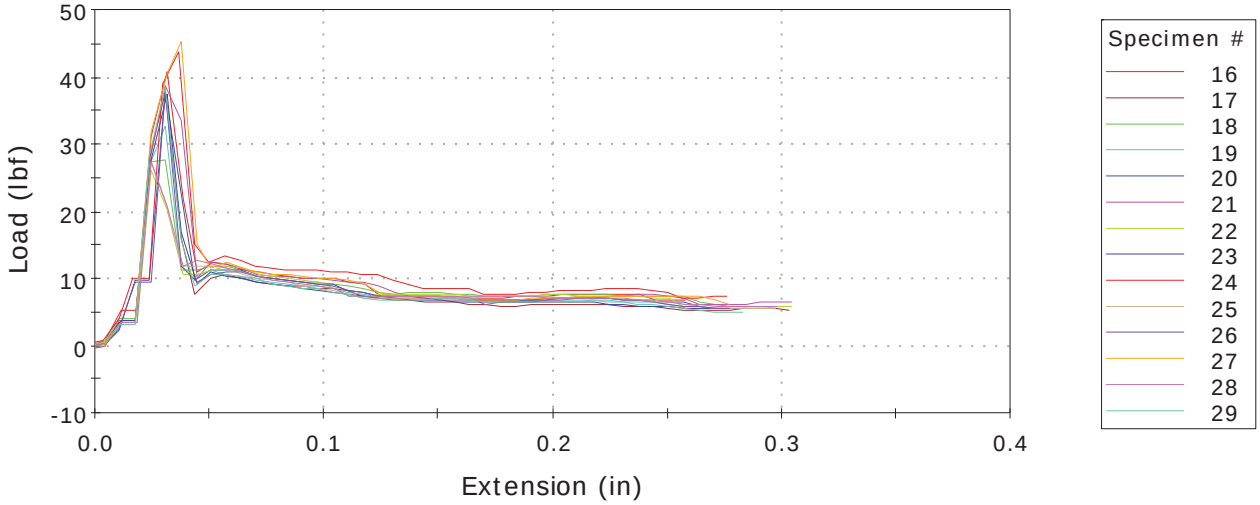
Monday, October 26, 2015 Weld Strength on ISOS2 ACE37H - 151361.is_tens

Specimen label	ACE37H LOT 151361

Specimen 1 to 15



Specimen 16 to 29



	Specimen label	Maximum Load (lbf)	Specimen note 1
1	ACE37H LOT 151361	43.81	Proximal End, Sample 1
2	ACE37H LOT 151361	44.99	Proximal End, Sample 2
3	ACE37H LOT 151361	27.60	Proximal End, Sample 3
4	ACE37H LOT 151361	45.45	Proximal End, Sample 4
5	ACE37H LOT 151361	41.45	Proximal End, Sample 5
6	ACE37H LOT 151361	46.15	Proximal End, Sample 6
7	ACE37H LOT 151361	27.81	Proximal End, Sample 7
8	ACE37H LOT 151361	40.48	Proximal End, Sample 8
9	ACE37H LOT 151361	47.09	Proximal End, Sample 10
10	ACE37H LOT 151361	44.89	Proximal End, Sample 11
11	ACE37H LOT 151361	39.97	Proximal End, Sample 12
12	ACE37H LOT 151361	28.54	Proximal End, Sample 13
13	ACE37H LOT 151361	22.07	Proximal End, Sample 14
14	ACE37H LOT 151361	35.84	Proximal End, Sample 15
15	ACE37H LOT 151361	27.25	Proximal End, Sample 16
16	ACE37H LOT 151361	40.70	Proximal End, Sample 17
17	ACE37H LOT 151361	37.88	Proximal End, Sample 18
18	ACE37H LOT 151361	27.62	Proximal End, Sample 19
19	ACE37H LOT 151361	32.83	Proximal End, Sample 20

	Specimen label	Maximum Load (lbf)	Specimen note 1
20	ACE37H LOT 151361	37.83	Proximal End, Sample 21
21	ACE37H LOT 151361	38.79	Proximal End, Sample 22
22	ACE37H LOT 151361	26.23	Proximal End, Sample 23
23	ACE37H LOT 151361	37.31	Proximal End, Sample 24
24	ACE37H LOT 151361	43.87	Proximal End, Sample 25
25	ACE37H LOT 151361	27.41	Proximal End, Sample 26
26	ACE37H LOT 151361	37.96	Proximal End, Sample 27
27	ACE37H LOT 151361	45.15	Proximal End, Sample 28
28	ACE37H LOT 151361	27.38	Proximal End, Sample 29
29	ACE37H LOT 151361	38.31	Proximal End, Sample 30
Maximum		47.09	
Mean		36.64	
Minimum		22.07	
Standard Deviation		7.48984	

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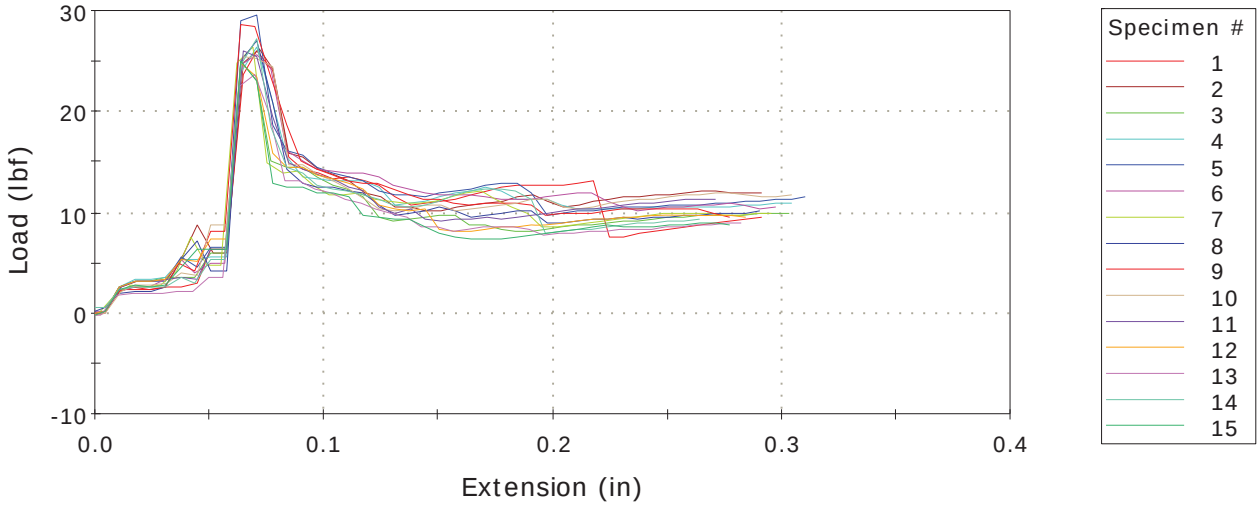
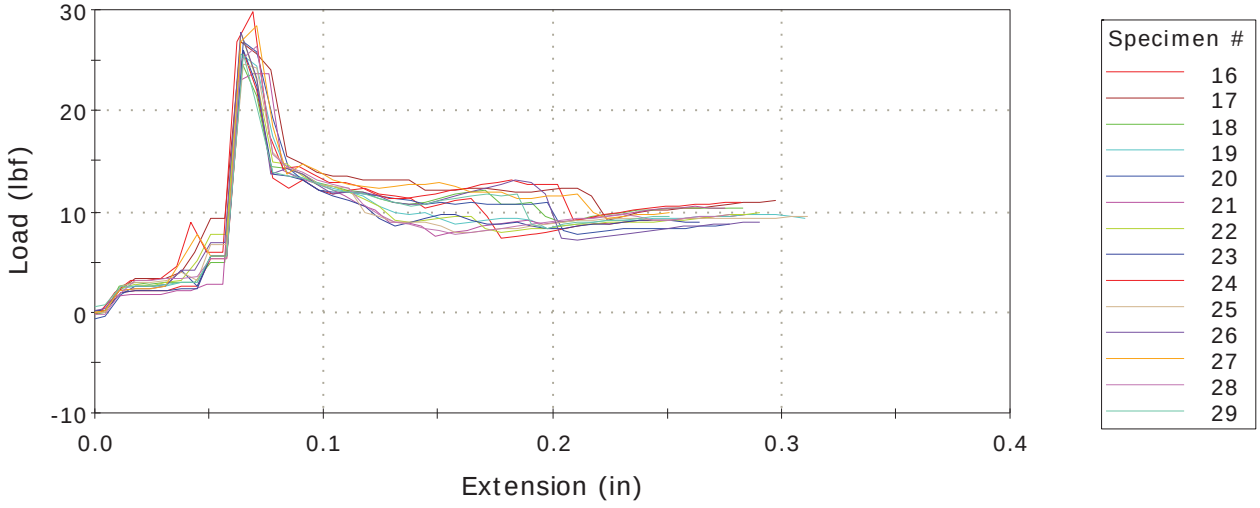
Specimen label	ACE37H LOT 151361

Specimen 1 to 15



Specimen 16 to 29



	Specimen label	Maximum Load (lbf)	Specimen note 1
1	ACE37H LOT 151361	26.09	Distal End, Sample 1
2	ACE37H LOT 151361	26.17	Distal End, Sample 2
3	ACE37H LOT 151361	25.02	Distal End, Sample 3
4	ACE37H LOT 151361	26.34	Distal End, Sample 4
5	ACE37H LOT 151361	29.69	Distal End, Sample 5
6	ACE37H LOT 151361	25.64	Distal End, Sample 6
7	ACE37H LOT 151361	26.42	Distal End, Sample 7
8	ACE37H LOT 151361	27.11	Distal End, Sample 8
9	ACE37H LOT 151361	28.70	Distal End, Sample 10
10	ACE37H LOT 151361	25.40	Distal End, Sample 11
11	ACE37H LOT 151361	26.01	Distal End, Sample 12
12	ACE37H LOT 151361	24.81	Distal End, Sample 13
13	ACE37H LOT 151361	23.65	Distal End, Sample 14
14	ACE37H LOT 151361	27.19	Distal End, Sample 15
15	ACE37H LOT 151361	24.97	Distal End, Sample 16
16	ACE37H LOT 151361	25.88	Distal End, Sample 17
17	ACE37H LOT 151361	26.85	Distal End, Sample 18
18	ACE37H LOT 151361	24.94	Distal End, Sample 19
19	ACE37H LOT 151361	25.56	Distal End, Sample 20

	Specimen label	Maximum Load (lbf)	Specimen note 1
20	ACE37H LOT 151361	26.79	Distal End, Sample 21
21	ACE37H LOT 151361	23.70	Distal End, Sample 22
22	ACE37H LOT 151361	27.76	Distal End, Sample 23
23	ACE37H LOT 151361	25.96	Distal End, Sample 24
24	ACE37H LOT 151361	29.74	Distal End, Sample 25
25	ACE37H LOT 151361	24.72	Distal End, Sample 26
26	ACE37H LOT 151361	27.78	Distal End, Sample 27
27	ACE37H LOT 151361	28.38	Distal End, Sample 28
28	ACE37H LOT 151361	26.44	Distal End, Sample 29
29	ACE37H LOT 151361	25.58	Distal End, Sample 30
Maximum		29.74	
Mean		26.32	
Minimum		23.65	
Standard Deviation		1.53848	