MEGADYNE® Est. 1985
The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-328

DOCUMENT TITLE: Test Protocol, Zip Pencil, Dielectric Withstand

DOCUMENT NOTES:

Initial release into MasterControl

Document Information

Revision: 001	Vault: MEG-Rel
Status: Release	Document Type: ENG-RPT

Date Information

Effective Date: 21 Mar 2014	Expiration Date:
Release Date: 21 Mar 2014	Next Review Date:

Control Information

Author: MGLASSETT	Owner: ENG-APPR
Previous Number: 1150718-01	Change Number: 14-037-01

Megadyne Medical Products, Inc.	TEST REPORT	Document Number 1150718-01
	Zip Pencil Dielectric Withstand	Revision: A
		Effective Date: 2014 MAR 21
	MASTER DOCUMENT	Page 1 of 10

Mark Glassett 21 Mar 2014 Engineering Verification:

Lucy Richards 21 Mar 2014 D.C. Verification:

Authored By: Mark Glassett

TABLE OF CONTENTS **Page**

1. ABSTRACT

Zip Pencil samples that have been exposed to three year accelerated aging and shipping cycle temperature extremes were subjected to the dielectric withstand tests required for compliance to IEC 60601-2-2: 2009. The Zip Pencil passed the requirements of the standard for these tests. The specific clause of the IEC 60601-2-2 standard for each test is listed below.

Required Test	IEC 60601-2-2 Clause
Zip Pencil HF Dielectric	201.8.8.3.103
Zip Pencil Mains Dielectric	201.8.8.3.104
Cable Leakage Current	201.8.8.3.102
Cable HF Dielectric	201.8.8.3.103
Cable Mains Dielectric	201.8.8.3.104
Plug Mains dielectric	201.8.8.3.104

An additional test for the HF and Mains dielectric withstand of the Holster was performed. This test is not required by standards.

2. OBJECTIVE

The objective of this test report is to document compliance of the Zip Pencil catalog items 2525-10 and 2525-15 with IEC60601-2-2: 2009 requirements for Dielectric Withstand after shipping extremes and accelerated aging to simulate three years expiration life.

3. RESULTS

3.1. Zip Pencil Handpiece High Frequency Dielectric Withstand

Thirty samples of the Zip Pencil were tested for high frequency dielectric withstand. Prior to application of high voltage for the dielectric test the continuity was checked for both the CUT and COAG circuits. The technician reported that two of the samples failed the test for continuity above 50 Ohms. After examination of the samples, engineering noted that the plug contact pins had some corrosion on them from the temperature and humidity cycling process. The plugs were removed and the tests were repeated with the ohm meter connected to the cable wires and the samples pass the test. Since this is a test of the Pencil and not the plug, testing continued and these two samples passed the HF test. All other samples passed the HF dielectric test also. This data is shown in Appendix I.

3.2. Zip Pencil Handpiece Mains Frequency Dielectric Withstand

Following the HF dielectric test, the same samples from the HF dielectric test were tested for Mains Dielectric. Twelve of the 30 samples failed this test. This was expected to happen because on 30 December 2013 the Pencil supplier, New Deantronics (ND), notified Megadyne that they had discovered a process problem that damaged the PTFE tape that protects the PCB and Dome switches when testing non-aged samples. These failures are considered to be process defects and not a design defect. See discussion in Appendix I

Additional testing of non-aged samples to verify that the process correction fixed the Mains dielectric failures was performed. All of the non-aged samples passed the HF dielectric test followed by the Mains dielectric test. This data is shown in Appendix I. The lot number of these samples is S130409 and S130410.

The substitution for non-aged samples for the Mains dielectric test is justified as follows: The failure was caused by damage to the PTFE tape. PTFE is designed for elevated temperature applications. Aging is performed at 55°C which is well within the operating range for the PTFE. It is not expected that the PTFE tape will degrade at 55°C and

therefore the T=0 samples are considered equivalent to T=3 with respect to the PTFE tape.

3.3. Cable Continuity

The samples used for cable testing were the same samples that were already used for Zip Pencil Handpiece testing above. The continuity test was performed on the full length of the cable as part of the HF and Mains testing. Therefore, the continuity was not repeated for the cables. This was considered acceptable because the reason for testing continuity is to make sure that the sample is not defective. The continuity test is not required by the IEC 60601-2-2 standard.

3.4. Cable Leakage Withstand

Thirty cable samples from the Zip Pencil were tested for high frequency leakage. The maximum allowable leakage is 120.96 mA. The highest value of leakage measured during testing was 36.0 mA. All samples passed the test. Refer to Appendix II for Cable test data.

3.5. Cable High Frequency Dielectric Withstand

Thirty cable samples from the Zip Pencil were tested for high frequency dielectric. All samples passed the application of 6.6 kV for 30 seconds without dielectric breakdown. Refer to Appendix II for Cable test data.

3.6. Cable Mains Frequency Dielectric Withstand

Thirty cable samples from the Zip Pencil were tested for mains frequency dielectric breakdown. All samples passed the application of 4,600 Vrms for 5 minutes without dielectric breakdown.

3.7. Plug Mains Frequency Dielectric Withstand

Thirty samples of the Zip Pencil Plug were tested for Mains frequency dielectric withstand. All samples passed the application of 4,600 Vrms for 30 seconds without dielectric breakdown. Refer to Appendix III for Plug test data

3.8. Holster High Frequency Dielectric Withstand

Thirty Holster samples from the Zip Pencil were tested for high frequency dielectric. All samples passed the application of 6.6 kV for 30 seconds without dielectric breakdown. Refer to Appendix IV for Holster test data.

3.9. Holster Mains Frequency Dielectric Withstand

Thirty Holster samples from the Zip Pencil were tested for mains frequency dielectric breakdown. All samples passed the application of 4,600 Vrms for 30 seconds without dielectric breakdown. Refer to Appendix IV for Holster test data.

4. DISCUSSION

The samples used for the testing were catalog 2525-10 Zip Pencils Lot #S130231 and catalog 2525-15 Lot #S130228. The 2525-10 and 2525-15 catalog numbers are the same product with the exception of tube and cord length. Samples from each of these catalog numbers were used to show compliance across different lots of product.

Prior to testing, these samples were subjected to accelerated aging at 55˚C to simulate three years shelf life. They were also exposed to temperature and humidity extremes to simulate possible exposure during the shipping and storage of the device. For documentation of this aging and conditioning refer to test report 1150720-01. The sample size required for each test was 30 units.

4.1. Zip Pencil Handpiece High Frequency Dielectric Withstand

As noted above, two of the 30 samples were reported as continuity failure with continuity above 50 Ohms. After examination of the samples, engineering noted that the plug contact pins had some corrosion on them from the temperature and humidity cycling process. The plugs were removed and the tests were repeated with the ohm meter connected to the cable wires and the samples pass the test. The purpose of this test is to insure that the test samples are not defective. This test is not required by the IEC 606012-2-2 standard. Therefore, the reported Failure is not a dielectric failure and the samples were tested with the plugs removed.

The corrosion on the plug contact pins was present because the pins were not nickel plated. The plated pins are specified for the final product but they were not available at the time the samples were assembled. Going into production this corrosion will not be an issue. The production pins will be nickel plated the same as the existing Megadyne disposable pencils which have a long history of no corrosion.

4.2. Zip Pencil Handpiece Mains Frequency Dielectric Withstand

As noted above, 12 of the 30 aged samples failed the mains frequency dielectric test. Megadyne had been notified on 30 December 2013 that this was likely to happen. The

supplier identified a process problem that damaged the PTFE tape that protects the PCB and Dome switches. These failures are considered to be process defects and not a design defects. Additional testing of non-aged samples to verify that the process correction fixed the Mains dielectric failures was performed. See discussion in Appendix I

4.3. Cable Leakage, HF Dielectric and Mains Dielectric

The Zip Pencil uses a cable that is new for Megadyne products. The cable has a Phthalate free Jacket that is preferred by health care providers in many countries. The material is PVC with Adipic Acid Plasticizer. This cable has the same interior insulation that other Megadyne disposable pencils have. The cable passed all of the tests required by IEC 60601-2-2.

4.4. Plug Mains Frequency Dielectric Withstand

The Zip Pencil plug is a new design for Megadyne. It is a cosmetically modified version of the New Deantronics two piece clam shell plug. The plug passed the Mains frequency dielectric withstand test that is required by IEC 60601-2-2.

4.5. Holster High Frequency and Mains Frequency Dielectric Withstand

Holster testing for dielectric strength is not required by the IEC 60601-2-2 standard. However, the healthcare provider is likely to store the Zip Pencil in the holster and the pencil could be inadvertently active while in the holster. Therefore it was determined that a holster test was appropriate.

5. CONCLUSIONS

This testing demonstrates that the Zip Pencil catalog numbers 2525-10 and 2525-15 comply with the required standards referenced in section 1 after three year accelerated aging and shipping and storage conditions.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Zip Pencil to IEC 6060 1-2-2: 2009 after three year accelerated aging to support the three year expiration life. This accelerated age test will support the three year expiration life of the product for market introduction. Real time age samples from the first production lot will be put aside for testing per Megadyne Protocol 1150309-10.

The testing also demonstrated compliance to IEC 6060 1-2-2: 2009 after exposure to extreme shipping and storage conditions. The shipping box labels of the products will show the international symbols for shipping and storage with temperatures of 5°C to 50°C and relative humidity of 15% to 95%. The IFU will include the note "Normal storage conditions are assumed. Brief excursion to temperature/humidity extremes is permitted".

7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-037-01	Initial Release	2014 MAR 21

APPENDIX I

Zip Pencil Handpiece High Frequency and Main Frequency Dielectric

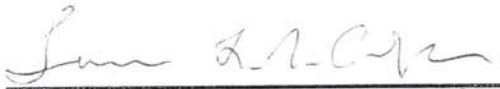
Pencil Dielectric Withstand Testing
Data Collection Form

Sample	Configuration	High Frequency		Mains	Button Activation
		Max V_{peak} (kV)	P/ F	P/ F	P/F
A2-1	2525-10 - LOT S130230	6.68	PASS	FAIL*	PASS
A2-2	2525-10 - LOT S130230	6.76	PASS	FAIL*	PASS
A2-3	2525-10 - LOT S130230	6.68	PASS	PASS	PASS
A2-4	2525-10 - LOT S130230	6.84	PASS	FAIL*	PASS
A2-5	2525-10 - LOT S130230	6.76	PASS	FAIL*	PASS
A2-6	2525-10 - LOT S130230	6.84	PASS	FAIL*	PASS
A2-7	2525-10 - LOT S130230	6.84	PASS	PASS	FAIL**
A2-8	2525-10 - LOT S130230	7.00	PASS	PASS	PASS
A2-9	2525-10 - LOT S130230	6.92	PASS	PASS	PASS
A2-10	2525-10 - LOT S130230	6.76	PASS	PASS	PASS
A2-11	2525-10 - LOT S130230	6.68	PASS	PASS	PASS
A2-12	2525-10 - LOT S130230	6.84	PASS	PASS	PASS
A2-13	2525-10 - LOT S130230	6.76	PASS	PASS	FAIL**
A2-14	2525-10 - LOT S130230	6.68	PASS	PASS	PASS
A2-15	2525-10 - LOT S130230	6.68	PASS	PASS	PASS
B2-1	2525-10 - LOT S130227	6.76	PASS	FAIL*	PASS
B2-2	2525-10 - LOT S130227	6.76	PASS	FAIL*	PASS
B2-3	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-4	2525-10 - LOT S130227	6.68	PASS	FAIL*	PASS
B2-5	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-6	2525-10 - LOT S130227	6.92	PASS	FAIL*	PASS
B2-7	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-8	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-9	2525-10 - LOT S130227	6.92	PASS	FAIL*	PASS
B2-10	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-11	2525-10 - LOT S130227	6.68	PASS	FAIL*	PASS
B2-12	2525-10 - LOT S130227	6.92	PASS	PASS	PASS
B2-13	2525-10 - LOT S130227	6.76	PASS	PASS	PASS
B2-14	2525-10 - LOT S130227	6.84	PASS	PASS	PASS
B2-15	2525-10 - LOT S130227	6.76	PASS	FAIL*	PASS
			2/6/2014 T.C.	2/6/2014 T.C	2/10/2014 T.C.

* Failure during Mains Withstand found to be due to New Dean manufacturing defect.
** Failure of button impedance found to be linked to corroded brass plug ends (uncoated brass).

Rated Accessory V_{peak}	5,500	V_{peak}
Minimum Mains Test Value	4,596	V_{RMS}
Actual Mains Test Value	4600	V_{RMS}
Mains Test Value Calculation:	(Rated Accessory V_{peak} +1000V_{peak}) / √2	

Thomas Carlyle — Operator Name — 2/10/2014 — Date



Operator Signature — Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter *Fluke 179 True-RMS Multimeter*	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
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:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester *Hipotronics Model HD 100 Series*	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe *Tektronix P6015A High Voltage Probe*	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

Secondary Equipment List (Station 2, Spare):

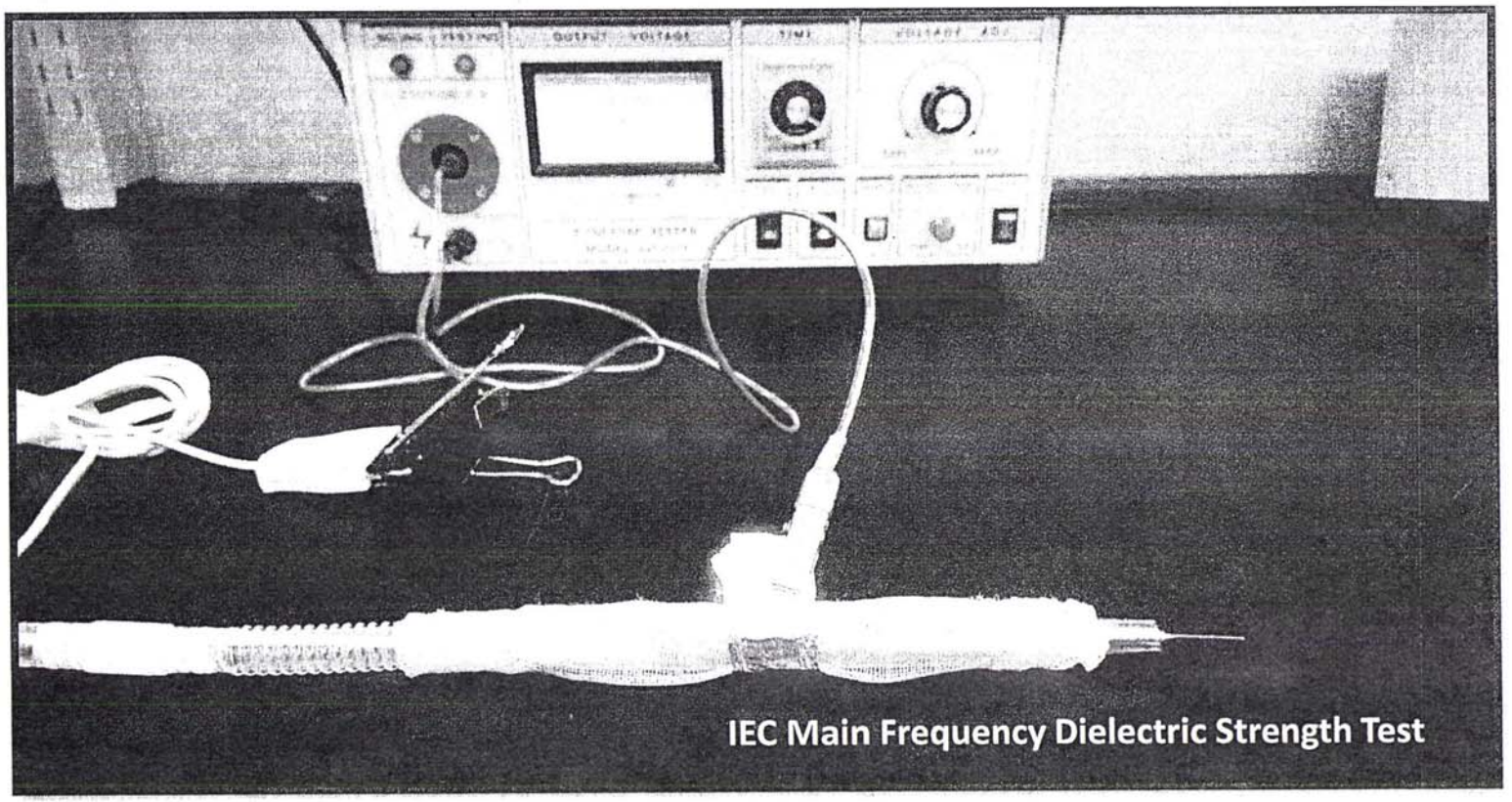
CALIBRATION INFORMATION	
Multimeter *Fluke 179 True-RMS Multimeter*	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
Generator *Mega Power 1000*	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope *Tektronix DPO 3012*	
Serial Number:	N/A
Megadyne Number:	01420
Calibration Date:	9/5/2013
Calibration Due:	9/30/2014
Hitpot Tester *Hipotronics Model HD 100 Series*	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe *Tektronix P6015A High Voltage Probe*	
Serial Number:	B032485
Megadyne Number:	01023
Calibration Date:	2/26/2013
Calibration Due:	2/28/2014
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	93808
Megadyne Number:	01094
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

NEW DEANTRONICS

PCB Overmold Discussion
12/30/2013

When we are making 120pcs ZIP PEN verification samples, we have also run a quick 30pcs verification test to go through the IEC test standard.

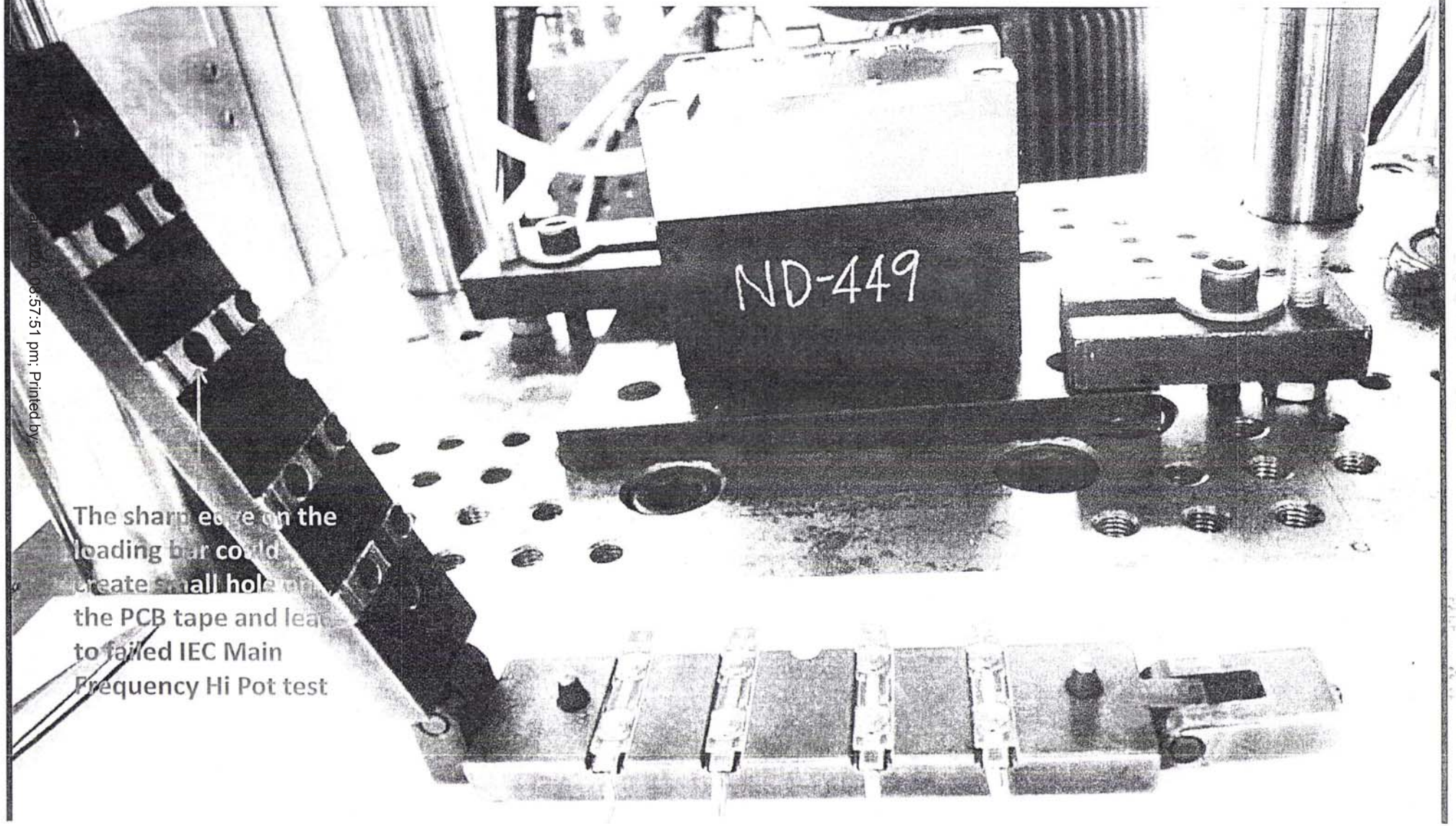
However, when running the IEC Main Frequency Dielectric Strength Test on the Handle with 30sec with 4Kvrms, we found some of the ZIP PEN might fail this test.



NEW DEANTRONICS

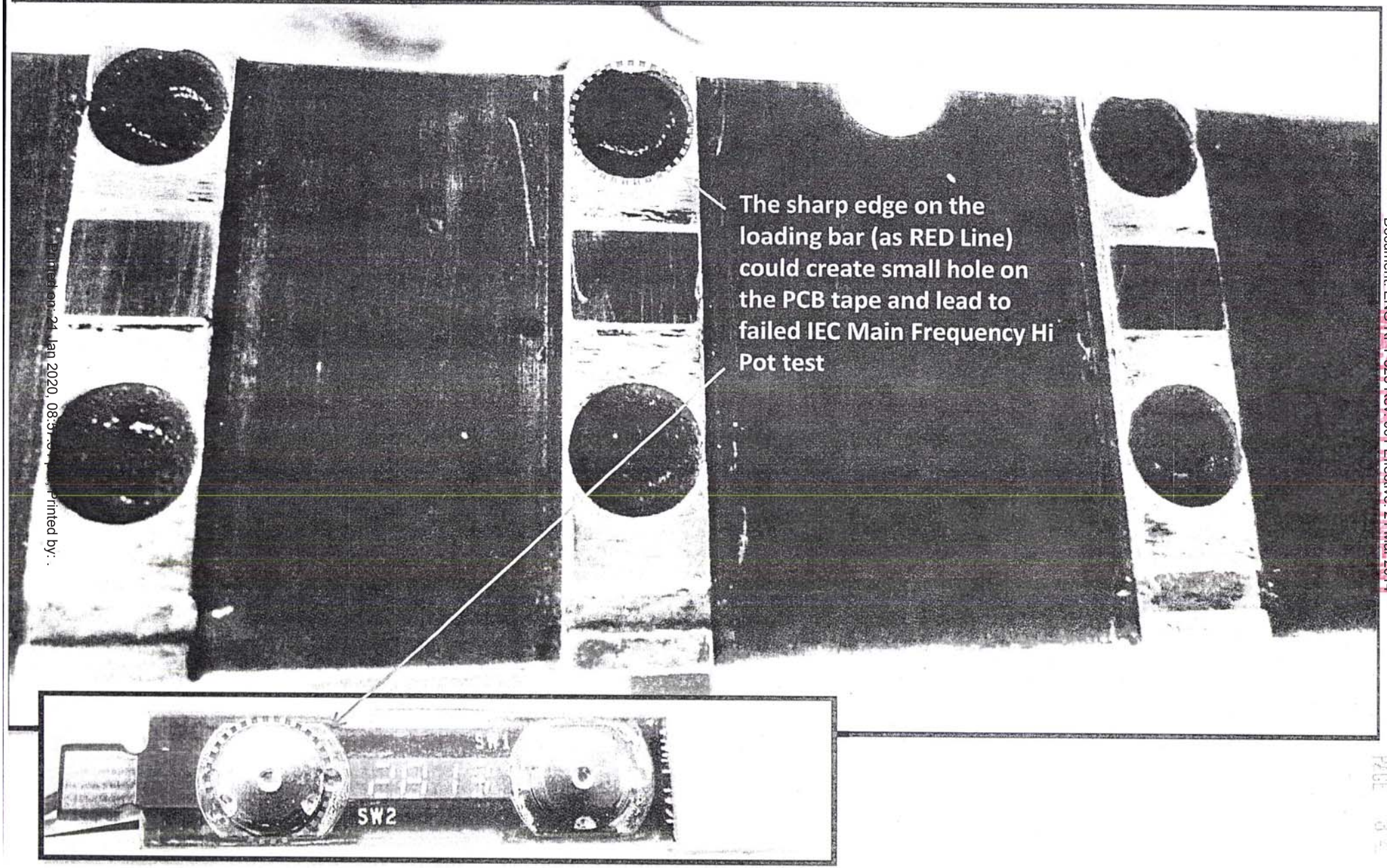
PCB Overmold Discussion
12/30/2013

We have further carefully looked into the issue and found that when doing PCB overmold, there is small sharp edge around the loading bar which could result in small holes on the tape.



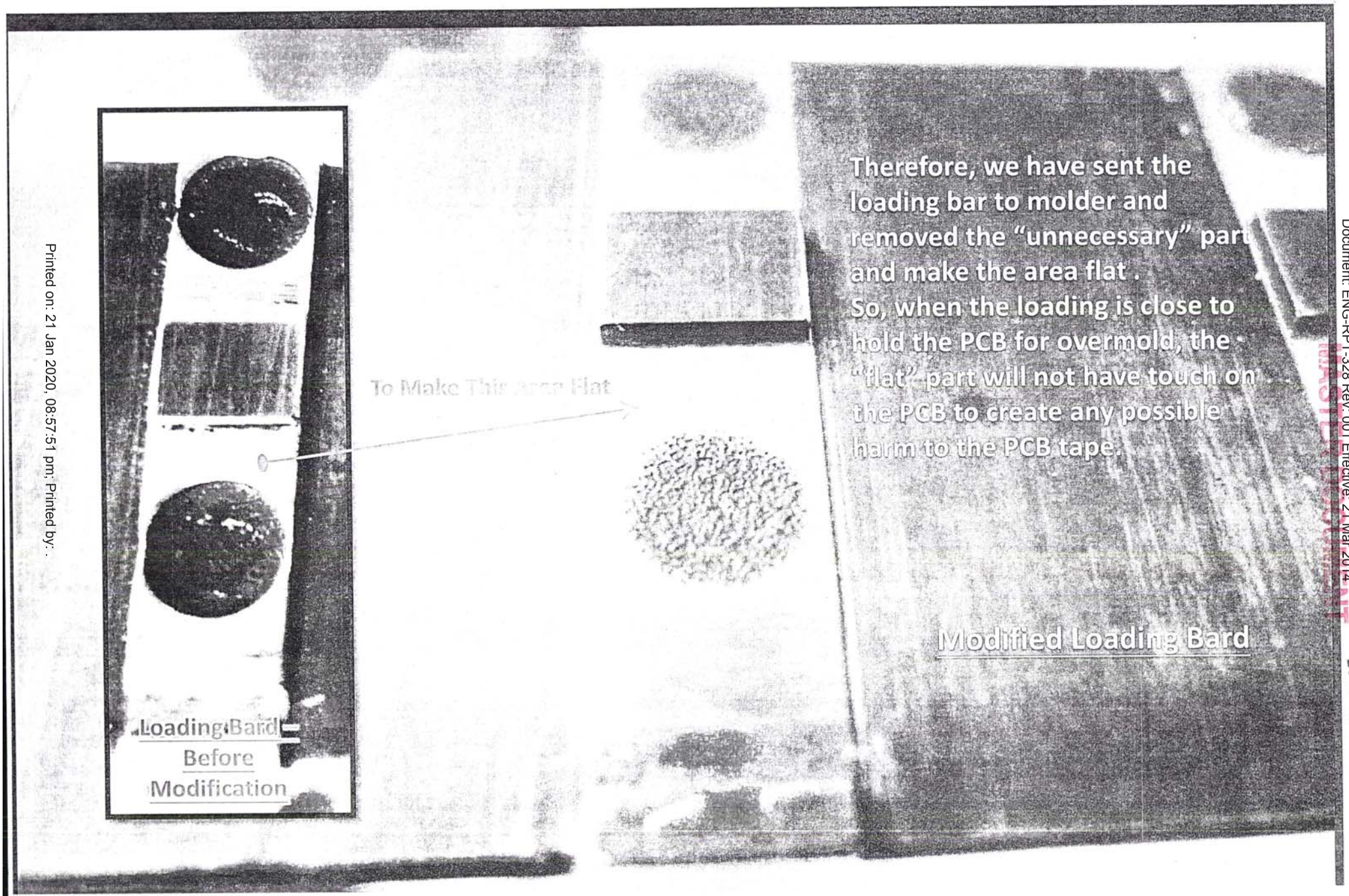
NEW DEANTRONICS

PCB Overmold Discussion
12/30/2013



NEW DEANTRONICS

PCB Overmold Discussion
12/30/2013



NEW DEANTRONICS

PCB Overmold Discussion
12/30/2013

So, after this improvement, we have further run 30pcs Verification test.

And all of the 30pcs could pass the total IEC tests.

Therefore, we have kept making the 120pcs verification samples. The 120pcs samples will be ready and sent for 50kGy GAMMA radiation on 12/30. Afterward, they could be sent out to you on 1/8

IEC Test Items	Visual Inspection	Continuity Test(Cut)	Continuity Test(Coag)	HF Dielectric Strength Test	Main Frequency Dielectris Strength	Fluid Ingress Test Before(Cut)	Fluid Ingress Test Before (Coag)	Fluid Ingress Test After(Cut)	Fluid Ingress Test After(Coag)

However, we have been thinking, if the accelerated aging samples will be tested in February with the same IEC test, the failed PCB hi pot might be caught as well.

If that is the case, we would like to discuss with you if this kind of fail could be defined as "process fail", rather than "product function/design fail".

We just thought to avoid having any delay due to the PCB overmold loading bar, is it possible if we could define it as "process flaw"? And after the loading bar improvement, will the product need to re-run the accelerated aging again?

Pencil Dielectric Withstand Testing

Data Collection Form

Sample	Configuration: T=0 Samples PENCILS	High Frequency		Mains	Button Activation
		Max V_{peak} (kV)	P/ F	P/ F	P/F
1	Zip Pen 2525-10 LOT S130409	6.68	PASS	PASS	PASS
2	Zip Pen 2525-10 LOT S130409	6.60	PASS	PASS	PASS
3	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
4	Zip Pen 2525-10 LOT S130409	6.68	PASS	PASS	PASS
5	Zip Pen 2525-10 LOT S130409	6.68	PASS	PASS	PASS
6	Zip Pen 2525-10 LOT S130409	6.60	PASS	PASS	PASS
7	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
8	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
9	Zip Pen 2525-10 LOT S130409	6.64	PASS	PASS	PASS
10	Zip Pen 2525-10 LOT S130409	6.76	PASS	PASS	PASS
11	Zip Pen 2525-10 LOT S130409	6.68	PASS	PASS	PASS
12	Zip Pen 2525-10 LOT S130409	6.60	PASS	PASS	PASS
13	Zip Pen 2525-10 LOT S130409	6.76	PASS	PASS	PASS
14	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
15	Zip Pen 2525-10 LOT S130409	6.60	PASS	PASS	PASS
16	Zip Pen 2525-10 LOT S130409	6.68	PASS	PASS	PASS
17	Zip Pen 2525-10 LOT S130409	6.60	PASS	PASS	PASS
18	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
19	Zip Pen 2525-10 LOT S130409	6.72	PASS	PASS	PASS
20	Zip Pen 2525-10 LOT S130409	6.76	PASS	PASS	PASS
21	Zip Pen 2525-10 LOT S130410	6.64	PASS	PASS	PASS
22	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
23	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
24	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
25	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
26	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
27	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
28	Zip Pen 2525-10 LOT S130410	6.76	PASS	PASS	PASS
29	Zip Pen 2525-10 LOT S130410	6.80	PASS	PASS	PASS
30	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
31	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
32	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
33	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
34	Zip Pen 2525-10 LOT S130410	6.64	PASS	PASS	PASS
35	Zip Pen 2525-10 LOT S130410	6.76	PASS	PASS	PASS
36	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
37	Zip Pen 2525-10 LOT S130410	6.60	PASS	PASS	PASS
38	Zip Pen 2525-10 LOT S130410	6.64	PASS	PASS	PASS
39	Zip Pen 2525-10 LOT S130410	6.64	PASS	PASS	PASS
40	Zip Pen 2525-10 LOT S130410	6.72	PASS	PASS	PASS
			1/21/2014 PV	1/27/2014 PV & TC	1/27-29/2014 PV & TC

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	

Paul Valpreda & Tom Carlyle — Operator Name — 1/29/2014 — Date

Paul Valpreda — Operator Signature — 1-29-2014 — Date

Operator Signature — Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter *Fluke 179 True-RMS Multimeter*	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2012
Calibration Due:	9/30/2014
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:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester *Hipotronics Model HD 100 Series*	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe *Tektronix P6015A High Voltage Probe*	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	1/25/2013
Calibration Due:	1/25/2014
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

APPENDIX II

Zip Pencil Cable Leakage, High Frequency and Main Frequency Dielectric

Cable Dielectric Withstand Testing
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-A2	2525-10 - LOT S130230	2.8	30	400	400	36.0	120.96	PASS	10
2-A2	2525-10 - LOT S130230	2.8	30	400	400	34.5	120.96	PASS	11
3-A2	2525-10 - LOT S130230	2.8	30	400	400	34.2	120.96	PASS	11
4-A2	2525-10 - LOT S130230	2.8	30	400	400	31.9	120.96	PASS	8
5-A2	2525-10 - LOT S130230	2.8	30	400	400	30.2	120.96	PASS	8
6-A2	2525-10 - LOT S130230	2.8	30	400	400	31.9	120.96	PASS	9
7-A2	2525-10 - LOT S130230	2.8	30	400	400	29.3	120.96	PASS	8
8-A2	2525-10 - LOT S130230	2.8	30	400	400	29.8	120.96	PASS	8
9-A2	2525-10 - LOT S130230	2.8	30	400	400	30.1	120.96	PASS	8
10-A2	2525-10 - LOT S130230	2.8	30	400	400	35.8	120.96	PASS	11
11-A2	2525-10 - LOT S130230	2.8	30	400	400	33.0	120.96	PASS	9
12-A2	2525-10 - LOT S130230	2.8	30	400	400	31.0	120.96	PASS	8
13-A2	2525-10 - LOT S130230	2.8	30	400	400	31.8	120.96	PASS	8
14-A2	2525-10 - LOT S130230	2.8	30	400	400	31.6	120.96	PASS	8
15-A2	2525-10 - LOT S130230	2.8	30	400	400	33.1	120.96	PASS	9
1-B2	2525-10 - LOT S130227	2.8	30	400	400	31.8	120.96	PASS	9
2-B2	2525-10 - LOT S130227	2.8	30	400	400	31.7	120.96	PASS	9
3-B2	2525-10 - LOT S130227	2.8	30	400	400	30.7	120.96	PASS	9
4-B2	2525-10 - LOT S130227	2.8	30	400	400	32.4	120.96	PASS	9
5-B2	2525-10 - LOT S130227	2.8	30	400	400	33.4	120.96	PASS	9
6-B2	2525-10 - LOT S130227	2.8	30	400	400	33.1	120.96	PASS	9
7-B2	2525-10 - LOT S130227	2.8	30	400	400	32.2	120.96	PASS	9
8-B2	2525-10 - LOT S130227	2.8	30	400	400	31.4	120.96	PASS	9
9-B2	2525-10 - LOT S130227	2.8	30	400	400	31.7	120.96	PASS	9
10-B2	2525-10 - LOT S130227	2.8	30	400	400	30.8	120.96	PASS	8
11-B2	2525-10 - LOT S130227	2.8	30	400	400	33.2	120.96	PASS	9
12-B2	2525-10 - LOT S130227	2.8	30	400	400	32.5	120.96	PASS	9
13-B2	2525-10 - LOT S130227	2.8	30	400	400	32.2	120.96	PASS	9
14-B2	2525-10 - LOT S130227	2.8	30	400	400	32.4	120.96	PASS	9
15-B2	2525-10 - LOT S130227	2.8	30	400	400	32.4	120.96	PASS	9
									2/7/2014 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-A2	2525-10 - LOT S130230	6.68	PASS	PASS
2-A2	2525-10 - LOT S130230	6.84	PASS	PASS
3-A2	2525-10 - LOT S130230	6.76	PASS	PASS
4-A2	2525-10 - LOT S130230	6.68	PASS	PASS
5-A2	2525-10 - LOT S130230	6.84	PASS	PASS
6-A2	2525-10 - LOT S130230	6.68	PASS	PASS
7-A2	2525-10 - LOT S130230	6.84	PASS	PASS
8-A2	2525-10 - LOT S130230	6.76	PASS	PASS
9-A2	2525-10 - LOT S130230	6.68	PASS	PASS
10-A2	2525-10 - LOT S130230	6.76	PASS	PASS
11-A2	2525-10 - LOT S130230	6.68	PASS	PASS
12-A2	2525-10 - LOT S130230	6.84	PASS	PASS
13-A2	2525-10 - LOT S130230	6.84	PASS	PASS
14-A2	2525-10 - LOT S130230	6.68	PASS	PASS
15-A2	2525-10 - LOT S130230	6.68	PASS	PASS
1-B2	2525-10 - LOT S130227	6.68	PASS	PASS
2-B2	2525-10 - LOT S130227	6.64	PASS	PASS
3-B2	2525-10 - LOT S130227	6.76	PASS	PASS
4-B2	2525-10 - LOT S130227	6.72	PASS	PASS
5-B2	2525-10 - LOT S130227	6.76	PASS	PASS
6-B2	2525-10 - LOT S130227	6.72	PASS	PASS
7-B2	2525-10 - LOT S130227	6.76	PASS	PASS
8-B2	2525-10 - LOT S130227	6.76	PASS	PASS
9-B2	2525-10 - LOT S130227	6.60	PASS	PASS
10-B2	2525-10 - LOT S130227	6.68	PASS	PASS
11-B2	2525-10 - LOT S130227	6.60	PASS	PASS
12-B2	2525-10 - LOT S130227	6.76	PASS	PASS
13-B2	2525-10 - LOT S130227	6.76	PASS	PASS
14-B2	2525-10 - LOT S130227	6.64	PASS	PASS
15-B2	2525-10 - LOT S130227	6.76	PASS	PASS
			2/7/2014 PV & TC	2/7/2014 TC

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 & Tom Carlyle — Operator Name — 2/7/2014 — Date

Paul Valpreda — Operator Signature — 2-7-2014 — Date

Operator Signature — Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True-RMS Multimeter	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
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:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

Secondary Equipment List (Station 2, Spa

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True-RMS Multimeter	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix DPO 3012	
Serial Number:	N/A
Megadyne Number:	01420
Calibration Date:	9/5/2013
Calibration Due:	9/30/2014
Hitpot Tester	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B032485
Megadyne Number:	01023
Calibration Date:	2/26/2013
Calibration Due:	2/28/2014
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	93808
Megadyne Number:	01094
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

APPENDIX III

Zip Pencil Plug Mains Frequency Dielectric Withstand

Plug Dielectric Withstand

Sample	Configuration	MAINS
		P/ F
A2-1	2525-10 - LOT S130230	PASS
A2-2	2525-10 - LOT S130230	PASS
A2-3	2525-10 - LOT S130230	PASS
A2-4	2525-10 - LOT S130230	PASS
A2-5	2525-10 - LOT S130230	PASS
A2-6	2525-10 - LOT S130230	PASS
A2-7	2525-10 - LOT S130230	PASS
A2-8	2525-10 - LOT S130230	PASS
A2-9	2525-10 - LOT S130230	PASS
A2-10	2525-10 - LOT S130230	PASS
A2-11	2525-10 - LOT S130230	PASS
A2-12	2525-10 - LOT S130230	PASS
A2-13	2525-10 - LOT S130230	PASS
A2-14	2525-10 - LOT S130230	PASS
A2-15	2525-10 - LOT S130230	PASS
B2-1	2525-10 - LOT S130227	PASS
B2-2	2525-10 - LOT S130227	PASS
B2-3	2525-10 - LOT S130227	PASS
B2-4	2525-10 - LOT S130227	PASS
B2-5	2525-10 - LOT S130227	PASS
B2-6	2525-10 - LOT S130227	PASS
B2-7	2525-10 - LOT S130227	PASS
B2-8	2525-10 - LOT S130227	PASS
B2-9	2525-10 - LOT S130227	PASS
B2-10	2525-10 - LOT S130227	PASS
B2-11	2525-10 - LOT S130227	PASS
B2-12	2525-10 - LOT S130227	PASS
B2-13	2525-10 - LOT S130227	PASS
B2-14	2525-10 - LOT S130227	PASS
B2-15	2525-10 - LOT S130227	PASS
		2/7/2014
		T.C.

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	4600	V_{RMS}

Thomas Carlyle — 2/7/2014

Operator Name — Date

Thomas L. Carlyle

Operator Signature — Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True-RMS Multimeter	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
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:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

Secondary Equipment List (Station 2, Spare):

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True-RMS Multimeter	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
Generator	
Mega Power 1000	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope	
Tektronix DPO 3012	
Serial Number:	N/A
Megadyne Number:	01420
Calibration Date:	9/5/2013
Calibration Due:	9/30/2014
Hitpot Tester	
Hipotronics Model HD 100 Series	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	B032485
Megadyne Number:	01023
Calibration Date:	2/26/2013
Calibration Due:	2/28/2014
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	93808
Megadyne Number:	01094
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

APPENDIX IV

Holster High Frequency and Main Frequency Dielectric

2014 MAR 21

Zip Pencil Holster Dielectric Withstand Testing
Data Collection Form

Sample	Configuration	High Frequency		Mains
		Max V_{peak} (kV)	P/ F	P/ F
A2-1	2525-10 - LOT S130230	6.76	PASS	PASS
A2-2	2525-10 - LOT S130230	6.76	PASS	PASS
A2-3	2525-10 - LOT S130230	6.68	PASS	PASS
A2-4	2525-10 - LOT S130230	6.76	PASS	PASS
A2-5	2525-10 - LOT S130230	6.60	PASS	PASS
A2-6	2525-10 - LOT S130230	6.92	PASS	PASS
A2-7	2525-10 - LOT S130230	6.84	PASS	PASS
A2-8	2525-10 - LOT S130230	6.84	PASS	PASS
A2-9	2525-10 - LOT S130230	7.00	PASS	PASS
A2-10	2525-10 - LOT S130230	6.76	PASS	PASS
A2-11	2525-10 - LOT S130230	6.84	PASS	PASS
A2-12	2525-10 - LOT S130230	6.76	PASS	PASS
A2-13	2525-10 - LOT S130230	6.76	PASS	PASS
A2-14	2525-10 - LOT S130230	6.76	PASS	PASS
A2-15	2525-10 - LOT S130230	6.68	PASS	PASS
B2-1	2525-10 - LOT S130227	6.84	PASS	PASS
B2-2	2525-10 - LOT S130227	6.76	PASS	PASS
B2-3	2525-10 - LOT S130227	6.68	PASS	PASS
B2-4	2525-10 - LOT S130227	6.68	PASS	PASS
B2-5	2525-10 - LOT S130227	6.68	PASS	PASS
B2-6	2525-10 - LOT S130227	6.76	PASS	PASS
B2-7	2525-10 - LOT S130227	6.68	PASS	PASS
B2-8	2525-10 - LOT S130227	6.68	PASS	PASS
B2-9	2525-10 - LOT S130227	6.68	PASS	PASS
B2-10	2525-10 - LOT S130227	6.68	PASS	PASS
B2-11	2525-10 - LOT S130227	6.76	PASS	PASS
B2-12	2525-10 - LOT S130227	6.84	PASS	PASS
B2-13	2525-10 - LOT S130227	6.76	PASS	PASS
B2-14	2525-10 - LOT S130227	6.68	PASS	PASS
B2-15	2525-10 - LOT S130227	6.68	PASS	PASS
			2/8/2014 T.C.	2/8/2014 T.C

Rated Accessory V_{peak}	5,500	V_{peak}
Minimum Mains Test Value	4,596	V_{RMS}
Actual Mains Test Value	4600	V_{RMS}
Mains Test Value Calculation:	(Rated Accessory V_{peak} +1000V_{peak}) / √2	

Thomas Carlyle — Operator Name — 2/14/2014 — Date

Operator Signature — Date

Primary Equipment List (Station 1, Paul's):

CALIBRATION INFORMATION	
Multimeter *Fluke 179 True-RMS Multimeter*	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
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:	10/19/2013
Calibration Due:	10/31/2014
Hitpot Tester *Hipotronics Model HD 100 Series*	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe *Tektronix P6015A High Voltage Probe*	
Serial Number:	B043063
Megadyne Number:	01138
Calibration Date:	7/23/2013
Calibration Due:	7/31/2014
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	109055
Megadyne Number:	01288
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4540017
Megadyne Number:	01255
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014

Secondary Equipment List (Station 2, Spare):

CALIBRATION INFORMATION	
Multimeter *Fluke 179 True-RMS Multimeter*	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/20/2013
Calibration Due:	9/30/2014
Generator *Mega Power 1000*	
Serial Number:	10353001
Megadyne Number:	N/A
Calibration Date:	N/A
Calibration Due:	N/A
Oscilloscope *Tektronix DPO 3012*	
Serial Number:	N/A
Megadyne Number:	01420
Calibration Date:	9/5/2013
Calibration Due:	9/30/2014
Hitpot Tester *Hipotronics Model HD 100 Series*	
Megadyne Number:	01037
Calibration Date:	8/27/2013
Calibration Due:	8/31/2014
High Voltage Probe *Tektronix P6015A High Voltage Probe*	
Serial Number:	B032485
Megadyne Number:	01023
Calibration Date:	2/26/2013
Calibration Due:	2/28/2014
Inductive Current Coil *Pearson Current Monitor, Model 2100*	
Serial Number:	93808
Megadyne Number:	01094
Calibration Date:	2/3/2014
Calibration Due:	2/3/2015
RMS Voltmeter *Fluke 8920A True RMS Voltmeter*	
Serial Number:	4220005
Megadyne Number:	01254
Calibration Date:	11/1/2013
Calibration Due:	11/1/2014