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DOCUMENT NUMBER: ENG-PRT-421

DOCUMENT TITLE: Gray Sumitomo A4 Heat Shrink Design Qualification

DOCUMENT NOTES:

Document Information

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

Date Information

Effective Date: 23 Aug 2017	Expiration Date:
Release Date: 23 Aug 2017	Next Review Date:

Control Information

Author: TSKINNER	Owner: TSKINNER
Previous Number:	Change Number: 2017-ENG-DCO-072

Signature Manifest

Document Number: ENG-PRT-421 **Revision:** 001

Title: Gray Sumitomo A4 Heat Shrink Design Qualification

All dates and times are in Mountain Standard Time.

Gray Insulation Design Verification

Change Request

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ENG-Approval

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Training Review

Name/Signature	Title	Date	Meaning/Reason
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Final Release

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)			
Lucy Richards (LRICHARDS)		23 Aug 2017, 02:02:38 PM	Approved

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TABLE OF CONTENTS **Page**

1. SCOPE

Gray Sumitomo A4 heat shrink (PN 4100048-06) with a new gray colorant as used in electrosurgical electrodes is evaluated.

2. PURPOSE

Successful completion of this protocol will demonstrate, through objective evidence that Gray Sumitomo A4 heat shrink (PN 4100048-06) meets DMR requirements (see ENG-DMR-001) and is considered safe for clinical use.

3. REFERENCES

X4100048	Tubing, Heat Shrink, Polyolefin, Sumitomo
QA-SOP-012	Sampling and Statistical Techniques
ENG-RMF-008	E-Z Clean Electrodes Risk Analysis
ENG-PRT-096	Dielectric Withstand of Medical Devices, Accessories, and Cables
IEC 60601-2-2 Ed. 5	Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment
ENG-PRT-106	Insulation Bond Strength Test Protocol
ENG-PRT-104	Electrode Insertion/Extraction Test Protocol
ENG-PRT-019	Heat Shrink Print Adhesion

4. BACKGROUND

The ACE blade electrode will be relaunched with a gray version of the current insulation (updated from violet). The same verified insulation material (Sumitomo A4 heat shrink) is used, with the only difference being the gray colorant. As such, this is primarily a due diligence study to ensure that no unforeseen risks are associated with this minor change.

5. EQUIPMENT

- Environmental Chamber
- LAB AccuDrop 160
- Martin Vibration Systems Vibration Table
- Metal shim 0.06 in thick, approximately 2 in wide
- See ENG-PRT-096 for Dielectric Test Equipment

- See ENG-PRT-106 for Bond Strength Test Equipment
- See ENG-PRT-104 for Electrode Insertion/Extraction Test Equipment
- See ENG-PRT-019 for Print Pad Adhesion Test Equipment

6. RISK ASSESSMENT

The FMEA for E-Z Clean Electrodes (ENG-RMF-008) was reviewed while considering the use of Gray Sumitomo A4 heat shrink. The following line items were found to be applicable:

Line Item	Failure Mode
22-D	Insulation does not have proper insulation effects
23-D	Distal end of insulation thermally degrades, deforms, splits or breaks off during use
25-D	Insulation is not biocompatible
26-D	Insulation damaged by sterilization
27-D	Insulation slips on substrate exposing conductive surface
29-D	Insulation lasts less than 5 years, degrades & falls off.
30-D	Electrode has potential alternate current pathway
31-D	Electrode has potential alternate current pathway
33-D	Marking is removed by exposure to fluid ingress in surgery
34-D	Pad print damaged by sterilization & flakes off
35-D	Pad print lasts less than 5 years, degrades and flakes off
60-D	PTFE insulation is pulled of when removing cap – Cap too tight
61-D	PTFE insulation is pulled of when removing cap – PTFE too large
62-D	PTFE insulation is pulled of when removing cap – Electrode undersized

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

- For line items 22-D, 23-D, 30-D and 31-D, dielectric testing will be performed as outlined in ENG-PRT-096.
- For line item 25-D, a biocompatibility study including Cytotoxicity (MEM), Sensitization, and Irritation testing will be performed per ISO 10993by Nelson Laboratories (see XENG-PRT-422).
- For line items 26-D and 34-D, all insulation and pad print test will be performed once post Gamma Sterilization and once post EO Sterilization.
- For line item 27-D, bond strength testing will be performed as outlined in ENG-PRT-106.
- For line item 29-D, 5-year aging will not be performed for the Gray Sumitomo A4 insulation (4100048-06) because acceptable 5-year accelerated aging data has been obtained for Sumitomo A4 insulation of other colors (see the reports for purple (ENG-RPT-175) and green (ENG-RPT-313). This supporting data provides reasonable assurance that the Gray Sumitomo A4 insulation shall have

similar 5-year accelerated aging properties. Therefore, there is negligible risk for not performing 5-year accelerated aging for the Gray Sumitomo A4 insulation.

Acceptable data from T=0 testing for the Gray Sumitomo A4 insulation, together with the supporting data from the purple and green Sumitomo A4 insulation, shall provide reasonable assurance that the material used for the Gray Sumitomo A4 insulation is functionally equivalent to the material used for the purple and green Sumitomo A4 insulation.

- For line item 33-D, pad print adhesion testing will be performed as outlined in ENG-PRT-019.
- For line item 35-D, 5-year accelerated aging tests will not be performed to verify the interactions between the pad printer ink and the gray insulation because acceptable 5-year accelerated aging data has been obtained for the interactions of the ink with other colors of the same type of insulation (see the reports for purple (ENG-RPT-046 & ENG-RPT-047) and green (ENG-RPT-313). This supporting data provides reasonable assurance that the interaction between the pad printer ink and the Gray Sumitomo A4 insulation shall have similar 5-year accelerated aging properties. Therefore, there is negligible risk for not performing 5-year accelerated aging pad print ink adhesion tests.

  Acceptable data from pad print adhesion T=0 testing evaluating the interaction between the pad printer ink and the Gray Sumitomo A4 insulation, together with the supporting data from the interaction between the pad printer ink and the purple and green Sumitomo A4 insulation, shall provide reasonable assurance that the interaction between the pad printer ink and the Gray Sumitomo A4 insulation is functionally equivalent to that of the purple and green Sumitomo A4 insulation.
- For line items 60-D, 61-D, and 62-D a modified insulation pull test will be performed as outlined in ENG-PRT-176.

  NOTE: Line item 28-D was reviewed for this project. The test prescribed by the FMEA does not address the lubriciousness of the insulation material. Only the substrate interacts with the collet during the insertion/extraction test. The lubricity of the insulation material with a new colorant does not affect the electrode extraction force. The bond strength test above adequately assesses friction in the insulation material. It will be recommended that this risk be removed from the FMEA.

7. EXPERIMENTAL DESIGN/SAMPLE SIZE JUSTIFICATION

7.1. Experimental Design

All visual inspections are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 - 18 inches, for no longer than 5 seconds.

7.1.1. Dielectric Testing

7.1.1.1. Dielectric Testing will be performed as outlined in ENG-PRT-096 Section 12.

7.1.1.2. XACE14M Rev A samples will be used for this test as the dielectric properties of the gray insulation function independent of insulation length. Therefore, XACE14M samples serve as a representative dielectric test sample for all electrode insulated with gray insulation (4100048-06).

7.1.2. Bond Strength Testing

7.1.2.1. Bond Strength Testing will be performed as outlined in ENG-PRT-106 Section 7.

7.1.2.2. X6020150 Rev A samples will be used for this test as the bond strength between the gray insulation (4100048-06) and electrode substrate are dependent upon the contact surface area. Therefore, X6020150 samples represent a worst-case scenario as the contact surface area is smaller than all other marketed electrodes lengths.

7.1.3. Pad Print Adhesion

7.1.3.1. Pad Print Adhesion Testing will be performed as outlined in ENG-PRT-019 Section 10.

7.1.3.2. XACE14M Rev A samples will be used as pad print adhesion testing verifies the interaction between the pad print and the insulation regardless of insulation length. Therefore, XACE14M samples serve as a representative pad print adhesion test sample for all electrodes insulated with gray insulation (4100048-06).

7.1.4. Modified Insulation Pull Test

7.1.4.1. Modified Insulation Pull Test will be performed as outlined in ENG-PRT-176 Section 7.8 and 7.9.

7.1.4.2. Engineering built 2.75" ACE Blades test samples with elongated 2.5" PTFE insulation and gray heat shrink insulation (4100048-06) will be used for modified pull force testing. The engineering built test samples will be built using normal manufacturing processes and accepted materials (see ZIP ACE DHF - Memo Date: 5/24/17 from Tyler Skinner). These samples are representative of all modified electrode blade lengths as the surface area interaction between the electrode substrate, PTFE insulation, and gray insulation does not vary with blade length.

7.2. Sample Size Justification

7.2.1. Dielectric Testing: A sample size of 22 (XACE14M Rev. A Lot#: Prototype) will be used for dielectric testing in a C = 0 sampling plan. This is based on a lot size of up to 10,000 and an AQL of 4.0. Although normally this defect classification is Critical (per QA-SOP-012), a classification of minor will be used as extensive dielectric data for the same material in different colors (green and purple) provides reasonable evidence to demonstrate the dielectric properties of the proposed gray insulation.

7.2.2. Bond Strength Testing: A sample size of 22 (X6020150 Lot#: GrayACE12) for bond strength testing will be used in a C = 0 sampling plan. This is based on a lot size of up to 10,000 and an AQL of 4.0. Although normally this defect classification is Critical (per QA-SOP-012), a classification of minor will be used as extensive bond strength data for the same material in different colors (green and purple) provides reasonable evidence to demonstrate the bond strength properties of the proposed gray insulation.

7.2.3. Pad Print Adhesion: A sample size of 22 (XACE14M Rev. A Lot#: Prototype) will be used for each solution during pad print adhesion testing in a C = 0 sampling plan. This is based on a lot size of up to 10,000 and an AQL of 4.0. Although normally this defect classification is Critical (per QA-SOP-012), a classification of minor will be used as extensive pad print adhesion data for the interaction between the pad printer ink and the same insulation material in different colors (green and purple) provides reasonable evidence to demonstrate the interaction between the pad printer ink and the proposed gray insulation.

7.2.4. Modified Insulation Pull Testing: A sample size of 22 of engineering built 2.75" ACE Blades with elongated 2.5" PTFE insulation and gray heat shrink insulation will be used for bond strength testing in a C = 0 sampling plan. This is based on a lot size of up to 10,000 and an AQL of 4.0. Although normally this defect classification is Critical (per QA-SOP-012), a classification of minor will be used as extensive modified pull test data for a similar product with purple heat shrink insulation provides reasonable evidence to demonstrate the retention force of the modified insulation.

8. SAMPLE PREPARATION

8.1. Sterilize all samples to be used in testing following the table below:

Test Description	Sample - Part #/ Lot #	Sterilization Required
Dielectric Testing	XACE14M Rev A / Prototype	2X Gamma & 2X EO
Bond Strength Testing	X6020150 / Gray ACE12	2X Gamma & 2X EO
Print Pad Adhesion	XACE14M Rev A / Prototype	2X Gamma & 2X EO
Modified Insulation Pull	Engineering Built – 2.75" Blade w/ 2.5" PTFE Insulation	2X EO

EO sterilization will be performed as follows:

Preconditioning Set Points:	
Temperature:	43.3°C
Relative Humidity:	60%
Time (Minimum):	24 hours
Time (Maximum)	n/a
Sterilization Set Points:	
EO Gas Concentration:	804 mg/L (100% EO)
Temperature:	48.9°C
Relative Humidity:	50%
Initial Vacuum:	1.0psia
EO Gas Dwell Time:	240 minutes
Steam Dwell Time:	60 minutes
Aeration Set Points:	
Temperature:	43.3 ± 5°C
Time (Minimum):	24 hours

Gamma Sterilization will be performed by Steris using a minimum specified dose of 25 kGy and maximum specified dose of 40 kGy.

NOTE: 2X Gamma and EO cycles are used to ensure that product has been exposed to a maximum sterilization dose.

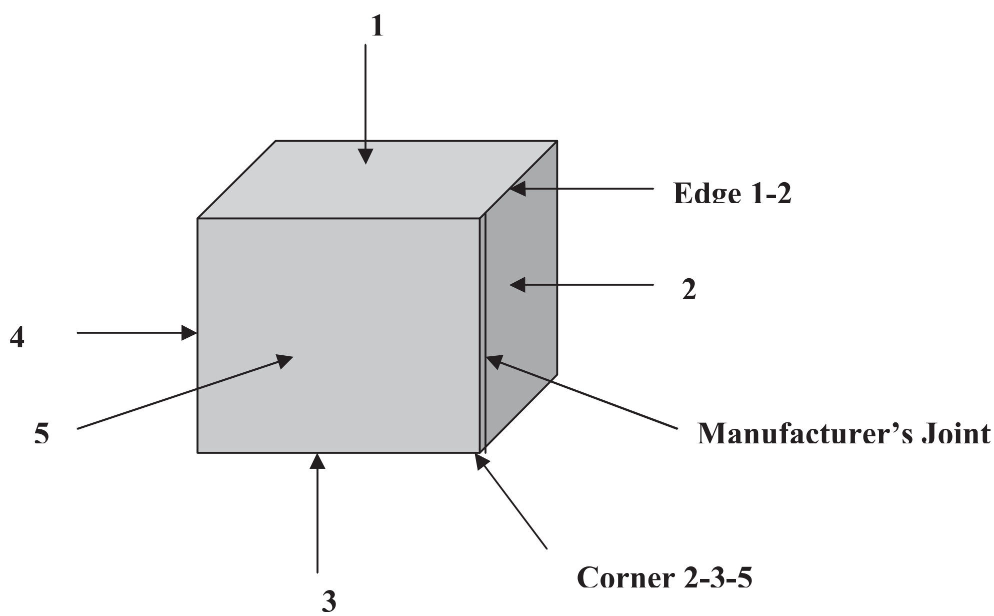
8.2. Precondition the product following the schedule the temperature and humidity schedule listed below.

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability

Hold -40°C no humidity control	4 hours
Transition from -40°C to 70°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 70°C to 70°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 95%RH	4 hours
Transition from 70°C and 95% RH to 70°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 15%RH	4 hours
Transition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 23°C and 50%RH	72 hours

8.3. Following preconditioning, perform a simulated shipping test.

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



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

8.6. Record the Catalog number of the product.

8.7. Record the Lot Number of the product.

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

8.8.1. The required drop height from ASTM D4169 paragraph 10.2.3, using assurance level II, is 15 inches for packages from 0 to 20 pounds. Package weight is approximately 2.5 pounds.

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

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

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

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

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

Where L is the computer load (lb), M is the mass, J = 1 lbf/lb, H= 108 in, h = height of package (in), and F = 3.0 (see 11.2 of ASTM D4169).

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

8.9.2. Place a wood board on top of the shipper box, such that the shipper box is centered underneath the board. The wood board must extend a minimum of two inches on all sides of the box.

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

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

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

8.10. Following the compression test, perform the Loose Load Vibration test per ENG-WI-007. Record information in Appendix I.

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

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

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

8.10.4. Check the frequency using the shim.

8.10.4.1. Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other. At this low frequency, the movement of the shim will be interrupted movement.

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

8.10.6. After 40 minutes of Loose Load Vibration, increase the frequency for the Vehicle vibration.

8.10.7. Check the frequency using the shim.

8.10.7.1. Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel uninterrupted on the long side of the box from one end of the box to the other.

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

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

8.11. Following the vibration test, perform a concentrated impact test.

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

8.11.2. The impact energy applied to each surface will be 4.0 ft-lbf (5.4 J). This energy will be achieved by dropping the cylinder mass defined within the ENG-DWG-768 equipment at a height of 32 in (0.8 m).

8.12. Following the concentrated impact test, perform the second package handling (drop test). Follow the sequence listed below. Make all of the drops from 15 inches except the final drop which is from 30 inches.

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

8.13. Record completion of sample preparation (Preconditioning and shipping simulation) in Appendix 1.

9. PROCEDURE

9.1. Dielectric Testing

9.1.1. Perform Leakage current, using a sample size of 22 (XACE14 Rev A. Lot#: Prototype), as outlined in ENG-PRT-096 Section 12.

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

9.1.3. Perform High Frequency Dielectric Withstand Testing, using the same sample size of 22 (XACE14 Rev A. Lot#: Prototype), as outlined in ENG-PRT-096 Section 12.

9.1.4. Record data in Appendix II and attach results to report.

9.1.5. Perform Mains Frequency Dielectric Withstand Testing, using the same sample size of 22 (XACE14 Rev A. Lot#: Prototype), as outlined in ENG-PRT-096 Section 12.

9.1.6. Record data in Appendix II and attach results to report.

9.2. Bond Strength Testing

9.2.1. Perform Bond Strength Testing, using a sample size of 22 (X6020150 Lot#: GrayACE12), as outlined in ENG-PRT-106 Section 7.

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

9.3. Pad Print Adhesion

9.3.1. Perform Pad Print Adhesion Testing, using a sample size of 22 (XACE14 Rev A. Lot#: Prototype) for each solution, as outlined in ENG-PRT-019 Section 10.

9.3.2. Record data in Appendix IV and attach results to report.

9.4. Modified Insulation Pull Test

9.4.1. Perform Modified Insulation Pull Force Testing, using a sample size of 22 engineering built 2.75” ACE Blades with elongated 2.5” PTFE insulation and gray heat shrink insulation, as outlined in ENG-PRT-176 Section 7.8 and 7.9.

9.4.2. Record data in Appendix V and attach results to report.

10. ACCEPTANCE CRITERIA

10.1. Dielectric Testing (see ENG-PRT-096 Section 14.4)

10.1.1. Leakage Current

10.1.1.1. The requirement indicates that high frequency leakage current, in RMS mA of electrodes intended for use with electrosurgical generators shall not exceed a calculated upper limit value of the formula:

$I_{leakage} = 9.0 \times 10^{-7} * d * L * f_{test} * U_{peak} =$ __________ (mA)

Where:

d = smallest outer dimension of the insulation (mm)

L = length of insulation where leakage current is being tested (mm)

f_{test} = test voltage frequency (kHz)

$U_{peak} = Vpp/2$

10.1.2. High Frequency Dielectric Withstand Testing

10.1.2.1. The device cable is considered acceptable if the 1.2 times (120%) voltage is maintained for 30 s, and;

10.1.2.2. There were no visible signs of damage such as melted insulation.

10.1.3. Mains Frequency Dielectric Withstand Testing

10.1.3.1. The cable and device are considered acceptable and pass this test if the full test voltage was reached and maintained for 30s and;

10.1.3.2. There were no visible signs of damage such as melted insulation and;

10.1.3.3. The HiPot did not alarm.

10.2. Bond Strength Testing (see ENG-PRT-106 Section 8)

10.2.1. The insulation should produce a minimum bond strength value of 10 lb.

10.2.2. The insulation jacket should not break loose and slip over non-coated portions of the electrode during testing. Accordion style compression of the insulation, without breaking loose and sliding, is considered acceptable.

10.3. Pad Print Adhesion (see ENG-PRT-019 Section 11)

10.3.1. After completion of soak and wipe procedures, the ink should still be legible.

10.4. Modified Insulation Pull Test (see ENG-PRT-176 Section 8)

10.4.1. The data of the test group should be statistically equal to or better than the control group data gathered in ENG-RPT-257. (Mean 4.40, -3 sigma 3.93, +3 sigma 4.87)

11. APPENDIX I – SAMPLE PREPARATION

Preconditioning:

Start Date: ____________________________ Chamber Number:__________

Completion Date: ____________________________ Last Calibration:___________

Signature/Date: ____________________________ Calibration due:____________

Drop Test:

Catalog _____________ Weight ___________ Drop Height: ______________

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

Comments:

Signature: ____________________________ Date: _______________

Compression Test:

Catalog ___________________ Pounds Force ____________________

Comments:

Signature: ____________________________ Date: _______________

Appendix I Continued
Sample Preparation

Vibration:

Low Frequency, 40 minutes, Initials_______ ______

High frequency 10 minutes, Initials ____________

Completion Date: ___________________

Signature: ____________________________ Date: _______________

Concentrated Impact Test:

Completion Date: ___________________

Signature: ____________________________ Date: _______________

Second Drop Test:
Catalog____________Weight _____________ Drop Height: _________

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

Comments:

Signature: ____ Date: ______________

12. APPENDIX II – DIELECTRIC TESTING

Electrode Dielectric Withstand Testing
Product Tested
Data Collection Form

Sample	Configuration	d (mm)	L (cm)	LEAKAGE ftest (kHz)	Upeak (Vp-p)/2	Measured Leakage	Calculated Leakage	Acceptable P/F	Power (W)
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
17									
18									
19									
20									
21									
22									

d = smallest measured outer dimension of insulation
L = length of 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				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				

Mains Test Value Calculation:
(Rated Accessory V_{peak} +1000V_{peak}) / √2

Rated Accessory V_{peak}		V_{peak}
Minimum Mains Test Value		V_{RMS}
Actual Mains Test Value		V_{RMS}

	1/30/2017
Operator Name	Date
Operator Signature	Date

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True RMS Multimeter	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
Generator	
Mega Power 1000	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
Oscilloscope	
Tektronix TDS 3012B	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
Hitpot Test Generator	
Hipotronics Model HD 100 Series	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
High Voltage Probe	
Tektronix P6015A High Voltage Probe	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
Inductive Current Coil	
Pearson Current Monitor, Model 2100	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
RMS Voltmeter	
Fluke 8920A True RMS Voltmeter	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	
Digital Calipers	
Starrett	
Serial Number:	
Megadyne Number:	
Calibration Date:	
Calibration Due:	

13. APPENDIX III – BOND STRENGTH TESTING

Sumitomo A4 Gray Insulation	
Sample #	(lbs.)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
Mean	
STD	
+ 3 Sig	
- 3 Sig	

Performed by: ____Date:_____________

14. APPENDIX IV – PAD PRINT ADHESION

Pad Print Adhesion Testing		
Sample #	P(Pass) / F(Fail) 0.9% Saline	P(Pass) / F(Fail) 70% IPA
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		

Performed by: ____Date:____________

15. APPENDIX IV – MODIFIED INSULATION PULL FORCE

PTFE Insulation Pull Data	
Sample #	(lbs.)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	
15	
16	
17	
18	
19	
20	
21	
22	
Mean	
STD	
+ 3 Sig	
- 3 Sig	

Performed by: ____Date:____________