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ISOS2 EO Compatibility Testing

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1. REFERENCES

IEC 60601-2-2:2009	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
IEC 60601-1: 2012	Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance
XENG-PS-010	Product Specification: Disposable Electrosurgical Pencil
XENG-RMF-001	Pencil Risk Analysis
XENG-IOM-014	Input/Output Conformance Matrix Disposable Electrosurgical Pencil
ENG-WI-001	Sterilization Chart

2. APPENDIX

I. Visual Attributes
II. Cord Length
III. Electrode Deviation (Wobble)
IV. Electrode Torque
V. Pencil Weight
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VII. Datasheet for Dielectric Testing
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3. SCOPE

This test protocol evaluates the function of the updated ISOS2 design after exposure to EO sterilization. Pencil characteristics related to standards and those that may be affected by the plastic will be tested.

This testing demonstrates that all pencil codes will remain functional after exposure to EO gas for sterilization prior to accelerated aging.

Testing in this protocol is relevant for product codes 0036, 0037, 0036H, 0037H, ACE36H, and ACE37H.

Both rocker and button switch pencils are covered in both finished sterile and bulk non-sterile configurations.

4. PURPOSE

This testing demonstrates design conformance to product specifications and industry standards. In every case, these specifications have been developed using company knowledge over years of marketing similar products, clinical experience, engineering expertise, knowledge of current standards, and applying well established risk management practices.

5. DEFINITIONS AND ACRONYMS

ESU	Electrosurgical Unit
IFU	Instructions for Use

6. APPARATUS

6.1. Torque Watch

6.2. Electrode Torque Fixture

6.3. Electrode Wobble Fixture

6.4. Tape Measure or other measurement device

6.5. Collet Stress fixture

6.6. ROI Visual Measurement System

6.7. Calculator

6.8. HiPot Tester

6.9. Ohmmeter (or multi-meter)

6.10. 0.9% Saline solution

6.11. Plastic holding tub for soaking cables

6.12. Valleylab Force FX ESU or equivalent (having an approximately sinusoidal waveform with frequency between 300 kHz and 1 MHz)

6.13. Modified Mega Power ESU or equivalent (having an approximately sinusoidal waveform with frequency between 300 kHz and 5 kHz with a Crest Factor = 6 +/- 10%)

6.14. Electrosurgical Unit (ESU) – Mega Power

6.15. TDS 2014 Tektronix Oscilloscope, or equivalent

6.16. 1000:1 High Voltage Probe

6.17. Saline (pickle jar) fixture

6.18. Electrosurgical generator foot switch

6.19. Inductive current coil with an output of 1Volt per 1 Amp

6.20. Workbench with insulated top (preferably wood)

6.21. 3:1 step-up transformer

6.22. Fluke 8920A True RMS Voltmeter, or equivalent

6.23. Solid 26 gage wire

6.24. Aluminum Foil

6.25. Paper towel or porous cloth

6.26. Appropriate leads for connection of the test set-up

6.27. Container to support device and hold 1 Liter of fluid

6.28. Stop watch or equivalent

6.29. Function generator

6.30. Current loop

6.31. Disposable Return Electrode

6.32. 0014 and 0014A EZ-Clean Electrodes

6.33. Thermal IR Camera, FLIR T300

6.34. Tripod

6.35. Digital Camera

6.36. Peel Strength Fixture

6.37. Distilled Water

6.38. Ethanol 96%

6.39. Isopropyl Alcohol 70%

6.40. Environmental Chamber

6.41. LAB AccuDrop 160

6.42. Martin Vibration Systems Vibration Table

6.43. Metal shim 0.06 in thick, approximately 2 in wide

7. RISK ASSESSMENT

7.1. Risk Analysis ENG-RMF-001 (Pencil Risk Analysis) identifies the risks associated with the disposable electrosurgical pencil. The highest severity rating is 10, attributable to potential user or patient injury.

Failure Mode	Cause	Mitigation	Verification
Self activation from fluid ingress	Fluid enters housing, causing short circuit	Splash proof design and fluid resistant materials	Meets requirements of IEC 60601-1
Fails dielectrically allowing burn thru.	Insufficient amount and/or dielectric strength of housing material, or inner conductors too close to housing walls	Handpiece design, material and product validation	Test according to requirements of IEC 60601-2-2
Cracks, fails, or falls apart.	Material Selection not gamma and/or ETO table. Fails from abuse when used as a prying instrument.	Identification and use of appropriately strong and biocompatible materials. Design with gamma and ETO stable materials.	Test according to applicable IEC Standards for single use electrosurgical accessories.

Failure Mode	Cause	Mitigation	Verification
Button/Rocker sticks, extending activation time.	Ingress of blood and/or other fluids causing “sticky” rocker. Design causes binding.	Design to keep fluid out or let fluid readily drain from button/rocker. Design to prevent binding.	Test for fluid ingress according to IEC 60601-1.
Selfactivation or no activation due to fluid ingress. Alternate current path due to poor seal.	Inadequate design	Design to keep fluid out.	Test for fluid ingress according to IEC 60601-1.
Improper activation (wrong mode).	Incorrect circuit connections. Poor design resulting in manufacturing defect – wrong wire connection.	Design to liminate wire connection errors.	Test according to IEC 60601-1 and 60601-2-2
No signal at active electrode	Incorrect circuit connections. Designed with weak material or poor specs. Collet broken or not connected. Cable leads not connected.	Proper circuit design. Design and specify proper materials and connections.	Test according to IEC 60601-1 and 60601-2-2
Activation doesn’t stop.	Conductive debris in contact with switch circuit.	Design for, and specify switch conductor cleanliness on drawing	Test according to IEC 60601-1 and 60601-2-2
Too hard to depress Too soft (no tactile response)	Incorrect geometry (or material type) of dome switch	Design and specify proper geometry and materials	Verify button force is validated at manufacturer
Switches too soft (no tactile feel) or Activation force too low resulting in inadvertent activation	Poor design resulting in out of spec dome.	Design and specify proper geometry and materials	Verify button force is validated at manufacturer
Selfactivation, no activation, or dielectric failure due to fluid ingress.	Poor design resulting in fluid ingress.	Design to keep fluid out or let fluid drain easily.	Test for fluid ingress according to IEC 60601-1.
Cracks, fails, or falls apart.	Material Selection not gamma and/or ETO stable.	Identification and use of appropriately strong and biocompatible materials.	Test according to applicable IEC Standards for single use electrosurgical accessories.
Exposed conductors	Incorrect wire insulation Insufficient strain relief and/or cable/housing junction features in handpiece.	Design using proper materials and strain relief features. See footnote 1	Test according to IEC 60601-2-2

Failure Mode	Cause	Mitigation	Verification
No E.S. current at electrode (inoperable unit) Cut switch activates coag or coag switch activates cut Unable to plug in connector	Cable leads not connected or incorrect connections to plug pins Plug pins broke off in generator socket Pin or cable resistance too high	Design to eliminate connection issues for cable to pins. Design for proper material strength and connections.	Test continuity according to IEC 60601-1 and 60601-2-2
Exposed plug pins at ESU connection	Not designed to IEC Standards	Design to IEC 60601-1 which requires pins to be covered prior to electrical contact See footnote 1	Test according to IEC 60601-1
Holster disconnects from drape and falls on floor	Poor design or material choice	Product design	Ensure material requirements are defined.
Does not protect user/patient from accidental activation (when pencil stored in holster). Allows electrode to pass through (i.e. drain holes in bottom)	Poor design or material choice.	Design using appropriate dielectric strength material and physical features.	Ensure material requirements are defined.
Cracks, fails, or falls apart.	Material Selection not gamma and/or ETO stable.	Identification and use of Appropriately strong and Biocompatible materials.	Test according to applicable IEC Standards for single use electrosurgical accessories.
Exposed conductors	Incorrect wire insulation Insufficient strain relief and/or cable/housing junction features in handpiece.	Design using proper materials and strain relief features.	Test according to IEC 60601-2-2
Increased bioburden (15 ft. cable)	Non-sterile product	Material selection, process control	Ensure material, assembly, and inspection requirements are defined. Bioburden testing
Packaging failure (15 ft. cable)	Increase in mass	Application of industry standards to package design	Test pouches after sterilization and shipping

7.2. Cord Length testing verifies that the cords meet design specifications.

8. EXPERIMENTAL DESIGN/SAMPLE JUSTIFICATION

8.1. Sterilization, accelerated aging, thermal cycling and other conditioning:

Product will be sterilized according to Sterilization chart specification found in Section 7.2.4 of ENG-WI-001.

Product will be Thermal/Humidity Cycled 15 – 95% Rh; -40C – 70C.

8.2. A summary of the experimental design is as follows:

EO Sterilization
Thermal Cycling
Ship Testing
Electrical/Standards Tests
Mechanical Testing
Dimensional and Chemical Tests
Destructive Testing

Test Description	Button Switch (ACE37H)	Rocker Switch (0036)
Electrical/Standards Testing		
Cable meets High Frequency Leakage (IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.102)	30 ea.	NA
Cable meets High Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.103)	30 ea.	NA
Pencil meets High Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.103; XENG-PS-010 4.1.4)	30 ea.	30 ea.
Holster meets High Frequency dielectric withstand after EO and gamma sterilization cycles. (IEC 60601-2-2 Clause 201.8.8.3.103; XENG-PS-010 4.1.4)	NA	30 ea.
Cable meets Mains Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.101 and 201.8.8.3.104)	30 ea.	NA
Pencil meets Mains Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.104)	30 ea.	30 ea.
Plug meets Mains Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.104)	NA	30 ea.
Holster meets Mains Frequency dielectric withstand (IEC 60601-2-2 Clause 201.8.8.3.104)	NA	30 ea.
Pen finger switch activation resistance of 50 ohms maximum	30 ea.	30 ea.
Pencil finger switch non-activation resistance of 100,000 ohms minimum	30 ea.	30 ea.
Fluid Ingress Test (IEC 60601-2-2 Clause 201.11.6.5 b)	30 ea.	30 ea.

Test Description	Button Switch (ACE37H)	Rocker Switch (0036)
Thermal Testing (IEC 60601-1: 2012 clause 11.1.2.2 and IEC 60601-2-2: 2009)	1	1
Mechanical Tests		
Electrode Deviation (Wobble)	30 ea.	30 ea.
Hand piece Cable Anchorage	30 ea.	30 ea.
Plug Cable Anchorage	30 ea.	30 ea.
Button Activation Force	30 ea.	30 ea.
Button Activation over Time	30 ea.	30 ea.
Dimensional and Chemical Tests		
Cord Length	30 ea.	30 ea.
Pad Print Resistance to Chemicals (IEC 60601-1:2012 Clause 7.1.3)	NA	30 ea.
The EP withstands normal cleaning solutions used in manufacturing processes.	30 ea.	NA
Destructive Test		
Pencil Body Peel Strength	30 ea.	30 ea.

9. SHIPPING AND STORAGE CYCLE AND PRECONDITIONING

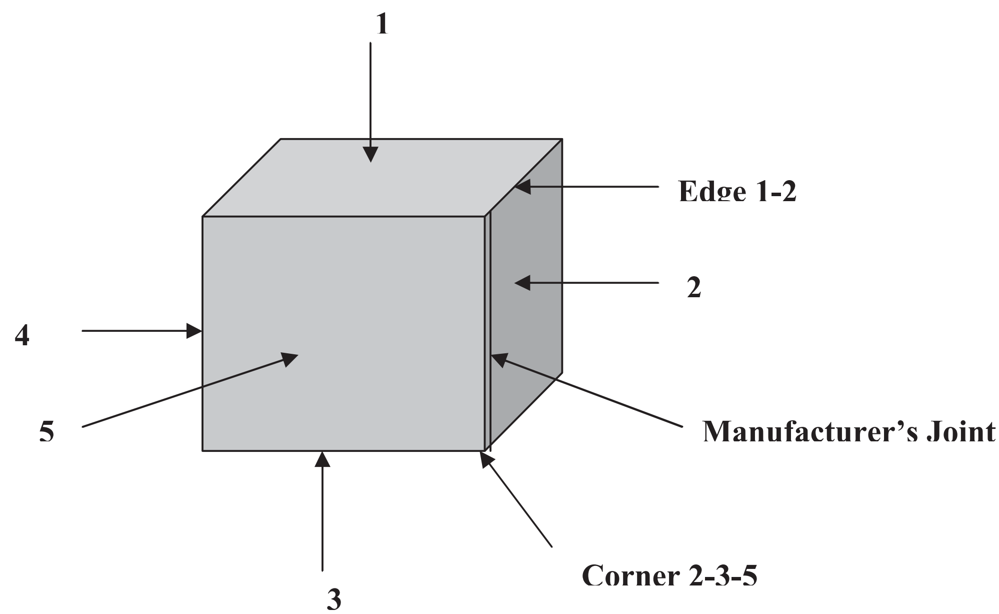
9.1. Pre-Conditioning will follow the temperature and humidity schedule listed below.

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 55°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

10. SHIPPING TEST

10.9. Following the conditioning, using a permanent marker, identify the faces of the shipping boxes according to the following diagram.



10.10. Record the gross weight (Wt.) of the shipper box containing product in pounds.

10.11. Record the Catalog number of the product.

10.12. Record the Lot Number of the product.

10.13. Perform the Handling test (drop test) on both boxes as follows.

10.13.1. 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 13 pounds.

10.13.2. 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

10.13.3. Record package drops on the data sheet in Appendix II.

10.14. Perform the compression tests.

10.14.1. **0036:** 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 III will be applied. The justification for this adjustment follows: Pallets are not stacked. Unit boxes are stacked 9 units high on the pallet for EO sterilization as documented in OPER-WI-048 in the worst case. These boxes are then sent by truck to a sterilization facility where they are exposed to heat and humidity, then sent on truck back to the warehouse for storage. A height of 54 inches will be used in the formula. The formula for the weight of the compression is as follows:

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

Where the mass M =9 lbs., J = 1 lbf/lb, H=54 inches, and h= 6 inches and F = 3.0, a factor to account for the combined effect of the individual factors taken from paragraph 11.2 of ASTM D4169. Record information in Appendix VIII.

Catalog Number	Carton Weight (lbs.)	Stack Height (ft.)	Compression (lbs.)
2525-10	9	4.5	216

The parts used for this testing are production equivalent.

10.14.1.1. Place *Face 3* of the shipper box on the ground.

10.14.1.2. 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.

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

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

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

10.14.2. **ACE37H:** 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 III will be applied. The justification for this adjustment follows: Pallets are not stacked. Unit boxes are stacked 9 units high on the pallet for EO sterilization as documented in OPER-WI-048 in the worst case. These boxes are then sent by truck to a sterilization facility where they are exposed to heat and humidity, then sent on truck back to the warehouse for storage. A height of 60 inches will be used in the formula. The formula for the weight of the compression is as follows:

$$L = M \text{ x } Jx((H-h)/h)xF$$

Where the mass M =12 lbs., J = 1 lbf/lb, H=60 inches, and h= 12 inches and F = 3.0, a factor to account for the combined effect of the individual factors taken from paragraph 11.2 of ASTM D4169. Record information in Appendix VIII.

Catalog Number	Carton Weight (lbs.)	Stack Height (ft.)	Compression (lbs.)
0036	12	5	144

The parts used for this testing are production equivalent.

10.14.2.1. Place *Face 3* of the shipper box on the ground.

10.14.2.2. 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.

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

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

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

10.15. Following the compression tests perform the Loose Load Vibration test, record information in Appendix VIII.

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

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

10.15.3. Slowly increase the frequency of the vibration until the shipper boxes begins to momentarily leave the surface of the platform.

10.15.4. Check the frequency using the shim.

10.15.4.1. Swipe the shim under each shipping box along the longest side from one 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.

10.15.5. Leave the boxes on the vibration table for a period of 40 minutes.

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

10.15.7. Check the frequency using the shim.

10.15.7.1. Swipe the shim under each shipping box along the longest side from one 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.

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

10.15.8. Leave the boxes on the vibration table for a period of 10 minutes.

10.16. Following the vibration test, perform the second package handling (drop test) on both boxes. Follow the sequence listed below on each box. 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.

10.17. Following the shipping test, evaluate the product as follows:

10.18. Inspect the exterior of each box and note any damage. Record pass/fail results in Appendix VIII.

11. GENERAL TESTING PROCEDURE

11.1. Document the manufacturer, model number, and calibration information for all equipment used throughout this procedure.

11.2. Assign each sample a unique identification and record on the sample.

HANDPIECE STANDARDS TESTING

12. CONTINUITY MEASUREMENT

12.9. Using an ohmmeter, measure and record the resistance of the device. Check all possible activation points. The device under test is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 10,000 ohms when the button is released. Do not use an out of tolerance pencil for testing.

12.10. Repeat 10.3.1 for all samples. Record results in spreadsheet.

13. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

13.1. Appendix I illustrates the equipment setup for this test. The equipment needs for this test are: modified Mega Power ESU, the 3:1 transformer, high voltage probe, and oscilloscope on the workbench.

13.2. Check that the high voltage probe is connected to the oscilloscope channel 1. Also check that channel 1 is set to read peak voltage.

13.3. Connect an appropriate test lead from the yellow output of the transformer to the common output of the ESU.

13.4. Connect an appropriate test lead from the brown output of the transformer to the return receptacle on the ESU.

13.5. Wrap the hand switching device in a cloth that is soaked in 0.9% saline. The cloth should be wet, but not dripping.

13.5.1. The cloth must extend a minimum of 6 inches (150 mm) onto the device's cord.

13.5.2. The IEC 60601-2-2 standard requires that the cloth must extend 0.2 inches (5 mm) onto an acceptable electrode that has been inserted into the hand switching device. On the Pencil the electrode is surrounded by the nozzle.

Therefore, position the cloth such that it extends a minimum of 0.2 inches (5 mm) into the nozzle.

13.6. Wrap the center of the cloth covered hand switching device in aluminum foil. The aluminum foil should be a minimum of ½ inch wide and make good contact with the cloth.

13.7. Check the plug on the hand switching device for multiple connections. If the plug has multiple connections short the connections together. This will be referred to as the *test cable's plug junction.*

13.8. Using an appropriate test lead, plug one end of the test lead into the red output of the transformer and the other end into the plug junction.

13.9. Using an appropriate test lead, attach one end of the test lead to the black output of the transformer and attach the other end to the aluminum foil wrapped around the device.

13.10. Clip the return of the high voltage probe to the end of the aluminum foil on the wrapped device.

13.11. Activate the SPRAY COAG mode using the foot switch and adjust the power on the ESU to achieve a minimum of 1.2 times (120%) the published Rated Accessory Voltage for the accessory being tested.

13.11.1. For a Rated Accessory Voltage greater than 4,000 Vpeak the Crest Factor of the test waveform must be 6 +/- 10%.

13.11.2. For a Rated Accessory Voltage (Uacc) greater than 1,600 Vpeak and less than or equal to 4,000 Vpeak the Crest Factor (cf) of the test waveform must be:

$$cf = (U_{acc} - 400 \text{ Vpeak}) / 600 \text{ Vpeak}.$$

13.12. Watch for breakdown. Breakdown is indicated by sparks, visible degradation, black smoke, or a sudden drop in voltage. Blue corona is normal and is not considered a failure.

13.13. Maintain the potential for 30 seconds using the stopwatch unless breakdown occurs first.

13.14. At the conclusion of 30 seconds, release the foot switch and disconnect the test cable.

13.15. Record sample number and maximum peak voltage seen on the oscilloscope. Also record whether the device passed or failed and if there was any damage.

13.16. Repeat 10.4.5 – 10.4.15 for all samples. Record results in spreadsheet.

14. HANDPIECE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

CAUTION: This is a high voltage test. Place a warning sign near the test apparatus as a notification that a dangerous test is in progress. Do not touch any portion of the device or the test setup while testing is in process.

14.1. This test must follow the high frequency dielectric withstand testing in 10.4.

14.2. Place the HiPot on the workbench and remove excess equipment.

14.3. Appendix II shows a set-up for mains frequency dielectric withstand testing of a hand switching device. This generic figure may be used as a reference to aid in setting up the mains frequency dielectric withstand test.

14.4. The hand switching device should be prepared for testing using saline and aluminum foil, following steps 10.4.5 to 10.4.7.

14.5. Attach the active lead from the HiPot to the device’s plug junction.

14.6. Place an appropriate test lead from the ground output on the HiPot to the end of the aluminum foil wrapped device.

14.7. Turn on the HiPot. Raise the voltage 500 V/s until the voltage reaches the required value for testing.

14.7.1. The standard states that the mains test voltage must be 1000 Vpeak more than the Rated Accessory Voltage. The test voltage is converted to Vrms and rounded up to the nearest increment on the HiPot.

14.8. Maintain the potential for at least 30 seconds using a stopwatch unless breakdown occurs first.

14.9. Watch for breakdown. Breakdown is indicated by the alarm on the HiPot.

14.10. At the conclusion of 30 seconds, turn the knob on the HiPot all the way down, and turn the power switch off. Disconnect the device.

14.11. Using an ohmmeter, measure the resistance of the depressed finger switch 10 times and verify switch is open (de-energized) when released.

14.12. If the device has more than one finger switch, repeat 10.5.11 above for all other hand switches.

14.13. Record sample number, all resistance values, and if there was dielectric breakdown.

14.14. Repeat all steps in sections 10.5.4- 10.5.13 for all samples. Record results in spreadsheet.

15. CABLE CONTINUITY TEST PROCEDURE

15.1. Document the manufacturer, model number, and calibration information for all equipment used throughout this procedure.

15.2. For this test, cut the cable away from the Pencil. Leave the plug on the cable for later testing. Assign each sample a unique identification and record on sample.

15.3. CABLE CONTINUITY MEASUREMENT

15.3.1. Using an ohmmeter, measure and record the resistance of each conductor of the cable. Check all possible activation points. The device under test is considered out of tolerance if the resistance is greater than 0.5 ohms. Do not use an out of tolerance cable for testing.

15.3.2. Repeat 11.3.1 for all samples.

15.4. SAMPLE PREPARATION

15.4.1. Fill plastic holding tub with 0.9% saline solution.

15.4.2. Immerse all of the cables to be tested in saline, leaving no more than 3.9 inches (10 cm) exposed (dry) on the ends. Make sure components connected to the cable ends do not come in contact with the saline solution.

15.4.3. Leave cables soaking in the saline for a minimum of 12 hours but no more than 24 hours.

15.4.3.1. It is permissible to place more than 1 cable at a time in the same container of saline solution.

15.5. Record results in spreadsheet.

16. CABLE LEAKAGE CURRENT TESTING

16.1. Appendix III shows a set-up for leakage current testing of a cable used for an electrosurgical pencil. This generic figure showing a pencil may be used as a reference to aid in setting up the leakage current test for any type of electrosurgical cable.

16.2. Place the Valleylab FX ESU on one side of the workbench and turn on.

16.3. Connect the foot switch to the proper connector on the generator and place the foot switch on the floor.

16.4. Place the oscilloscope on the workbench away from the ESU and turn on - Adjust channel 1 of the oscilloscope to measure volts peak.

16.5. Connect the high voltage probe to the oscilloscope input channel 1.

16.6. Clip the return of the high voltage probe to the ESU's return (neutral) patient electrode socket.

16.7. Place the True RMS Volt meter on the workbench.

16.8. Connect one end of a coax cable to the connector of the inductive current coil. Connect the other end of the coax to the True RMS Volt meter.

16.9. Fill the saline fixture with 0.9% saline and place it on the workbench.

16.10. Thread one end of an appropriate test lead through the center hole of the inductive current loop. Connect the appropriate end of the test lead to the ESU's return (neutral) patient electrode socket.

16.11. Connect the other end of the test lead of 11.5.10 to the center electrode of the saline fixture.

16.12. Select a cable from the saline preconditioning bath and shake off excess fluid.

16.13. Record the cable's identification.

16.14. Mark and constrain 11.8 inches (30 cm) of cord in the saline fixture such that the two sections (the up and down) of the cable in the fixture are parallel to the center rod of the fixture. (Ensure that the 11.8 inches (30 cm) of cable in use is NOT the unconditioned 3.9 inches (10 cm) of cable that is located at the ends.)

16.14.1. A smaller length of cable may be used, but it cannot be longer than 11.8 inches (30 cm).

16.14.2. Check to make sure that the two marks indicating the 11.8 inches (30 cm) are at the top level of the saline solution. The amount of saline in the fixture may be adjusted to accomplish this.

16.15. Short one end of the test cable. This will be referred to as the *test cable's plug junction.*

16.16. Connect a lead from the test cable's plug junction to the monopolar output of the ESU.

16.17. Connect the center electrode of the high voltage probe to the test cable's plug junction using an appropriate test lead.

16.18. Depress the PURE CUT foot switch and slowly adjust the PURE CUT output up until a minimum of 400 Vpeak (800 Vpp) is seen on the oscilloscope display.

16.19. Read and record the peak voltage (Oscilloscope) and current (RMS Voltmeter).

16.20. Let go of the foot switch to deactivate the ESU. Return PURE CUT power on ESU to 1 Watt.

16.21. Repeat sections 16.12 – 16.20 until all samples have been tested. Record results in spreadsheet.

17. CABLE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

17.1. This test must follow the leakage current testing in 11.5.

17.2. Appendix II illustrates the equipment setup for this test.

17.3. Check that the high voltage probe is connected to the oscilloscope channel 1. Also check that channel 1 is set to read peak voltage.

17.4. Connect an appropriate test lead from the yellow output of the transformer to the common output of the ESU.

17.5. Connect an appropriate test lead from the brown output of the transformer to the return receptacle on the ESU.

17.6. Using a piece of 26 gage solid, bare wire, wrap the wire around a portion of the cable without deforming the surface such that there is a minimum of 0.12 inches (3 mm) between wraps and no more than 5 wire wraps total. Leave approximately 1-2 inches (2.54 - 5.08 cm) of wire to extend off of the cable.

17.7. Using an appropriate test lead, plug one end of the test lead into the red output of the transformer and the other end into the plug junction.

17.8. Using an appropriate test lead, attach one end of the test lead to the black output of the transformer and attach the other end to the 26 gage wire that is extending off of the wrapped cable.

17.9. Clip the return of the high voltage probe to the end of the 26 gage wire that is extending off of the wrapped cable.

17.10. Activate the SPRAY COAG mode using the foot switch and adjust the power on the ESU to achieve a minimum of 1.2 times (120%) the published Rated Accessory Voltage for the accessory being tested.

17.10.1. For a Rated Accessory Voltage greater than 4,000 Vpeak the Crest Factor of the test waveform must be 6 +/- 10%.

17.10.2. For a Rated Accessory Voltage (Uacc) greater than 1,600 Vpeak and less than or equal to 4,000 Vpeak the Crest Factor (cf) of the test waveform must be:

$$cf = (Uacc – 400 \text{ Vpeak}) / 600 \text{ Vpeak}$$

17.11. Watch for breakdown. Breakdown is indicated by sparks or visible degradation in the insulation of the cable (such as melting). A sudden drop in voltage indicates breakdown. Blue corona is normal and is not considered a failure.

17.12. Maintain the potential for 30 seconds using the stopwatch unless breakdown occurs first.

17.13. At the conclusion of 30 seconds, release the foot switch, disconnect the test cable, and inspect the sample for signs of damage.

17.14. Record sample number and maximum peak voltage seen on the oscilloscope. Also record if the device passed or failed and if there was any damage.

17.15. Repeat steps 17.6 – 17.14 for each sample. Record results in spreadsheet.

18. CABLE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

CAUTION: This is a high voltage test. Place a warning sign near the test apparatus as a notification that a dangerous test is in progress. Do not touch any portion of the device or the test setup while testing is in process.

18.1. This test must follow the high frequency dielectric withstand testing in 11.6.

18.2. Place the HiPot and the saline fixture on the workbench. Clear excess equipment.

18.3. Appendix V shows a set-up for mains frequency dielectric withstand testing of a cable. This generic figure may be used as a reference to aid in setting up the mains frequency dielectric withstand test.

18.4. Move one cable to be tested to the saline test vessel filled with saline. Place the entire length of cable into the saline leaving 3.9 ± 0.39 inches (10 ± 1 cm) exposed (dry) on each end of the cable. Leave the cables not being tested soaking. (The wire wrap should have been removed from the cable.)

18.5. Attach the active lead from the HiPot to the cable's plug junction.

18.6. Place an appropriate test lead from the ground output on the HiPot to the center electrode of the saline fixture.

18.7. Turn on the HiPot. Raise voltage 500 V/s until voltage reaches the required value for testing.

18.7.1. The standard states that the mains test voltage must be 1000 Vpeak more than the Rated Accessory Voltage. The test voltage is converted to Vrms and rounded up to the nearest increment on the HiPot.

18.8. Maintain the potential for at least 5 minutes using a stopwatch unless breakdown occurs first.

18.9. Watch for breakdown. Breakdown is indicated by the alarm on the HiPot.

18.10. At the conclusion of 5 minutes, turn the knob on the HiPot all the way down, and turn the power switch off.

18.11. Measure the resistance of the cable using an ohmmeter as described in section 11.3.

18.12. Record sample number, final resistance value, and if there was dielectric break down.

18.13. Repeat 18.4 – 18.12 for all samples. Record results in spreadsheet.

DEVICE PLUG PROCEDURE (ESU CONNECTION)

19. PLUG MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

CAUTION: This is a high voltage test. Place a warning sign near the test apparatus as a notification that a dangerous test is in progress. Do not touch any portion of the device or the test setup while testing is in process.

19.1. Place the HiPot on the workbench and remove excess equipment.

19.2. Appendix II shows a set-up for mains frequency dielectric withstand testing of a medical device. This generic figure may be used as a reference to aid in setting up the mains frequency dielectric withstand test.

19.3. Wrap the device plug in a cloth that is soaked in 0.9% saline. The cloth should be wet, but not dripping.

19.3.1. The cloth must be kept a minimum of 0.4 inches (10 mm) away from the exposed conductors on the plug.

19.4. Wrap the center of the cloth covered device plug in aluminum foil. The aluminum foil needs to cover the area of interest.

19.5. Attach the active lead from the HiPot to the devices plug junction or exposed conductive region.

19.6. Place an appropriate test lead from the ground output on the HiPot to the end of the aluminum foil wrapped device.

19.7. Turn on the HiPot. Raise voltage 500 V/s until reaching the required value for testing.

19.7.1. The standard states that the mains test voltage must be 1000 Vpeak more than the Rated Accessory Voltage. The test voltage is converted to Vrms and rounded up to the nearest increment on the HiPot.

19.8. Maintain the potential for at least 30 seconds using a stopwatch unless breakdown occurs first.

19.9. Watch for breakdown. Breakdown is indicated by the alarm on the HiPot.

19.10. At the conclusion of 30 seconds, turn the knob on the HiPot all the way down, and turn the power switch off.

19.11. Record sample number and if there was dielectric break down. Record results in spreadsheet.

HOLSTER PROCEDURE

20. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

20.1. Appendix I illustrates the equipment setup for this test. The equipment needs for this test are: modified Mega Power ESU, the 3:1 transformer, high voltage probe, and oscilloscope on the workbench.

20.2. Check that the high voltage probe is connected to the oscilloscope channel 1. Also check that channel 1 is set to read peak voltage.

20.3. Connect an appropriate test lead from the yellow output of the transformer to the common output of the ESU.

20.4. Connect an appropriate test lead from the brown output of the transformer to the return receptacle on the ESU.

20.5. Wrap the Holster in a cloth that is soaked in 0.9% saline. The cloth should be wet, but not dripping.

20.6. Place a pencil with electrode inside of the holster.

20.7. Wrap the center of the cloth covered holster in a band of aluminum foil that is 0.5 to 1 inches wide. The aluminum foil should have a tab at the ends to attach the lead wire.

20.8. Check the plug on the hand switching device for multiple connections. If the plug has multiple connections short the connections together. This will be referred to as the *test cable's plug junction.*

20.9. Using an appropriate test lead, plug one end of the test lead into the red output of the transformer and the other end into the plug junction.

20.10. Using an appropriate test lead, attach one end of the test lead to the black output of the transformer and attach the other end to the aluminum foil wrapped around the holster.

20.11. Clip the return of the high voltage probe to the end of the aluminum foil on the wrapped device.

20.12. Activate the SPRAY COAG mode using the foot switch and adjust the power on the ESU to achieve a minimum of 1.2 times (120%) the published Rated Accessory Voltage for the accessory being tested.

20.12.1. For a Rated Accessory Voltage greater than 4,000 Vpeak the Crest Factor of the test waveform must be 6 +/- 10%.

20.12.2. For a Rated Accessory Voltage (Uacc) greater than 1,600 Vpeak and less than or equal to 4,000 Vpeak the Crest Factor (cf) of the test waveform must be:

$$cf = (Uacc – 400 \text{ Vpeak}) / 600 \text{ Vpeak}.$$

20.13. Watch for breakdown. Breakdown is indicated by sparks, visible degradation, black smoke, or a sudden drop in voltage. Blue corona is normal and is not considered a failure.

20.14. Maintain the potential for 30 seconds using the stopwatch unless breakdown occurs first.

20.15. At the conclusion of 30 seconds, release the foot switch and disconnect the test cable.

20.16. Record sample number and maximum peak voltage seen on the oscilloscope. Also record whether the device passed or failed and if there was any damage.

20.17. Repeat 20.5 – 20.16 for all samples. Record results in spreadsheet.

21. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

CAUTION: This is a high voltage test. Place a warning sign near the test apparatus as a notification that a dangerous test is in progress. Do not touch any portion of the device or the test setup while testing is in process.

21.1. This test must follow the high frequency dielectric withstand testing in 13.1.

21.2. Place the HiPot on the workbench and remove excess equipment.

21.3. Appendix II shows a set-up for mains frequency dielectric withstand testing of a hand switching device. This generic figure may be used as a reference to aid in setting up the mains frequency dielectric withstand test.

21.4. The Holster should be prepared for testing using saline and aluminum foil, following steps 21.5 to 21.8.

21.5. Attach the active lead from the HiPot to the device's plug junction.

21.6. Place an appropriate test lead from the ground output on the HiPot to the end of the aluminum foil wrapped device.

21.7. Turn on the HiPot. Raise voltage 500 V/s until voltage reaches the required value for testing.

21.7.1. The standard states that the mains test voltage must be 1000 Vpeak more than the Rated Accessory Voltage. The test voltage is converted to Vrms and rounded up to the nearest increment on the HiPot.

21.8. Maintain the potential for at least 30 seconds using a stopwatch unless breakdown occurs first.

21.9. Watch for breakdown. Breakdown is indicated by the alarm on the HiPot.

21.10. At the conclusion of 30 seconds, turn the knob on the HiPot all the way down, and turn the power switch off. Disconnect the device.

21.11. Record sample number and if there was dielectric break down

21.12. Repeat all steps in sections 21.4- 21.11 for all samples. Record results in spreadsheet.

22. FLUID INGRESS TEST PROCEDURE

22.1. Document the manufacturer, model number, and calibration information for all equipment used throughout this procedure.

22.2. Assign each sample a unique identifier and record on sample with permanent marker or other permanent method.

22.3. Prior to testing, use an ohmmeter to measure and record the resistance of each Pencil. Check both Cut and Coag switches. A device is considered out of tolerance if the resistance is greater than 50 ohms when the button is depressed or less than 100,000 ohms when the button is released. Do not use an out of tolerance pencil for testing.

22.4. Appendix I shows the setup used for fluid ingress testing. Place the function generator, current loop, oscilloscope, 1 liter saline solution, stop watch, and container on workbench.

22.5. Turn on function generator and set for 10 V_{p-p} and 1 kHz.

22.5.1. Ensure the offset = 0

22.5.2. Ensure the waveform is sinusoidal.

22.6. Connect one end of a coax cable to the connector of the current loop. Connect the other end of the coax to channel 1 on the oscilloscope (make sure channel 1 is set to read a 1x probe). When measuring current with the loop, voltage is displayed on the oscilloscope as a 1 to 1 correlation (1 amp = 1 volt)

22.7. Turn the oscilloscope on and set the display to show 250 ms/division and 5 mV/division.

22.8. Set the cursors on the oscilloscope to be ± 2.5 mV or as close to this setting as possible.

22.9. Using the trigger menu, set the *Slope* to “Rising” and the *Mode* to “Normal”.

22.10. Set the trigger point to approximately 2.5 mV using the trigger knob.

22.11. Connect the appropriate lead to the function generator.

22.12. Place the Pencil to be tested in the container with the cord and plug out of the container.

22.13. Using the test lead identified in 22.11, connect one wire to the common pin on the Pencil plug and the other wire to the cut or COAG pin on the plug (depending on which mode is being tested).

22.14. The wire connected to the plug's common pin must go through the current loop before connecting to the pin.

22.15. Center the signal on the oscilloscope around the center line, i.e. 0 Volts.

22.16. Verify that the signal is between the cursors, or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

22.17. Disconnect the test lead from the current activation pin (cut or COAG) and connect to the remaining activation pin on the plug (cut or COAG).

22.18. Verify that the signal is between the cursors, or is less than or equal to ± 2.5 mV. If not, mark the sample as defective, remove it from the test and replace with a new sample.

22.19. With the test cable connected, hold the Pencil handle horizontally at least 2 inches above the bottom of the container with the buttons on top.

22.20. Pour 1 liter of 0.9% saline over the pencil housing during a 15 second interval so that it wets the entire length of the handle.

22.21. Allow the fluid to drain away freely.

22.22. Immediately press the button of the mode being tested and release. After the button release measure the voltage value at 500 ms on the oscilloscope.

22.22.1. The voltage should be between the cursor lines, or less than or equal to ± 2.5 mV.

22.22.2. When the button on the Pencil is pressed, the voltage on the screen should go up. The signal should extend past the cursors.

22.22.3. After the button is released, the voltage should drop to less than or equal to ± 2.5 mV. The time is measured beginning from the last high point, before it drops.

22.23. Record in Appendix II if the sample passed or failed (i.e. measured between the cursor lines at the 500 ms mark or not).

22.24. Repeat steps 22.22 through 22.23 nine more times

22.25. Change the test cable connection on the Pencil plug to measure the remaining mode.

22.26. Repeat 22.22 through 22.24 for the remaining mode.

22.27. Repeat all steps, 22.12 – 22.26 for each sample. Record results in spreadsheet.

23. IEC 60601-1 TEMPERATURE TEST

23.1. Record all calibration information in Appendix I.

23.2. Obtain sample size one electrosurgical pencil.

23.3. Remove any electrode contained in each of the samples and replace it with a stainless steel test electrode listed in the table above. This electrode change facilitates the electrical connection to the proper test electrode. The stainless steel test electrodes are equivalent to coated electrodes except for the PTFE coating on the distal 2 cm at the end of the electrode.

23.4. Record catalog number and lot number on data collection sheet in Appendix I. Only the button pencil will be tested since it is the most commonly used Megadyne pencil. Materials, construction and electrical circuits in both the button and rocker pencils are nearly identical with difference being trivial from a temperature rise perspective.

23.5. Use a Mega Power ESU. Record the ESU serial Number on the data collection sheet in Appendix I.

23.6. Use the calibrated FLIR T300 thermal camera set on the tripod. Record the identification number, last calibration date, and calibration due date of the camera on the data sheet in Appendix I.

23.7. Set up the function generator to activate the ESU through the foot control connector. Set the function generator to activate the ESU for 10 seconds and then deactivate the ESU for 30 seconds on a repetitive cycle.

23.8. Setup the test under the laboratory hood but do not turn on the air flow. This is a safety precaution to contain any test materials in the event they overheat during the test. Plug the Pencil under test into the ESU. Use a laboratory stand to suspend the Pencil in air where the camera can be focused on the Pencil.

23.9. Attach one end of a test lead to the Pencil electrode and the other end to the load resistor. For Cut mode testing use a 300 ohm load resistor and for Coag testing use a 500 ohm load resistor.

23.10. Connect the other side of the load resistor to the Patient return on the ESU.

23.11. Take an initial temperature with the FLIR Camera and record the maximum temperature as a baseline on the data sheet in appendix I.

23.12. Set the ESU for 300 Watts Cut.

23.13. Activate the ESU on the duty cycle and allow it to run for 1 hour.

23.14. At the end of the one hour activation, stop the ESU.

23.15. Take the temperature of the Pencil and Nozzle Extension with the FLIR camera and record the maximum Cut temperature on the data sheet in appendix I.

23.16. With the ESU off, allow the Pencil to stabilize back to room temperature for a minimum of 30 minutes.

23.17. Again, take the temperature of the Pencil and Nozzle Extension with the FLIR camera and record the maximum temperature as a baseline on the data sheet in appendix I.

23.18. Set the ESU for 120 Watts Coag.

23.19. Activate the ESU on the duty cycle and allow it to run for 1 hour.

23.20. At the end of the one hour activation, stop the ESU.

23.21. Take the temperature of the Pencil and Nozzle Extension with the FLIR camera and record the maximum Coag temperature on the data sheet in appendix I.

23.22. Repeat the above Cut and Coag Tests with each of the three nozzle lengths.

24. PLUG STRAIN RELIEF (ROTATIONAL) TEST

24.1. Obtain 30 samples of Pencil. Use of the samples from previous tests is acceptable.

24.2. Cut the cable of the Pencil approximately 48 inches from the plug. Remove the outer jacket of the cable and strip the ends of the three inner wires to expose enough bare conductors to attach the Multimeter leads.

24.3. Test the continuity of each circuit of the device from the plug contact to the bare wire with an ohm meter. Record the values on the data sheet in Appendix III.

24.4. Clamp the plug of the Pencil in the holding fixture of the rotation test fixture 2010210-01.

24.5. Set the white cable guide approximately 30 cm below the plug.

24.6. Place the 50 gram hanging weight onto the cord below the white cable guide.

24.7. The cycle fixture is designed to rotate the plug strain relief in excess of +/- 45° from vertical at a rate of 30 cycles per minute. The requirement from IEC 60601-2-2:2009 clause 201.8.10.4.2 is that the anchorage of cables of Active Connectors shall be cycled 100 times for single use devices.

24.8. Set the rotation fixture to run continuously. Start the fixture and watch the counter until a minimum of 100 cycles has been completed, stop the fixture.

24.9. Replace the 50 g weight with the 1 kg weight and measure the continuity of each of the circuits. Record the resistance reading on the form in Appendix IV.

24.10. Visually check the cord for damage or migration from the plug at the strain relief. If damage is present record it on the form in Appendix IV.

24.11. Repeat the rotation test for all of the 30 samples.

24.12. Record pass/fail results on the log sheet in Appendix IV. Record results in spreadsheet.

25. HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

25.1. Obtain 30 samples of Pencil. Use of the samples from previous tests is acceptable.

25.2. If not previously completed, cut the cable of the Pencil a few inches past the tube connector where the cable exist the tube. Remove the outer jacket of the cable and strip the ends of the three inner wires to expose enough bare conductor to attach the Multimeter leads.

25.3. Test the continuity of each circuit of the device in both open loop and closed loop condition with an ohm meter. Record the values on the data sheet in Appendix IV.

25.4. Clamp the Pencil handle in the holding fixture of the rotation test fixture 2010210-01.

25.5. Attach a 200 gram weight onto the tubing/cord approximately 30 cm below the Pencil.

25.6. The cycle fixture is designed to rotate the device in excess of +/- 45° from vertical at a rate of 30 cycles per minute. The requirement from IEC 60601-2-2:2009 clause 201.8.10.4.2 is that the anchorage of Active Handles be cycled 200 times for single use devices.

25.7. Set the rotation fixture to run continuously. Start the fixture and watch the counter until a minimum of 200 cycles has been completed, stop the fixture.

25.8. Replace the 200 g weight with the 1 kg weight and measure the continuity of each of the circuits. Record the resistance reading on the form in Appendix IV.

25.9. Visually check the tubing/cord for damage or migration from the pencil at the connection. If damage is present record it on the form in Appendix V.

25.10. Repeat the rotation test for all of the 30 samples. Record results in spreadsheet.

26. ACTIVATION FORCE TESTING

26.1. Obtain 30 samples of Pencil. Use of the samples from previous tests is acceptable.

26.2. Install the 10 pound load cell in the Instron. Set the cross head speed to 0.787 inch per minute (20mm/minute). The travel of a dome switch is .012” nominal. Devise a program in the Instron that will travel at this rate for this distance.

26.3. Insert a test pin suitable for button force testing in the load cell mounting socket.

26.4. Use an engineering supplied holding fixture in the vise. Insert the Pencil under test in the holding fixture with the Cut button directly below the test pin in the load cell.

26.5. Identify the sample in the Instron test software.

26.6. Balance the load to zero the Instron.

26.7. Run the test.

26.8. Reposition the Pencil to test the Coag button and repeat the test.

26.9. Repeat the above test for the remaining samples.

26.9.1. Record results in spreadsheet. Provide the test data to engineering for use in the Test Report.

27. ACTIVATION OVER TIME

27.1. For all samples, test the continuity of the circuit in the activated condition. Record the resistance in the lab notebook next to the identifying numbers of each device. Continuity must be below 50 Ω, and if it is not, make a note of it in your lab book and set sample aside.

27.2. Depress the CUT button 500 times.

27.3. Test the continuity of the pencil with button depressed. Record the resistance in the table provided.

27.4. Test the continuity of the pencil with button released. Record the resistance in the table provided.

27.5. Depress the COAG button 500 times.

27.6. Test the continuity of the pencil. Record the resistance in the table provided.

27.7. Test the continuity of the pencil with button released. Record the resistance in the table provided.

28. ELECTRODE WOBBLE

28.1. Obtain samples of product codes as determined in section 8.2.

28.2. Use engineering supplied holding fixture on the ROI optical measuring system.

28.3. Install one sample of the control (current design) pencil in the holding fixture such that the distal end of the electrode is visible on the ROI field of view.

28.4. Apply a compressive force of approximately 450 grams (controlled by the spring force of the fixture) to the tip of the electrode.

28.5. Set the crosshairs of the ROI at the distal edge of the electrode. Zero the ROI in the 'Y' direction. Release the compression force.

28.6. Apply the force of approximately 450 grams (controlled by the spring force of the fixture) to the tip of the electrode in the opposite direction.

28.7. Use the ROI to measure the distance of electrode movement. Note the distance of the movement and release the compressive force.

28.8. Record the measurement on the data collection sheet in Appendix III.

28.9. Repeat the measurement above for the remaining control samples.

28.10. Perform the same measurements on the ISOS2 Pencil samples and record the measurement values on the data sheet in Appendix III.

29. CORD LENGTH

29.1. Remove 30 samples of pencils from packaging. Remove paper cable wrap. Extend cord to full length.

29.2. Measure the length of the cable from the base of the pencil to the base of the plug. Record the measurement in Appendix V.

30. DURABILITY OF PRINT (ROCKER PENCIL ONLY)

30.1.1. Record PN and LOT of solutions used for test.

30.1.2. Dip gauze in Saline.

30.1.3. Set timer for 15 seconds.

30.1.4. Simultaneously start timer and rub Saline dampened cloth on pad printed (yellow) end of rocker until timer alarm sounds.

30.1.5. Orient pencil and observe whether the yellow mark is visible at 1 meter. See Appendix III for setup instructions and illustrations.

30.1.5.1. Place pencil sideways against the 30^{o} angle block.. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.5.2. Place pencil lengthwise against 30^{o} angle block with the cord oriented upward. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.5.3. Place pencil lengthwise against 30^{o} angle block with the plug oriented upward. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.6. Record results in table provided. Record “V” if the ink is clearly visible at the angle listed in the column of Appendix IV.

30.1.7. Repeat steps 12.2 – 12.6 until all samples have been tested with Saline. Allow all rocker switch samples to dry completely before proceeding with the next test step.

30.1.8. Dip a separate gauze pad in lactated ringers.

30.1.9. Set timer for 15 seconds.

30.1.10. Simultaneously start timer and rub Lactated Ringers dampened cloth on pad printed (yellow) end of rocker until timer alarm sounds.

30.1.11. Orient pencil and observe whether the yellow mark is visible. See Appendix III for setup instructions and illustrations.

30.1.11.1. Place pencil sideways against block with 30° angle. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.11.2. Place pencil lengthwise against 30° angle block with the electrode oriented upward. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.11.3. Place pencil lengthwise against 30° angle block with the cable oriented upward. Observe rocker switch and record whether yellow ink is clearly visible at 1 meter.

30.1.12. Test all pencils. Record results in table provided. Record "V" if the ink is clearly visible at the angle listed in the column of Appendix IV.

31. RESISTANCE TO ISOPROPYL ALCOHOL

31.1. Dip a cloth in 70% isopropyl alcohol.

31.2. Set timer for 15 seconds.

31.3. Simultaneously start timer and rub isopropyl alcohol dampened cloth on pencil including yellow button, blue button, and penbody until timer alarm sounds.

31.4. Observe pencil for any discoloration or dissolved material.

32. RECORD RESULTS IN APPENDIX IV. PENCIL BODY PEEL STRENGTH

32.1. Record calibration information for all test equipment.

32.2. Cut pencils into 2 halves behind the “M” in the Megadyne logo.

32.3. Using a permanent marker, mark all sample with a unique identification number on the proximal and distal end of the hand piece as needed.

32.4. Secure the 2 halves of the holding fixture to the upper and lower jaws of the Instron. See Appendix VI for setup illustration.

32.5. Place pencil in position as shown. See Appendix VI for details.

32.6. Set gauge length to zero.

32.7. Balance load.

32.8. Place the hand piece in the holding fixture, with the weld joint horizontal and buttons up. See Appendix VI for illustration of placement.

32.8.1. Using the Instron, pull at a rate of 8 inch/min (200 mm/min, until failure occurs or the ½ inch distance is reached.

32.8.2. The operator may need to hold the nose of the hand piece in place so that the device does not come off of the holding fixture.

32.9. Repeat steps 31.1 through 31.7 for each sample and both ends of the pencil. Record results.

33. ACCEPTANCE CRITERIA

33.1. SHIPPING TEST

33.1.1. Each box shall remain intact and not break open during the test. Indentations on edges or corners are acceptable.

33.2. CONTINUITY MEASUREMENT

33.2.1. The device is considered acceptable if the continuity of each circuit, cut and COAG, is less than 50 ohms with the appropriate button depressed.

33.2.2. The device is considered acceptable if the open circuit continuity of each circuit, cut and COAG, is greater than 10,000 ohms without the appropriate button depressed.

33.3. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

33.3.1. The device is considered acceptable if the test voltage is maintained for 30 seconds, and;

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

33.4. HANDPIECE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

33.4.1. The device is considered acceptable and passes this test if the test voltage was reached and maintained for 30 seconds and;

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

33.4.3. The HiPot did not alarm.

33.5. CABLE CONTINUITY

33.5.1. The device cable is considered acceptable if the continuity of each circuit in the cable is less than 0.5 ohms.

33.6. CABLE LEAKAGE TESTING

33.6.1. The device cable is considered acceptable and passes this test if the measured leakage is below the calculated maximum allowed leakage and;

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

33.6.2.1. The maximum leakage current in milliamps is calculated as follows.

Monopolar

$I_{leakage} = 9.0 \text{ x}10^{-6}*d*L*f_{test}*U_{peak}$

where:

d = smallest outer dimension of the insulation (mm)

L = length of cable where leakage current is being tested (cm). (Step 10.5.14)

f_{test} = test voltage frequency in kHz

U_{peak} = Vpp / 2

33.7. CABLE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

33.7.1. The device cable is considered acceptable if the test voltages is maintained for 30 seconds, and;

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

33.8. CABLE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

33.8.1. The device cable is considered acceptable and passes this test if the test voltage was reached and maintained for 5 minutes and;

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

33.8.3. The HiPot did not alarm.

33.9. PLUG MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

33.9.1. The device cable is considered acceptable and passes this test if the test voltage was reached and maintained for 5 minutes and;

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

33.9.3. The HiPot did not alarm.

33.10. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

33.10.1. The holster is considered acceptable if the test voltages is maintained for 30 seconds, and;

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

33.11. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

33.11.1. The holster is considered acceptable and passes this test if the test voltage was reached and maintained for 30 seconds and;

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

33.11.3. The HiPot did not alarm.

33.12. FLUID INGRESS TESTING

33.12.1. The device is considered acceptable if, after applying saline in the Standard orientation, the button can be operated 10 times with the current being less than or equal to 2.5 mA (measured as 2.5 mV on the oscilloscope) at a time period of 0.5 seconds after the button is released. (The standard requires the AC impedance of the switch to exceed 2.0 kW within 0.5 seconds after release. Using a voltage of 10 V_{p-p}, a current of 5.0 mA or less is necessary to meet this requirement).

33.12.2. The inverted orientation test of Pencil (buttons down) is performed as a worst case situation and is not a requirement of the Standard. With that noted, any inadvertent activation of the Pencil due to fluid ingress in this orientation should be noted and Engineering notified for further investigation.

33.13. IEC 60601-1 Temperature Test

33.13.1. The temperature of the Pencil cannot exceed 48°C.

33.13.2. The Pencil should not exceed 41°C. If the temperature of the Pencil exceeds 41°C, the IFU for the product needs to be revised to add the maximum temperature.

33.14. Plug Strain Relief

33.14.1. The plug strain relief shall pass the requirements of IEC 60601-2-2 clause 8.10.4.2.

33.15. Handpiece Strain Relief

33.15.1. The Handpiece strain relief shall meet the requirements of IEC 60601-2-2 clause 201.8.10.4.2.

33.16. Activation Force

33.16.1. The Pencil button activation force shall be within the range specified by the DMR. This range is 300 to 700 grams.

33.17. Activation over time

33.17.1. Button resistance is less than 50 Ω after 500 activations. Resistance is 100,000 when button is not depressed after 500 activations.

33.18. Electrode Wobble

33.18.1. Electrode wobble is lower than standard pencil by t-test.

33.19. Cord Length

33.19.1. All cords are 180 ± 6 inches long.

33.20. Durability of Print

33.20.1. Print does not smear or degrade after test.

33.21. Resistance to Isopropyl alcohol

33.21.1. Materials do not smear or degrade after test.

33.22. Pencil body peel strength

33.22.1. All peel strength values are greater than 10 lbs.

34. REVISION HISTORY

Revision	Document Change Order Number	Description Of Change	Effective Date
See Master Control for revision history.			

Appendix I:
Pencil Temperature

Pencil Catalog# ___________________ **Lot#** ____________________________

Electrode 3012 Lot #___________________

Mega Power ESU S/N ____________________________

FLIR Camera ID# ____________________________

Camera Calibration Date ____________________________

Camera Calibration Due Date ____________________________

Pencil Test	**CUT**		**Pencil Test**	**COAG**	
Sample #	**Temperature**		**Sample #**	**Temperature**	
	Before	**After**		**Before**	**After**
1.			**1.**		

Comments: ____

____

Test Performed by: ______________________________________ Date: ________________

Appendix II:
ELECTRODE DEVIATION WOBBLE

		Control	
PN:	Lot #	PN:	Lot#
Sample #	Wobble	Sample #	Wobble
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	
7		7	
8		8	
9		9	
10		10	
11		11	
12		12	
13		13	
14		14	
15		15	
16		16	
17		17	
18		18	
19		19	
20		20	
21		21	
22		22	
23		23	
24		24	
25		25	
26		26	
27		27	
28		28	
29		29	
30		30	

Comments: ____

____

Test Performed by: _________________________________ Date: ______________

Appendix III:
CORD LENGTH

BUTTON		ROCKER	
ND PN:	Lot #	ND PN:	Lot#
Sample #	Cable Length	Sample #	Cable Length
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	
7		7	
8		8	
9		9	
10		10	
11		11	
12		12	
13		13	
14		14	
15		15	
16		16	
17		17	
18		18	
19		19	
20		20	
21		21	
22		22	
23		23	
24		24	
25		25	
26		26	
27		27	
28		28	
29		29	
30		30	

Comments: ____

____

Test Performed by: ______________________ Date: ____________

Appendix IV:
DURABILITY OF PRINT/ISOPROPYL ALCOHOL TEST

ROCKER: 0036				Distilled Water: MFG: Part # LOT #
ND PN:		Lot #		
Sample #	DISTILLED H20	ETHANOL (96%)	IPA (70%)	
1				
2				
3				
4				
5				
6				
7				Ethanol 96% MFG Part # LOT #
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				Isopropyl Alcohol 70% MFG Part# LOT #
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

Comments: ____

____

Test Performed by: ______________________________ Date: ______________

Appendix IV:
DURABILITY OF PRINT/ISOPROPYL ALCOHOL TEST

BUTTON: ACE37H

ND PN: | **Lot #**

Sample #	IPA (70%)	
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		

Distilled Water:
MFG:

Part #

LOT #

Ethanol 96%
MFG

Part #

LOT #

Isopropyl Alcohol 70%
MFG

Part#

LOT #

Comments: ____

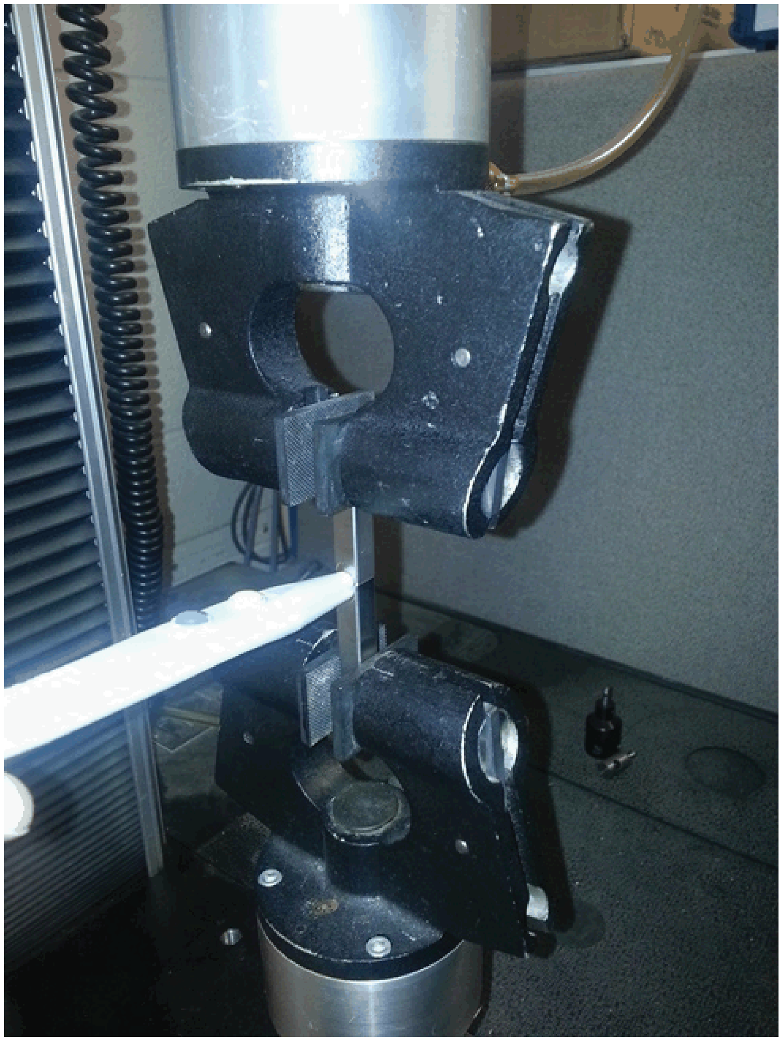
____

Test Performed by: ____________________________ Date: __________________

Appendix VI
PEEL TEST SETUP

PENCIL ULTRASONIC WELD PEEL FORCE TEST

Align both halves of the fixture vertically as shown. Both pin ends are aligned so that one does not extend past the other.



Insert the pencil over the pins of the fixture as shown. Both pins should be inserted at equal depths in the pencil. Pencil buttons should be facing upward

Appendix VII Datasheet for High Frequency Dielectric Withstand Testing

High Frequency Dielectric Withstand Testing

Data Collection Form

Sample	Configuration	High Frequency		Mains	Button Activation			
					CUT		COAG	
		Max V_{peak} (kV)	P/ F	P/ F	Open Ω	Closed Ω	Open Ω	Closed Ω
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
11								
12								
13								
14								
15								
16								
17								
18								
19								
20								
21								
22								
23								
24								
25								
26								
27								
28								
29								
30								
31								
32								

In **Closed Ω** column, PASS = > 50 MΩ

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 Calculat	(Rated Accessory V_{peak} +1000V	

CALIBRATION INFORMATION	
Multimeter	
Fluke 179 True-RMS Multimeter	
Serial Number:	93480388
Megadyne Number:	01372
Calibration Date:	9/12/2014
Calibration Due:	9/30/2015
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

Operator Name Date

Operator Signature Date

Appendix VII
Shipping Test Log Sheet

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
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials_______ High frequency 10 minutes, Initials ____________

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: ______________