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3. SCOPE

This protocol pertains to the Zip Pencil Catalog number 2525-10 and 2525-15. For these tests, the two catalog numbers are considered equivalent and either may be tested to represent the other.

4. PURPOSE

The purpose of this test protocol is to specify dielectric withstand testing required on the Zip Pencil to show compliance with IEC60601-2-2: 2009.

5. BACKGROUND

The Zip Pencil is a new design of smoke evacuation pencil for Megadyne and requires testing to show conformance to standards. This pencil has a new design for the hand held pencil, cable and plug that require validation.

6. DEFINITIONS AND ACRONYMS

ESU	Electrosurgical Unit
HF	High Frequency

7. APPARATUS

7.1.1. HiPot Tester

7.1.2. Ohmmeter (or multi-meter)

7.1.3. 0.9% Saline solution

7.1.4. Plastic holding tub for soaking cables

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

7.1.6. 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%)

7.1.7. Oscilloscope

7.1.8. 1000:1 High Voltage Probe

7.1.9. Saline (pickle jar) fixture

7.1.10. Electrosurgical generator foot switch

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

7.1.12. Workbench with insulated top (preferably wood)

7.1.13. 3:1 step-up transformer

7.1.14. Stopwatch or equivalent

7.1.15. Fluke 8920A True RMS Voltmeter, or equivalent

7.1.16. Solid 26 gage wire

7.1.17. Aluminum Foil

7.1.18. Paper towel or porous cloth

7.1.19. Test leads

8. RISK ASSESSMENT

8.1. Document 1300041-10 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with dielectric breakdown. The highest severity rating is 10 attributable to patient burn. The failure modes, cause, mitigation and verification listed in the FMEA are as follows:

Failure Mode	Cause	Mitigation	Verification
Dielectric failure of cable	Incorrect wire insulation	Material selection	Test per IEC 60601-2-2 per this protocol
Exposed wire at Pencil or plug	Insufficient strain relief, incorrect cable insulation	Material selection, Design strain relief that meets standards	Test per IEC 60601-2-2 per this protocol
Burn hole through pencil housing	Insufficient dielectric strength or inner conductors too close to housing wall	Handpiece design, material selection and product validation	Test per IEC 60601-2-2 per this protocol
Holster does not protect patient from accidental activation when pencil is stored in holster	Inadequate dielectric strength of holster	Holster design, material selection, product validation	Dielectric strength test per this protocol

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

9.1. All test samples will be sterilized with Gamma Irradiation to a minimum dose of 50 kGy. Prior to the electrical testing, all test samples will be subjected to

accelerated aging per 1150279-01 to simulate 3 years. The aging temperature will be 55°C and the aging duration per the protocol is 111 days. The accelerated aging will be documented in the test report.

9.2. After accelerated aging, and prior to evaluation, the samples will be subjected to a shipping and storage cycle. This cycle includes temperatures from -40°C to 70°C and humidity's from 15% to 95%. This temperature and humidity cycling will be documented in the test report.

9.3. The sample size of 30 will be used for this test protocol. The use of 30 samples has statistical significance as identified in SOP 1010035-10, Sampling and Statistical Techniques.

9.4. The published rated voltage for the Zip Pen is ≤5,500 V peak.

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

Accelerated aging
Shipping and storage cycle and preconditioning
Continuity Measurement
Handpiece High Frequency Dielectric Withstand
Handpiece Mains Frequency Dielectric Withstand
Cable Continuity Measurement
Cable Leakage Current
Cable High Frequency Dielectric Withstand
Cable Mains Frequency Dielectric Withstand
Plug Mains Frequency Dielectric Withstand
Holster High Frequency Dielectric Withstand
Holster Mains Frequency Dielectric Withstand

10. ZIP PENCIL PROCEDURE

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

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

10.3. CONTINUITY MEASUREMENT

10.3.1. 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.

10.3.2. Repeat 10.3.1 for all samples.

10.4. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

10.4.1. 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.

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

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

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

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

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

10.4.5.2. 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 ZIP 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.

10.4.6. 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.

10.4.7. 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.*

10.4.8. 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.

10.4.9. 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.

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

10.4.11. 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.

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

10.4.11.2. 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:

$$cf = (Uacc - 400\ Vpeak) / 600\ Vpeak.$$

10.4.12. 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.

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

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

10.4.15. 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.

10.4.16. Repeat 10.4.5 – 10.4.15 for all samples.

10.5. 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.

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

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

10.5.3. 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.

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

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

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

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

10.5.7.1. 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.

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

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

10.5.10. 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.

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

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

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

10.5.14. Repeat all steps in sections 10.5.4- 10.5.13 for all samples.

11. CABLE TEST PROCEDURE

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

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

11.3. CABLE CONTINUITY MEASUREMENT

11.3.1. 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.

11.3.2. Repeat 11.3.1 for all samples.

11.4. SAMPLE PREPARATION

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

11.4.2. 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.

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

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

11.5. CABLE LEAKAGE CURRENT TESTING

11.5.1. 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.

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

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

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

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

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

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

11.5.8. 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.

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

11.5.10. 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.

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

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

11.5.13. Record the cable's identification.

11.5.14. 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.)

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

11.5.14.2. 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.

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

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

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

11.5.18. 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.

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

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

11.5.21. Repeat sections 11.5.12 – 11.5.20 until all samples have been tested.

11.6. CABLE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

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

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

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

11.6.6. 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.

11.6.7. 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.

11.6.8. 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.

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

11.6.10. 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.

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

11.6.10.2. 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:

$$cf = (Uacc - 400\ Vpeak) / 600\ Vpeak$$

11.6.11. 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.

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

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

11.6.14. 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.

11.6.15. Repeat steps 11.6.6 – 11.6.14 for each sample.

11.7. 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.

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

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

11.7.3. 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.

11.7.4. 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.)

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

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

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

11.7.7.1. 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.

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

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

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

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

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

11.7.13. Repeat 11.7.4 – 11.7.12 for all samples.

12. DEVICE PLUG PROCEDURE (ESU CONNECTION)

12.1. 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.

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

12.1.2. 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.

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

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

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

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

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

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

12.1.7.1. 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.

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

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

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

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

13. HOLSTER PROCEDURE

13.1. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

13.1.1. 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.

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

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

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

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

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

13.1.7. 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.

13.1.8. 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.*

13.1.9. 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.

13.1.10. 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.

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

13.1.12. 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.

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

13.1.12.2. 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 Vpeak) / 600 Vpeak.

13.1.13. 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.

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

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

13.1.16. 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.

13.1.17. Repeat 13.1.5 – 13.1.16 for all samples.

13.2. 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.

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

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

13.2.3. 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.

13.2.4. The Holster should be prepared for testing using saline and aluminum foil, following steps 13.1.5 to 13.1.8.

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

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

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

13.2.7.1. 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.

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

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

13.2.10. 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.

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

13.2.12. Repeat all steps in sections 13.2.4- 13.2.11 for all samples.

14. ACCEPTANCE CRITERIA

14.1. CONTINUITY

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

14.1.2. 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.

14.2. HANDPIECE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

14.3. HANDPIECE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

14.3.3. The HiPot did not alarm.

14.4. CABLE CONTINUITY

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

14.5. CABLE LEAKAGE TESTING

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

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

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

Monopolar

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

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

14.6. CABLE HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

14.7. CABLE MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

14.7.3. The HiPot did not alarm.

14.8. HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

14.9. HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

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

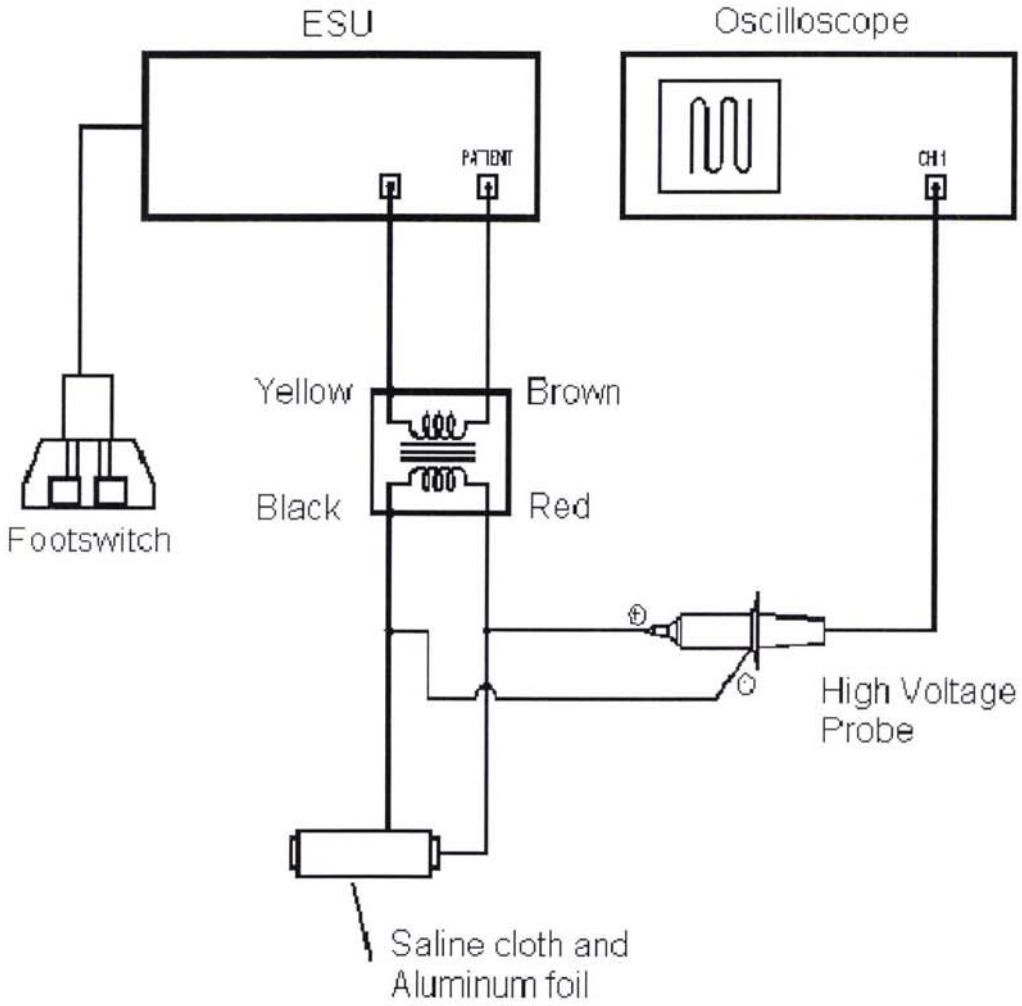
14.9.2. There were no visible signs of damage such as melted insulation and;

14.9.3. The HiPot did not alarm.

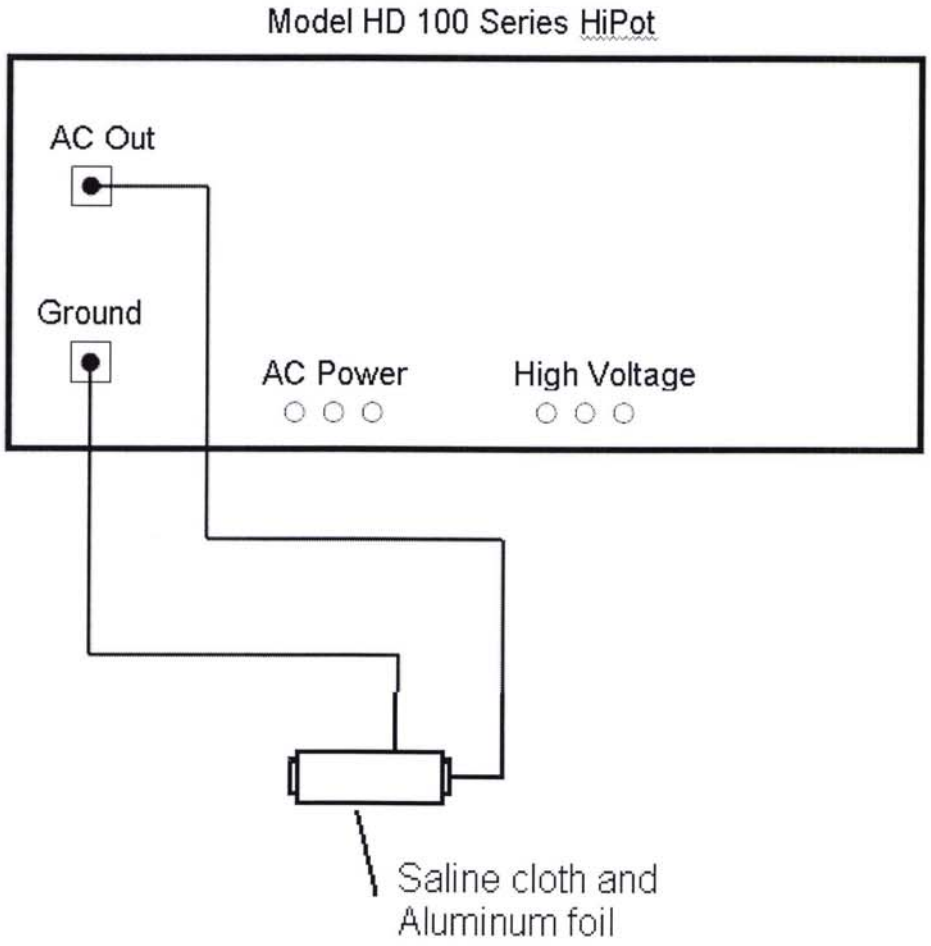
15. REVISION HISTORY

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

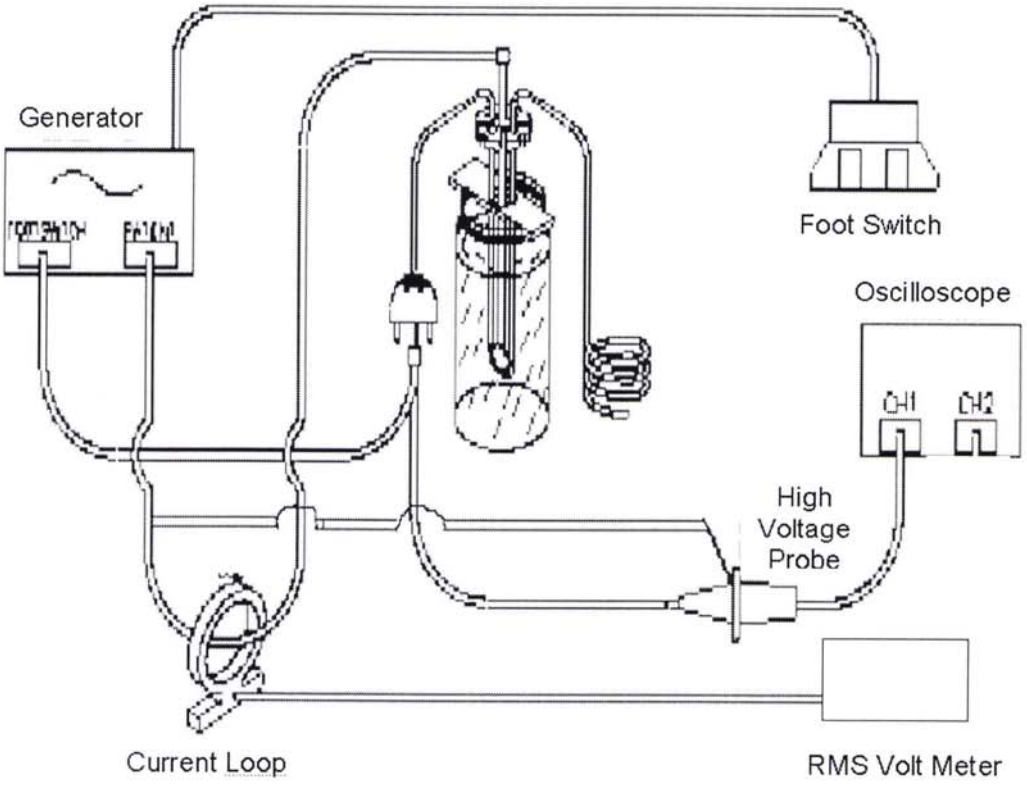
Appendix I: Device High Frequency Dielectric Strength Test Setup for Pencil and Cable



Appendix II: Mains Frequency Dielectric Strength Test Setup for Pencil and Plug



Appendix II: Cable Leakage Test Setup



Appendix IV: Cable Mains Frequency Dielectric Strength Test Setup