Authored By: Mark Glassett

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# 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 |

# Appendix

1. High Frequency test setup for Zip Pen testing
2. Mains Frequency test setup for Zip Pen testing

# Scope

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

# Purpose

The purpose of this test protocol is to specify testing required on the Zip Pen sterilized by EO gas to show compliance with IEC60601-2-2: 2009. This is a protocol for demonstration of EO compatibility and not an EO validation.

# Background

The Zip Pen is a smoke evacuation pencil that has been sold as a sterile product for approximately one year. Megadyne desires to sell the Zip Pen to kit packers as a bulk non-sterile product. Kit packers often use EO sterilization. Testing per this protocol will demonstrate compatibility of the Zip Pen with EO sterilization. EO sterilization validation will be the responsibility of the kit packer.

# Definitions and Acronyms

|  |  |
| --- | --- |
| ESU | Electrosurgical Unit |
| HF | High Frequency |

# 

# Apparatus

### HiPot Tester

### Ohmmeter (or multi-meter)

### 0.9% Saline solution

### 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%)

### TDS 2014 Tektronix Oscilloscope, or equivalent

### Appropriate leads for connection of the test set-up

### Stop watch or equivalent

### 1000:1 High Voltage Probe

### Electrosurgical generator monopolar foot switch

### Workbench with insulated top (preferably wood)

### 3:1 step-up transformer

### Aluminum Foil

### Paper towel or porous cloth

# Risk Assessment

## Document ENG-RMF-045 (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 |
| 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 |
| Product adversely affected by sterilization, material break down | Materials have insufficient insulation properties after sterilization | Design, material selection to withstand sterilization | 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 |

# EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

## All test samples will be sterilized with Ethylene Oxide gas for two periods of 4 hours each. The two periods of exposure simulate the worst case exposure that the product may see in sterilization.

## Prior to the testing, all test samples will be subjected to accelerated aging per ENG-PRT-049 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.

## After accelerated aging, and prior to evaluation, the samples will be subjected to a shipping and storage cycle, preconditioning and transit testing. Perform the shipping and storage cycle, preconditioning and transit test per XENG-PRT-325 paragraphs 10 and 11. Document these activities in the test report.

## The sample size of 30 will be used for this test protocol. The use of 30 samples has statistical significance as identified in QA-SOP-012, Sampling and Statistical Techniques.

## The Zip Pen cable and plug will not be tested. The cable and plug are the same cable and plug used on the standard Megadyne electrosurgical pencil, e.g. 0036 and 0037. Refer to test report ENG-RPT-452 for cable and plug test results.

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

## A summary of the experimental design is as follows:

EO sterilization exposure

Accelerated aging

Shipping and storage cycle and preconditioning

Transit test

Continuity Measurement

Handpiece High Frequency Dielectric Withstand

Handpiece Mains Frequency Dielectric Withstand

Holster High Frequency Dielectric Withstand

Holster Mains Frequency Dielectric Withstand

# ZIP PEN Procedure

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

## Assign each sample a unique identification and record on the sample with permanent marker or other permanent method.

## ZIP PEN CONDITIONING AND TRANSIT TEST

### Perform the shipping and storage cycle, preconditioning and transit test per XENG-PRT-325 paragraphs 10 and 11. Document these activities in the test report.

### Document the shipping and storage cycle, preconditioning and transit test in the test report.

## ZIP PEN CONTINUITY MEASUREMENT

### 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 Zip Pen for testing.

### Repeat 10.4.1 for all samples.

## ZIP PEN HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

### 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.

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

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

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

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

#### The cloth must extend a minimum of 6 inches (150 mm) onto the device’s cord. On the ZIP Pen the cord is surrounded by the tubing. Therefore, position the cloth such that it extends a minimum of 6 inches (150 mm) into the tubing.

#### 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 Pen 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.

### Wrap the center of the cloth covered Zip Pen in aluminum foil. The aluminum foil should be a minimum of ½ inch wide and make good contact with the cloth.

### Short the three connectors of the plug on the Zip Pen together. This will be referred to as the *test cable’s plug junction.*

### 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.

### 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.

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

### 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.

#### For a Rated Accessory Voltage greater than 4,000 Vpeak the Crest Factor of the test waveform must be 6 ± 10%.

#### 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.

### 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.

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

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

### 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.

### Repeat 10.5.5 – 10.5.15 for all samples.

## ZIP PEN 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.

### This test must follow the high frequency dielectric withstand testing in 10.5.

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

### 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.

### The Zip Pen should be prepared for testing using a saline soaked cloth and aluminum foil, following steps 10.5.5 to 10.5.7.

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

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

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

#### 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.

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

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

### 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.

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

### Repeat 10.7.11 above for the Coag mode finger switch.

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

### Repeat all steps in sections 10.6.4- 10.6.13 for all samples.

# HOLSTER procedure

## HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

### 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.

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

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

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

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

### Place a Zip Pen with electrode inside of the holster.

### 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.

### Short the three connectors of the plug on the Zip Pen together. This will be referred to as the *test cable’s plug junction.*

### 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.

### 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.

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

### 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.

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

#### 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.

### 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.

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

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

### 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.

### Repeat 11.1.5 – 11.1.16 for all samples.

## 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.

### This test must follow the high frequency dielectric withstand testing in 11.1.

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

### 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.

### The Holster should be prepared for testing using a saline soaked cloth and aluminum foil, following steps 11.1.5 to 11.1.8.

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

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

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

#### 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.

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

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

### 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.

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

### Repeat all steps in sections 11.2.4- 11.2.11 for all samples.

# Acceptance Criteria

## CONDITIONING AND TRANSIT TEST

### There is no acceptance criteria for Conditioning and Transit Test. This is not a package test. This is preconditioning of the product prior to performing the fluid ingress and electrical tests.

## ZIP PEN CONTINUITY

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

### 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.

## ZIP PEN HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

## ZIP PEN MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

### The HiPot did not alarm.

## ZIP PEN HOLSTER HIGH FREQUENCY DIELECTRIC WITHSTAND TESTING

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

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

## ZIP PEN HOLSTER MAINS FREQUENCY DIELECTRIC WITHSTAND TESTING

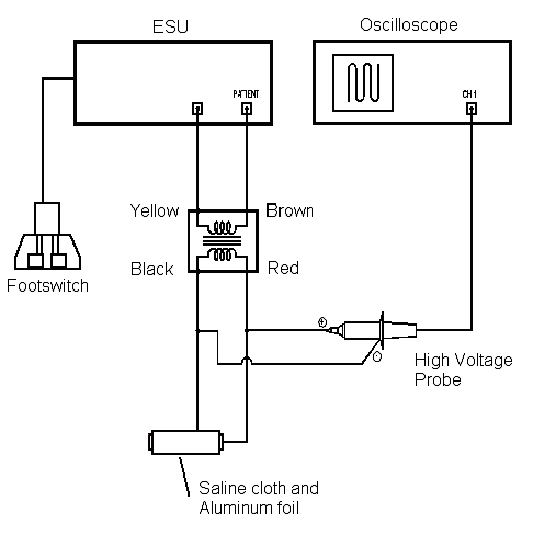
### The holster is considered acceptable and passes this test if the test voltage was reached and maintained for 30 seconds and;

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

### The HiPot did not alarm.

# Appendix

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



**Appendix II: Mains Frequency Dielectric Strength Test Setup for Zip Pen**

