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The Electrosurgical Authority®

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Engineering Verification:

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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

2. APPENDIX

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II. **Electrode Wobble Test Log Sheet**
III. **Electrode Retention Test Log Sheet**
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V. **Handpiece Strain Relief Test Log Sheet**

3. SCOPE

This protocol pertains to the Zip Pencil Catalog number 2525-10 and 2525-15. These two catalog numbers are identical except for the length of cable and tubing. The 2525-10 has 10 foot cable and tubing and the 2525-15 has 15 foot cable and tubing.

4. PURPOSE

The purpose of this test protocol is to specify mechanical testing required on the Zip Pencil to show compliance with IEC 60601-2-2: 2009. Additional tests beyond what the standard requires may be specified to demonstrate usability, meet risk analysis requirements and to show product robustness.

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, plug, holster and packaging that require validation.

6. DEFINITIONS AND ACRONYMS

ESU	Electrosurgical Unit

7. APPARATUS

7.1.1. Instron Force Tester

7.1.2. Rotational Cycle Tester 2010210-01

7.1.3. 50 gram hanging weight

7.1.4. 200 gram hanging weight

7.1.5. 1 kg hanging weight

7.1.6. Digital Multimeter

8. RISK ASSESSMENT

8.1. Document 1300041-10 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with Mechanical Failures. The highest severity rating is 10 attributable to buttons too soft that stay activated when released.

Failure Mode	Cause	Mitigation	Verification
Tubing disconnects from connector	Poor fitting design	Design connector such that the connection is stronger than the tubing	Test Report 1150719-01
Connector does not fit smoke box	Wrong size connector, user does not use Megadyne smoke evacuator	Connector designed to fit filter for Megadyne smoke evacuator, Design connector to be universal for competitive smoke evacuators	Test Report 1150719-01
Electrode falls out (possibly during procedure)	Collet diameter designed too large or out of tolerance	Validate extraction force, process control at supplier	Test Report 1150719-01, OQ, PQ at supplier
Buttons too hard or too easy to press	Incorrect geometry of dome switch or incorrect material type	Validate button activation force, process control at supplier	Test Report 1150719-01
Plug difficult to insert into ESU	Incorrect plug pin spacing, pins too large	Design for compatibility, test for insertion force comparable to similar devices	Test Report 1150719-01

Exposed wire at pencil or plug	Inadequate strain relief at pencil or plug	Validate strain relief	Test Report 1150719-01

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

9.1. Prior to the mechanical testing, all test samples will be sterilized with Gamma Irradiation to a minimum dose of 50 kGy. All test samples will also 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. For variables data, a 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. Where there is variables data that is being compared to control samples, the sample size will be 11. This number is adequate for performing a 'T' test comparison of means.

9.4. For Pass/Fail tests, 30 samples will be used. These tests are required by IEC 60601-2-2. And 30 samples has been the norm at Megadyne for these tests for many years.

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

Test Description	Test Type	Sterile Samples 2525-10	Sterile Samples 2525-15
Flow Rate	Measurement	11 ea. [1]	11 ea. [1]
Electrode Wobble	Measurement	11 ea. [1]	N/A [2]
Plug Insertion/extraction force	Measurement	11 ea. [1]	N/A [2]
Tubing Strength	Measurement	30 ea.	N/A [2]
Proximal Connector Removal Force	Measurement	11 ea. [1]	N/A [2]
Electrode Extraction Force and retention test	Measurement Pass/Fail	30 ea.	N/A [2]
Button force	Measurement	30 ea.	N/A [2]
Plug Strain Relief (Rotational Test)	Pass/Fail	30 ea.	N/A [2]
Handpiece Strain Relief (Rotational Test)	Pass/Fail	30 ea.	N/A [2]
Nozzle Pry force	Measurement	30 ea.	N/A [2]

[1] Eleven samples plus 11 control samples
[2] Samples from either catalog number can be used for this test

10. ZIP PENCIL PROCEDURE

10.1. FLOW RATE

10.1.1. Obtain sample size of 11 Zip Pencils. Also obtain a sample of 11 REF 2110-10 for controls.

10.1.2. Number each Zip Pencil sample and each 2110-10 sample with a unique identification number.

10.1.3. Remove the electrode cap from each of the samples and discard.

10.1.4. Record Zip Pencil Catalog number and lot number on data collection sheet in Appendix I, also record the control catalog number and lot number.

10.1.5. Use a current MegaVac Plus Smoke Evacuation device with a new filter. Record the MegaVac Serial number on the data Sheet in Appendix I

10.1.6. Use the calibrated TSI 4000 Series flow meter attached to the MegaVac filter. Record the identification number, last calibration date, and calibration due date of the flow meter on the data sheet in Appendix I

10.1.7. Attach the 2110-10 control sample Pencil to the flow meter and lay the tubing out on the table. Be sure that there are no kinks in the tubing. Attach the flow meter to the smoke evacuation filter on the smoke evacuation device.

10.1.8. Set the MegaVac to maximum flow in Open mode. Record the settings on the data sheet.

10.1.9. Activate the MegaVac for 5 seconds.

10.1.10. Observe the maximum reading on the flow meter and record the value on the data collection sheet in Appendix I.

10.1.11. Repeat the flow test steps 10.1.7 through 10.1.10 for each of the 2110-10 and Zip Pencil samples and record the values on the data sheet in Appendix I.

10.1.12. Repeat the flow tests with each of the 2110-10 and Zip samples using the Buffalo filter ViroVac, Conmed Aer Defense and Lina Safe Air system. Make all of the measurements with the smoke evacuation system set a maximum flow. These measurements with competitive smoke evacuators is not required for evaluation of the Zip Pencil but is included in the protocol for acquiring Marketing Data. The acceptance of the Zip Pencil per the protocol will be based on the data obtained from the test with the MegaVac system.

10.2. ELECTRODE WOBBLE

10.2.1. Obtain sample size of 11 Zip Pencils.

10.2.2. Obtain a sample of 11 each, REF 0035 (or equivalent) disposable pencils for controls.

10.2.3. Use Engineering supplied holding fixture on the ROI optical measuring system.

10.2.4. Install one sample of the disposable pencil in the holding fixture such that the distal end of the electrode is visible on the ROI field of view.

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

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

10.2.7. 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.

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

10.2.9. Record the measurement on the data collection sheet in Appendix II.

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

10.2.11. Perform the same measurements on the Zip Pencil samples and record the measurement values on the data sheet in Appendix II.

10.3. PLUG INSERTION / EXTRACTION FORCE TEST

INSERTION TEST

10.3.1. Obtain a sample size of 11 ZIP Pencils and 11 disposable pencils (0035 or equivalent). The Zip Samples from the above tests may be reused for this test.

10.3.2. Number each sample with unique identification numbers as required.

10.3.3. Use the 100 lb. load cell in the Instron.

10.3.4. Place a representative Mega Power ESU connector block in the lower jaws of the Instron.

10.3.5. Set the connector pins of the pencil plug on the connector block receptacles so that they align properly for insertion.

10.3.6. Lower the upper jaws of the Instron so that they can grasp the initial 0.25" of the test plug, actuate the jaws to grasp the plug.

10.3.7. Program the Instron for a speed of 7.87 inches per minute (200 mm per minute) and a travel distance of 0.1 inches (2.54 mm).

10.3.8. Select "Balance Load" to zero the load cell.

10.3.9. Press Start to perform the test to measure the insertion force.

EXTRACTION TEST

10.3.10. With the plug still inserted in the test connector, select "Balance Load" to zero the load cell.

10.3.11. Using the same speed as above, pull the plug out of the connector measuring the extraction force.

10.3.12. Repeat the test for 11 Zip Pen samples and 11 disposable pencil samples.

10.3.13. Print out the results for use in the test report.

10.4. TUBING STRENGTH

10.4.1. This pull test is intended to test which breaks first, the tubing or the connection of the tubing to the connector. This connection of the tube to the connector is the same dimensions as three other connections on the product. This test is representative of all of the tube connections.

10.4.2. This test also make a comparison between tubing from two different suppliers, Global Med and Smooth Bor.

10.4.3. Obtain 15 samples manufactured with Global Med tubing and 15 samples manufactured with Smooth Bor tubing.

10.4.4. Program the Instron for a speed of 30 inches per minute (762 mm per minute) and a travel distance of 1.0 inches (25.4 mm).

10.4.5. Clamp the Tube Connector in the lower jaws of the Instron. Clamp the connector in such a way that the Instron jaws are holding on to the side of the connector that contains the cable.

10.4.6. Clamp the tubing (portion of tubing without the cable inside) in the upper jaws of the Instron with an approximately 10 inch gap in between the Jaws.

10.4.7. Select "Balance Load" to zero the load cell.

10.4.8. Select Start and pull the tubing until either the tube or the connection fails.

10.4.9. Repeat the test for 15 Zip Pen samples with Global Med tubing and 15 Zip Pen samples with Smooth Bor tubing.

10.4.10. Print out the results for use in the test report.

10.5. PROXIMAL CONNECTOR REMOVAL FORCE TEST

10.5.1. This test is to insure that the tubing connector stays firmly attached to smoke box coupler in comparison to competitive connectors.

10.5.2. Obtain 11 samples of Zip Pen and 11 samples of 2110-09EC.

10.5.3. Program the Instron for a speed of 7.87 inches per minute (200 mm per minute) and a travel distance of 0.1 inches (2.54 mm). Use the ten pound load cell.

10.5.4. Clamp a 22mm connector in the lower jaws of the Instron. For this test, use the Megadyne ULPA Replacement filter connector. This is a new connector in development and Engineering will supply the connector.

10.5.5. Press the Proximal Connector onto the 22mm connector.

10.5.6. Clamp the tubing in the upper jaws of the Instron with an approximately 10 inch gap in between the Jaws.

10.5.7. Select "Balance Load" to zero the load cell.

10.5.8. Select Start and pull the tubing until the connection disengages.

10.5.9. Repeat the test for 11 Zip Pen and 2110-09 samples.

10.5.10. Print out the results for use in the test report.

10.5.11. Additional tests may be done with competitive connectors for comparison.

10.6. ELECTRODE EXTRACTION FORCE

10.6.1. Use the 10 lb. load cell in the Instron.

10.6.2. Obtain 30 Zip Pen samples that have not had the electrode removed.

10.6.3. Number the samples with unique identification numbers.

10.6.4. Remove the electrode that is in the pencil.

10.6.5. Perform electrode extraction using a .0930 bi-lateral X Class pin gage.

10.6.6. Program the Instron for a speed of 7.87 inches per minute (200 mm per minute) and a travel distance of 0.9 inches (23 mm).

10.6.7. Insert the .0930 pin gage into the Zip Pen so that the pin engages with the full length of the collet. The minimum insertion depth is .75 inches.

10.6.8. Place the pencil in the Instron holding fixture provided by engineering.

10.6.9. Clamp the exposed length of the pin gage into the upper jaws of the Instron.

10.6.10. Select "Balance Load" to zero the load cell.

10.6.11. Press Start to perform the test to measure the extraction force.

10.6.12. Repeat the test for 30 Zip Pen samples.

10.6.13. Print out the results for use in the test report.

10.6.14. Following the extraction force test above, insert the original electrode back into the Zip Pen for the electrode retention force test.

10.6.15. Remove the electrode from each sample and re-insert it nine more times. This will account for a total of ten insertion extraction cycles.

10.6.16. Following the ten insertion extraction cycles, hold the Zip pen verticle with the electrode facing down and hang a 60 gram weight on the electrode (calculated from the weight of an 0014 electrode of 5.8g times 10 and rounded up). Hold the sample in this position for 60 seconds. The electrode with the weight shall remain in the Zip Pen with the weight attached, Reference IEC 60601-2-2 clause 201.15,4,1,102.

10.6.17. Record the pass/fail results from the retention test on the log sheet in Appendix III

10.7. BUTTON FORCE TESTING

10.7.1. Obtain 30 samples of Zip Pen. Use of the samples from previous tests is acceptable.

10.7.2. 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.

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

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

10.7.5. Identify the sample in the Instron test software.

10.7.6. Balance the load to zero the Instron.

10.7.7. Run the test.

10.7.8. Reposition the Zip Pen to test the Coag button and repeat the test.

10.7.9. Repeat the above test for the remaining samples.

10.7.10. Provide the test data to engineering for use in the Test Report

10.8. PLUG STRAIN RELIEF (ROTATIONAL) TEST

10.8.1. Obtain 30 samples of Zip Pen. Use of the samples from previous tests is acceptable.

10.8.2. Cut the cable of the Zip Pen 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.

10.8.3. 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.

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

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

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

10.8.7. 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.

10.8.8. 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.

10.8.9. 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.

10.8.10. 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.

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

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

10.9. HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

10.9.1. Obtain 30 samples of Zip Pen. Use of the samples from previous tests is acceptable.

10.9.2. If not previously completed, cut the cable of the Zip Pen 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.

10.9.3. 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.

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

10.9.5. Attach a 200 gram weight onto the tubing/cord approximately 30 cm below the Zip Pen.

10.9.6. 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.

10.9.7. 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.

10.9.8. 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.

10.9.9. 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.

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

10.10. NOZZLE PRY FORCE TEST

10.10.1. Obtain 30 samples of Zip Pen. Use of the samples from previous tests is acceptable. Note that this test is a destructive test and therefore needs to be done last.

10.10.2. Install the 100 pound load cell in the Instron. Set the cross head speed to 12.0 inches per minute.

10.10.3. Insert a test pin suitable for Nozzle force testing in the load cell mounting socket.

10.10.4. Use an engineering supplied holding fixture in the vise. Insert the Zip Pen under test in the holding fixture with the Nozzle end directly below the test pin in the load cell.

10.10.5. Identify the sample in the Instron test software.

10.10.6. Balance the load to zero the Instron.

10.10.7. Apply a force of up to 20 pounds to the tip of the Zip Pen nozzle. Apply the force until either the Zip Pen breaks or the 20 pound load is reached.

10.10.8. Repeat the above test for the remaining samples.

10.10.9. Provide the test data to engineering for use in the Test Report.

11. ACCEPTANCE CRITERIA

11.1. Flow Rate

11.1.1. The flow rate of the Zip Pencil shall be equal to or greater than the flow rate of the 2110-10 as determined by the "t test".

11.2. Electrode Wobble

11.2.1. The electrode wobble shall not be greater than the wobble of the disposable pencil as determined by the "t test".

11.3. Plug Insertion Extraction Force

11.3.1. The Zip Pen Plug insertion and extraction force shall be equal to the disposable pencil as determined by the "t test".

11.4. Tubing Strength

11.4.1. The connection of the tubing to the tube connector shall be stronger than the tubing, i.e. the tubing will break before the connection comes loose.

11.5. Proximal Connector Removal Force

11.5.1. The Zip Pen Proximal Connector removal force shall be approximately equal to the 2110-09EC connector. If the removal force is lower, further evaluation by engineering and marketing will be performed to determine if the connector removal force is adequate.

11.6. Electrode Extraction and Retention

11.6.1. The electrode extraction force shall be within the range specified by the DMR. This range is 1.5 to 4.5 pounds.

11.6.2. The electrode retention after 10 insertions shall pass the retention requirements of IEC 60601-2-2:2009 clause 201.15.4.1.102.

11.7. Button Force

11.7.1. The Zip Pen button activation force shall be within the range specified by the DMR. This range is 300 to 700 grams.

11.8. Plug Strain Relief

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

11.9. Handpiece Strain Relief

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

11.10. Nozzle Pry Force

11.10.1. The nozzle pry force test is being performed to determine if the Zip Pen has adequate mechanical strength. Adequate strength is believed to be 10

pounds. The Zip Pen shall not break or the snap features come unsnapped before ten pounds is applied.

11.10.2. The force is being applied up to 20 pounds to determine where breakage or disassembly actually occurs.

12. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-052-01	Initial Release	2014 MAR 28

Appendix I:
FLOW RATE

Flow Meter ID# _____

Flow Meter Last Calibration Date _____

Flow Meter Calibration Due Date _____

Smoke Evacuator Make and Model _____

Smoke Evacuator Serial Number _____

Zip Pen Catalog 2525-10	Lot #	UltraVac Catalog 2110-10	Lot#

Sample #	Flow Rate	Sample #	Flow Rate
1		1	
2		2	
3		3	
4		4	
5		5	
6		6	
7		7	
8		8	
9		9	
10		10	
11		11	

Test Performed by: _____ Date: _____

Appendix II
ELECTRODE WOBBLE

Zip Pen Catalog 2525-10	Lot #	Disposable Pencil Catalog	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	

Test Performed by: _____ Date: _____

Appendix III

ELECTRODE RETENTION TEST

Zip Pen Catalog 2525-10	Lot #		
Sample #	Pass/Fail	Sample #	Pass/Fail
1		16	
2		17	
3		18	
4		19	
5		20	
6		21	
7		22	
8		23	
9		24	
10		25	
11		26	
12		27	
13		28	
14		29	
15		30	

Test Performed by: _____ Date: _____

Appendix IV

PLUG STRAIN RELIEF (ROTATIONAL) TEST

Zip Pen Catalog 2525-10	Lot #		
Sample #	Pass/Fail	Sample #	Pass/Fail
1		16	
2		17	
3		18	
4		19	
5		20	
6		21	
7		22	
8		23	
9		24	
10		25	
11		26	
12		27	
13		28	
14		29	
15		30	

Test Performed by: _____ Date: _____

Appendix V

HANDPIECE STRAIN RELIEF (ROTATIONAL) TEST

Zip Pen Catalog 2525-10	Lot #		
Sample #	**Pass/Fail**	**Sample #**	**Pass/Fail**
1		16	
2		17	
3		18	
4		19	
5		20	
6		21	
7		22	
8		23	
9		24	
10		25	
11		26	
12		27	
13		28	
14		29	
15		30	

Test Performed by: _____ Date: _____