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Zip Pen Flow Report and Doc Update

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1. REFERENCES

ENG-RMF-045	Smoke Evacuation Accessories Risk Analysis
ENG-PRT-720	Shipping Test, Zip Pen, Test Protocol
ENG-RPT-401	Zip Pen Extension Nozzles, Three Year Accelerated Aging

2. APPENDIX

I. **Zip Pen Flow Test Sheet w/ Mega Vac Plus**
II. **Zip Pen Flow Test Sheet w/ Buffalo Filter ViroVac**
III. **Zip Pen Flow Test Sheet w/ Conmed AER Defense**
IV. **Zip Pen Flow Test Sheet w/ Lina Safe Air**

3. SCOPE

This protocol pertains to the Zip Pen Catalog number 2525-10 and 2525-15. The two Zip Pen 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. For the purpose of this testing the two Zip Pen devices are considered equivalent. Previous testing has shown that the extra five feet of tubing on the 2525-15 has little or no effect on the flow of the device.

4. PURPOSE

The purpose of this test protocol is to establish flow rate characteristics of the Zip Pen and compare them to the UltraVac 2110-10 (predicate Device) using the MegaVac Plus and other competitive smoke evacuation devices.

5. BACKGROUND

The Zip Pen is a new design of smoke evacuation electrosurgical pencil for Megadyne and requires testing to show equivalence to the predicate device. The testing will also establish maximum flow rate characteristics for the Zip Pen based on the highest flow rate smoke box available for testing.

6. DEFINITIONS AND ACRONYMS

IFU	Instructions for Use
ULPA	Ultra Low Particulate Air

7. APPARATUS

7.1.1. Mega Vac Plus Smoke Evacuation Device with ULPA Filter

7.1.2. Buffalo Filter ViroVac Smoke Evacuation Device

7.1.3. Conmed AER Defense Smoke Evacuation Device

7.1.4. Lina Safe Air Smoke Evacuation Device

7.1.5. Calibrated TSI 4000 Series Flow Meter

8. RISK ASSESSMENT

8.1. Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with Zip Pen flow volume. The highest severity rating is 3 attributable to customer dissatisfaction.

Failure Mode	Cause	Mitigation	Verification
Does not remove smoke adequately Air Flow Not Adequate	Improper flow path design Inadequate Design for Flow	Test for Flow Volume	Test Report ENG-RPT-403

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

9.1. Prior to the flow 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 ENG-PRT-720 to simulate 3 years. The aging temperature will be 55°C and the aging duration per the protocol is 111 days. The samples used for this protocol are the same lot used in test report ENG-RPT-377. See that test report for documentation of the aging and preconditioning.

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%. The samples used for this protocol are the same lot used in test report ENG-RPT-377. See that test report for documentation of the aging and preconditioning.

9.3. This test is comparing maximum flow rate of the Zip Pen 2525-15 to the UltraVac 2110-10 (predicate) when attached to the Megadyne MegaVac Plus and other competitive smoke evacuation devices. For the comparison 11 units of each device will be used. Eleven devices is the minimum required number to determine a comparison of means using a 't' test.

9.4. This protocol also tests whether the device is damaged or the tubing collapses under occluded conditions in order to insure that the device is not damaged by vacuum. This testing will use the same 11 samples from the flow tests. This is an investigative test to determine if there is a limit of the tubing to maintain patency under vacuum.

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

Test Description	Test Type	Sterile Sample Quantity
Zip Pen 2525-10 Flow and occlusion test	Measurement	11 ea.
Ultra Vac 2110-10 Flow and occlusion test	Measurement	11 ea.

10. ZIP PEN FLOW AND OCCLUSION TESTING PROCEDURE

10.1. Obtain sample size of 11 Zip Pen's.

10.2. Number each Zip Pen sample with a unique number.

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

10.4. Record Zip Pen Catalog number and lot number on data collection sheet in Appendix I.

10.5. Perform the following test for all pencil samples using the MegaVac Plus Smoke Evacuation Device with a new ULPA filter and record the data In Appendix I.

10.6. Use the Smoke Evacuation device with a new filter. Set the flow rate to the maximum flow for open type surgery. Record the Smoke Evacuation Device Serial number and the Filter Lot number on the data Sheet.

10.7. Attach the TSI Series 4000 Flow Meter to the filter outlet of the Smoke Evacuation device.

10.8. Prior to testing any Smoke Evacuation Pencils, activate the Smoke Evacuation Device at the maximum flow setting and record the maximum flow without the Zip Pen attached. Record this maximum flow value on the data sheet.

10.9. Attach the Zip Pen to the TSI Series 4000 Flow Meter. Extend the Zip Pen tubing along the workbench making sure there are not any kinks in the tubing.

10.10. Activate the Smoke Evacuation device for a minimum of 30 seconds or until the flow reading on the flow meter is stable. Record the flow on the data sheet in Appendix I.

10.11. After the flow test, remove the electrode and occlude the device by putting a soft piece of rubber sheet held by your finger over the end of the nozzle.

10.12. Observe the effect of the occlusion. Note the effect on the Zip Pen. Things to look for are tubing collapse, accordion of the tubing and damage.

10.13. Repeat the above test using the UltraVac 2110-10 for comparison.

10.14. Repeat steps 10.6 through 10.13 for each of the 11 samples using the different smoke evacuation devices listed below.

10.15. Repeat the above tests with the Buffalo Filter Viro Vac Smoke Evacuation device and record the data In Appendix II.

10.16. Repeat the above tests with the Conmed AER Defense Smoke Evacuation device and record the data In Appendix III.

10.17. Repeat the above tests with the Lina Safe Air Smoke Evacuation device and record the data In Appendix VI.

11. ACCEPTANCE CRITERIA

11.1. The Zip Pen 2525-15 flow rate shall be equal to or greater than the Ultra Vac 2110-10.

11.2. There shall be no damage to the Zip Pen when occluded.

11.3. The flow rating for the Zip Pen shall be established at the level of the Smoke Evacuation Device with the maximum flow value.

Appendix I:
Zip Pen Flow Test Data Sheet
Mega Vac Plus

Zip Pen Catalog# _____ **Lot#** _____

Ultra Vac Catalog# _____ **Lot#** _____

Mega Vac Plus S/N _____

ULPA Filter Lot# _____

Maximum Flow of the Mega Vac Plus _____

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-10	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	
7.		7.	
8.		8.	
9.		9.	
10.		10.	
11.		11.	

Comments on Zip Pen Occlusion: _____

_____

Test Performed by: _____ Date: _____

Appendix II:
Zip Pen Flow Test Data Sheet
Buffalo Filter Viro Vac

Zip Pen Catalog# _____ **Lot#** _____

Ultra Vac Catalog# _____ **Lot#** _____

Viro Vac S/N _____

Maximum Flow of the Buffalo Filter Viro Vac _____

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-10	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	
7.		7.	
8.		8.	
9.		9.	
10.		10.	
11.		11.	

Comments on Zip Pen Occlusion: _____

_____

Test Performed by: _____ Date: _____

Appendix III:
Zip Pen Flow Test Data Sheet
Conmed AER Defense

Zip Pen Catalog# _____ **Lot#** _____

Ultra Vac Catalog# _____ **Lot#** _____

AER Defense S/N _____

Maximum Flow of the Conmed AER Defense _____

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-10	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	
7.		7.	
8.		8.	
9.		9.	
10.		10.	
11.		11.	

Comments on Zip Pen Occlusion: _____

_____

Test Performed by: _____ Date: _____

Appendix VI:
Zip Pen Flow Test Data Sheet
Lina Safe Air SFR-0200

Zip Pen Catalog# _____ **Lot#** _____

Ultra Vac Catalog# _____ **Lot#** _____

Safe Air S/N _____

Maximum Flow of the Lina Safe Air SFR-0200 _____

Zip Pen Flow Test		Control Samples Flow Test	
Sample #	Zip Pen 2525-10	Sample #	Ultra Vac 2110-10
	Flow		Flow
1.		1.	
2.		2.	
3.		3.	
4.		4.	
5.		5.	
6.		6.	
7.		7.	
8.		8.	
9.		9.	
10.		10.	
11.		11.	

Comments on Zip Pen Occlusion: _____

_____

Test Performed by: _____ Date: _____