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Zip Pen Thermal Protocol and Report

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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

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performance

ENG-RMF-045 Smoke Evacuation Accessories Risk Analysis

ENG-PRT-720 Shipping Test, Zip Pen, Test Protocol

2. APPENDIX

- I. Zip Pen Temperature Data Sheet
- II. Zip Pen Simulated Use Thermal Investigation

3. SCOPE

This protocol pertains to the Zip Pen Catalog number 2525-10 and 2525-15 and Extension Nozzles 2540 and 2560. 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.

4. PURPOSE

The purpose of this test protocol is to specify thermal testing required on the Zip Pen and Extension Nozzles to show compliance with IEC 60601-1: 2012 and IEC 60601-2-2: 2009. Note that the standards' testing specifically applies to heating caused by the electrical current conducted through the device.

Outside of the standards requirements, the protocol also has an investigative section to measure temperatures of the device that may be caused by active electrosurgery in combination with smoke evacuation.

5. DEFINITIONS AND ACRONYMS

ESU	Electrosurgical Unit
IFU	Instructions for Use

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6. APPARATUS

- 6.1.1. Electrosurgical Unit (ESU) – Mega Power
- 6.1.2. Mega Vac Smoke Evacuation Device with ULPA Filter
- 6.1.3. Monopolar footswitch
- 6.1.4. Disposable Return Electrode
- 6.1.5. 0014 and 0014A EZ-Clean Electrodes
- 6.1.6. Thermal IR Camera, FLIR T300
- 6.1.7. Tripod
- 6.1.8. Digital Camera
- 6.1.9. Stop Watch
- 6.1.10. Function Generator

7. RISK ASSESSMENT

- 7.1. Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with Zip Pen and Extension nozzles overheating. The highest severity rating is 10, attributable to potential user or patient injury.

Failure Mode	Cause	Mitigation	Verification
Pencil overheats and melts	Insufficient contact area between electrode and electrical connector	Product validation	Test Report ENG-RPT-391

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- 7.2. The Zip Pen handle is not an applied part, however, for the Zip Pen and Nozzle Extensions, there is a high probability of patient contact. Therefore, these will be treated as applied parts not intended to supply heat to the patient. The duration of contact is estimated to be anywhere between 1 minute and 10 minutes. Under this condition, the maximum allowable temperature is 48°C. Additionally, if the temperature exceeds 41°C, additional information is required to be included in the Instructions for Use. Refer to IEC 60601-1: 2012 clause 11.1.2.2.

8. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

- 8.1. Prior to the thermal 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 accelerated aging will be documented in the test report.
- 8.2. 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 humidities from 15% to 95%. This temperature and humidity cycling will be documented in the test report.
- 8.3. This test evaluates the maximum temperature rise of the applied part from conduction of electricity under controlled conditions. It is not expected that there will be a high level of variation. For the evaluation, three samples will be used, one for each length of Zip Pen and Nozzle combination. If there is high variation in the data from these samples, additional samples may be added to the test.

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

Test Description	Electrode	Sterile Sample Quantity
Zip Pen Handle and Electrode Temperature with no extension, Ref 2525-10 or Ref 2525-15	0312	1 ea.
Zip Pen Handle and Electrode Temperature with 2.7" Nozzle Extension Ref 2540	0314A	1 ea.
Zip Pen Handle and Electrode Temperature with 5.2" Nozzle Extension Ref 2560	0314	1 ea.

9. ZIP PEN IEC 60601-1 TEMPERATURE TEST

- 9.1. Obtain sample size of 3 Zip Pen's, one of each Nozzle Extension and the electrodes shown in the table above.
- 9.2. Number each Zip Pen sample with a unique number.
- 9.3. 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.
- 9.4. Install the Extension Nozzle as required by the table above.
- 9.5. Record Zip Pen Catalog number and lot number on data collection sheet in Appendix I.

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- 9.6. Record the Extension Nozzle and electrode lot numbers on the data collection sheet in Appendix I.
- 9.7. Use a Mega Power ESU. Record the ESU serial Number on the data collection sheet in Appendix I.
- 9.8. 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.
- 9.9. 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.
- 9.10. 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 Zip Pencil under test into the ESU. Use a laboratory stand to suspend the Zip Pencil in air where the camera can be focused on the Zip Pen.
- 9.11. Attach one end of a test lead to the Zip Pen 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.
- 9.12. Connect the other side of the load resistor to the Patient return on the ESU.
- 9.13. Take an initial temperature with the FLIR Camera and record the maximum temperature as a baseline on the data sheet in appendix I.
- 9.14. Set the ESU for 300 Watts Cut.
- 9.15. Activate the ESU on the duty cycle and allow it to run for 1 hour.
- 9.16. At the end of the one hour activation, stop the ESU.

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- 9.17. Take the temperature of the Zip Pen and Nozzle Extension with the FLIR camera and record the maximum Cut temperature on the data sheet in appendix I.
- 9.18. With the ESU off, allow the Zip Pen to stabilize back to room temperature for a minimum of 30 minutes.
- 9.19. Again, take the temperature of the Zip Pen and Nozzle Extension with the FLIR camera and record the maximum temperature as a baseline on the data sheet in appendix I.
- 9.20. Set the ESU for 120 Watts Coag.
- 9.21. Activate the ESU on the duty cycle and allow it to run for 1 hour.
- 9.22. At the end of the one hour activation, stop the ESU.
- 9.23. Take the temperature of the Zip Pen and Nozzle Extension with the FLIR camera and record the maximum Coag temperature on the data sheet in appendix I.
- 9.24. Repeat the above Cut and Coag Tests with each of the three nozzle lengths.

10. SIMULATED USE THERMAL INVESTIGATION

- 10.1. Using the ESU, MegaVac Plus and disposable return electrode, prepare to perform electrosurgery trials on raw chicken breast tissue, warmed to room temperature. The number of samples and activation power settings are shown below.

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10.2. Use the Zip Pen with the smoke evacuation tube connected to the Mega Vac Plus. Set the Mega Vac Plus to open mode at maximum flow rate. Set the time to minimum delay.

10.3. Record the equipment serial numbers and accessory lot numbers in appendix II.

Cut Mode, 50 Watts	Coag Mode, 50 Watts
1 of each length of nozzle	1 of each length of nozzle

10.4. For Cut mode, activate for 10 seconds with the electrode tip inserted up to ½ inch into the chicken breast. Continuously move the electrode in a cutting motion.

10.5. For Coag mode, arc to the chicken breast with the end of the electrode for 10 seconds. Continuously move the electrode in a fulguration motion.

10.6. Prior to the activations, use the IR camera to record the image of the surface temperature of the Handle and Nozzle being tested. Capture the image of the surface from the button area to the start of the distal end of the Nozzle.

10.7. Perform the activation test as follows. Hold the Zip Pen handle behind the button area. Use the Monopolar foot pedal to activate the Zip Pen. This method will insure that heat from the operator's fingers does not affect the temperature of the test area. Make the Cut activation as described above.

10.8. After the activation, immediately use the IR camera to record the image of the surface temperature of the handle being tested. Capture the image of the surface from the button area to the start of the distal end of the Nozzle.

10.9. Repeat the above process for the Coag activation.

10.10. Repeat the process with each of the three samples.

10.11. Take pictures of the samples to include in the test report.

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11. ACCEPTANCE CRITERIA

11.1. Zip Pen IEC 60601-1 Temperature Test

11.1.1. The temperature of the Zip Pen cannot exceed 48°C.

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

11.2. Simulated Use Thermal Investigation

11.2.1. There is no specific acceptance criterion for this test. The intent of the test is to observe whether the Nozzle of the product is melted or damaged by the heat of electrosurgery. The effect of electrosurgery on the Nozzle material will be discussed in the test report.

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**Appendix I:
Zip Pen Temperature**

Zip Pen Catalog# _____ Lot# _____

Extension Nozzle 2540 Lot # _____ Extension Nozzle 2560 Lot # _____

Electrode 3012 Lot # _____ Electrode 3014 Lot # _____

Electrode 3014A Lot # _____

Mega Power ESU S/N _____

FLIR Camera ID# _____

Camera Calibration Date _____

Camera Calibration Due Date _____

Zip Pen Test		CUT		Zip Pen Test		COAG	
Sample #	Temperature			Sample #	Temperature		
	Before	After			Before	After	
1.				1.			
2. (2540)				2. (2540)			
3. (2560)				3. (2560)			

Comments: _____

Test Performed by: _____ Date: _____

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**Appendix II:
Zip Pen Simulated Use Thermal Investigation**

Zip Pen Catalog # _____ Lot # _____

Extension Nozzle 2540 Lot # _____ Extension Nozzle 2560 Lot # _____

Electrode 0014A Lot # _____ Electrode 0014 Lot # _____

Mega Power ESU S/N _____

Mega Vac Plus S/N _____

FLIR Camera ID# _____

Camera Calibration Date _____

Camera Calibration Due Date _____

Comments: _____

Test Performed by: _____ Date: _____

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