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### Zip Product Spec Verification

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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
ENG-PS-007	Product Specification, Smoke Evacuation Pencil and Accessories
ENG-IOM-012	Input/Output Conformance Test Matrix, Zip Project

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## 2. APPENDIX

- I. Button Size Acceptance Sheet
- II. Branding Acceptance Sheet
- III. Tip Exposure Acceptance Sheet
- IV. Nozzle Acceptance Sheet
- V. Cord Containment Acceptance Sheet
- VI. Tubing Swivel Acceptance Sheet
- VII. Tubing Ergonomics Acceptance Sheet
- VIII. Button Location Acceptance Sheet
- IX. ULPA Filter Efficiency Acceptance Sheet
- X. ULPA Filter Fluid Trap Acceptance Sheet
- XI. ULPA Filter Connector Acceptance Sheet
- XII. Charcoal Filter Carbon Acceptance Sheet
- XIII. Zip Electrode Insertion Acceptance Sheet
- XIV. Zip Pen Packaging Acceptance Sheet
- XV. Zip Extension Nozzle Packaging Acceptance Sheet
- XVI. Zip Pen and Extension Nozzles Unit Labeling Acceptance Sheet
- XVII. Zip Pen and Extensions Nozzles Shipper Labeling Acceptance Sheet
- XVIII. ULPA and Carbon Filter Unit Labeling Acceptance Sheet
- XIX. ULPA and Carbon Filter Shipper Labeling Acceptance Sheet

## 3. SCOPE

This protocol pertains to the Zip Pen Cat numbers 2525-10 and 2525-15, ULPA Replacement Filter Cat 2211 and Carbon Filter Cat 2220.

## 4. PURPOSE

The purpose of this test protocol is to specify verification requirements to show compliance with Product Specification ENG-PS-007 for requirements that are not tested under other protocols.

## 5. BACKGROUND

The Zip Pen is a new design of smoke evacuation pencil for Megadyne. The ULPA Replacement Filter is an existing accessory that is being redesigned and sourced from a different supplier. The Carbon Filter is an existing accessory that is being documented for purchase from a different supplier. These accessories have been subject of several verification protocols. This protocol is intended to document remaining requirements that are not documented in other protocols. For all other test documentation, refer to Input/Output Conformance Test Matrix ENG-IOM-012.

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## 6. DEFINITIONS AND ACRONYMS

N/A

## 7. APPARATUS

### 7.1.1. Calibrated Calipers

## 8. RISK ASSESSMENT

- 8.1. Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with these devices. The highest severity rating is 1 attributable to user dissatisfaction.

Failure Mode	Cause	Mitigation	Verification
Sore finger	Button too small	Design button to be the same size or larger than current disposable pencil	Test Report ENG-RPT-418
User not aware of product brand	Branding not on product	Design with brand on the product	Test Report ENG-RPT-418

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## 9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

9.1. The majority of the attributes in this verification are design attributes only. These will be verified by inspection of documentation. Therefore, the sample size is one. In the case of the measurement for electrode exposure from the end of the nozzle to the end of the electrode, this is a comparison measurement and a sample size of 11 will be used. This is an adequate sample size for a comparison test. For the electrode insertion test, a functional test of 11 units will be used. The product was intentionally designed to pass this test so a small sample size is adequate to verify that the design goal has been met.

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

Test Description	Test Type	Samples 2525-10
Button size	Drawing comparison	N/A
Branding	Drawing comparison	N/A
Tip Exposure	Measurement	11 ea. <sup>1</sup>
Nozzle Clear	Drawing inspection	N/A
Cord in tube	Drawing inspection	N/A
Tubing swivel	Drawing inspection	N/A
Tubing Ergonomics	Visual/ Photographs	N/A
Button Location	Drawing inspection	N/A
ULPA Filter Efficiency	Specification inspection	N/A
ULPA Filter Fluid Trap	Drawing inspection	N/A
ULPA Filter Connector	Drawing inspection	N/A

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Carbon in Charcoal Filter	Specification inspection	N/A
Zip Electrode Insertion	Functional	11 ea.
Zip Pen packaging	Drawing inspection	N/A
Zip Extension Nozzle Packaging	Drawing inspection	N/A
Zip Pen and Extension Nozzle Unit Labeling	Drawing inspection	N/A
Zip Pen and Extension Nozzle Shipper Labeling	Drawing inspection	N/A
ULPA and Carbon Filter Unit Labeling	Drawing inspection	N/A
ULPA and Carbon Filter Shipper Labeling	Drawing inspection	N/A

<sup>1</sup> Eleven samples plus 11 control samples

## 10. PROCEDURE

### 10.1. BUTTON SIZE

10.1.1. Measure the length and width of the button on a Zip Pen. Refer to Zip Pen Button Drawing ENG-DWG-588.

10.1.2. Calculate the surface area of the usable surface of the button, record the value in Appendix I.

10.1.3. Measure the diameter of the button on a disposable pencil catalog number 0035 or 0039. Calculate the surface area and record the value in Appendix I.

10.1.4. Compare the values.

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## 10.2. BRANDING

10.2.1. Refer to Zip Pen Body Drawing ENG-DWG-650.

10.2.2. Verify that the pen body color is Gray Pantone 356 with Green Pantone 427 TPR, record acceptance in Appendix II.

10.2.3. Verify that the Megadyne name is on the product, record acceptance in Appendix II.

## 10.3. TIP EXPOSURE

10.3.1. Obtain 11 Samples of Zip pen 2525-10 and 11 samples of Ultra Vac 2110-10.

10.3.2. Record the lot numbers of each set of samples on the data sheet in appendix III.

10.3.3. Measure the distance from the end of the nozzle to the end of the electrode on each sample and record the data on the form in appendix III. Note that the Zip Pen nozzle is angled. Use the longest measurement obtainable.

10.3.4. Repeat the test for 11 Zip Pen samples and 11 Ultra Vac samples.

## 10.4. NOZZLE CLARITY

10.4.1. Refer to Zip Pen Nozzle Drawing ENG-DWG-594.

10.4.2. Verify that the material used is clear and not opaque. Review of an actual component may be required for this verification, record acceptance in Appendix IV.

## 10.5. CORD CONTAINMENT

10.5.1. Refer to Zip Pen Assembly Drawing ENG-DWG-716.

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10.5.2. Verify that the assembly specifies that the cord will be inside of the tubing for the first 64 inches of tubing. Review of an actual component may be required for this verification, record acceptance in Appendix V.

#### 10.6. TUBING SWIVEL

10.6.1. Refer to Zip Pen Assembly Drawing ENG-DWG-716.

10.6.2. Verify that the assembly specifies a swivel component located approximately eight inches from the Zip Pen Handle. Review of an actual component may be required for this verification, record acceptance in Appendix VI.

#### 10.7. TUBING ERGONOMICS

10.7.1. Obtain a sample of the Zip Pen. Photograph the three different tube options as they are shown in the IFU.

10.7.2. Insure that it is possible to configure the tubing as shown in the IFU. Record acceptance in Appendix VII.

#### 10.8. BUTTON LOCATION

10.8.1. Refer to Zip Pen Assembly Drawing ENG-DWG-716.

10.8.2. Verify that the assembly specifies that the yellow Cut button is located closest to the electrode and the blue Coag button is located farthest from the electrode. Review of an actual component may be required for this verification, record acceptance in Appendix VIII

#### 10.9. ULPA FILTER EFFICIENCY

10.9.1. Refer to drawing ENG-DWG-1015 for the ULPA filter media.

10.9.2. Review the drawing and insure that the filter efficiency is 99.999% at a minimum, record acceptance in Appendix IX.

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#### 10.10. ULPA FILTER FLUID TRAP

10.10.1.Refer to the ULPA Replacement Filter Drawing ENG-DWG-1017.

10.10.2.Review the drawing and insure that the ULPA Filter has a fluid trap.  
Review of the actual component may be required for this verification,  
record acceptance in Appendix X

#### 10.11. ULPA FILTER CONNECTOR

10.11.1.Refer to the ULPA Replacement Filter Inlet Drawing ENG-DWG-1017.

10.11.2.Review the drawing to insure that the ULPA filter connector is  
compatible with the Zip Pen Proximal Adapter P/N ENG-DWG-1160.  
Alternatively, connection of actual components can be used for this  
verification, record acceptance in Appendix XI.

#### 10.12. CHARCOAL FILTER CARBON

10.12.1.Obtain a sample of the 2220 carbon filter. Verify that it connects to the  
outlet of a Mega Vac and Mega Vac Plus. Review the specification sheet  
to insure that it contains charcoal. Record acceptance in Appendix XII

#### 10.13. ZIP ELECTRODE INSERTION

10.13.1.Obtain 11 samples of Zip Pen Cat #2525-10 or 2525-15 and 11 samples  
of electrode Cat# 0014 or 0014A. Record the lot numbers of each set of  
samples.

10.13.2.Remove the 0012 electrode that comes with the Zip Pen. Install the 0014  
or 0014A electrode in place of the 0012. In the process of installing the  
electrodes try to install them incorrectly.

10.13.3.Verify correct installation by checking continuity between the active pin  
on the plug to the electrode tip.

10.13.4.Record on the data sheet in Appendix XIII whether the installation passed  
or failed.

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#### 10.14. ZIP PEN PACKAGING

10.14.1. Review drawings 2525-10 and 2525-15. Verify that the shipping box is an RSC (regular slotted container) design and that an IFU is required for each box.

10.14.2. Verify that the products are packaged 20 in a box.

10.14.3. Record acceptance on the data sheet in Appendix XIV.

#### 10.15. ZIP EXTENSION NOZZLE PACKAGING

10.15.1. Review drawings 2540 and 2560. Verify that the shipping box is an RSC (regular slotted container) design and that an IFU is required for each box.

10.15.2. Verify that the products are packaged 10 in a box

10.15.3. Record acceptance on the data sheet in Appendix XV.

#### 10.16. ZIP PEN AND EXTENSION NOZZLE UNIT LABELING

10.16.1. Review the drawings for the ZIP Pen and Extension Nozzle unit labels against the requirements of the Product specification.

10.16.2. Verify that the required elements from the Product specification are present on the labels. The unit label part numbers are ENG-DWG-272, ENG-DWG-277, MKT-LBL-514, and MKT-LBL-517. The product specification number is ENG-PS-007.

10.16.3. Record acceptance on the data sheet in appendix XVI.

#### 10.17. ZIP PEN AND EXTENSION NOZZLE SHIPPER LABELING

10.17.1. Review the drawings for the ZIP Pen and Extension Nozzle shipper labels against the requirements of the Product specification.

10.17.2. Verify that the required elements from the Product specification are present on the labels. The shipper label part numbers are MKT-LBL-499,

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MKT-LBL-510, MKT-LBL-515, and MKT-LBL-516. The product specification number is ENG-PS-007.

10.17.3. Record acceptance on the data sheet in appendix XVII.

#### 10.18. ULPA AND CARBON FILTER UNIT LABELING

10.18.1. Review the drawings for the ULPA Replacement Filter and Carbon Filter unit labels against the requirements of the Product specification.

10.18.2. Verify that the required elements from the Product specification are present on the labels. The Unit label part numbers are MKT-LBL-518 and MKT-LBL-522. The product specification number is ENG-PS-007.

10.18.3. Record acceptance on the data sheet in appendix XVIII.

#### 10.19. ULPA AND CARBON FILTER SHIPPER LABELING

10.19.1. Review the drawings for the ULPA Replacement Filter and Carbon Filter shipper labels against the requirements of the Product specification.

10.19.2. Verify that the required elements from the Product specification are present on the labels. The Shipper label part numbers are MKT-LBL-519 and MKT-LBL-523. The product specification number is ENG-PS-007.

10.19.3. Record acceptance on the data sheet in appendix XIX.

### 11. ACCEPTANCE CRITERIA

#### 11.1. BUTTON SIZE

11.1.1. The button surface area shall be approximately equal to or greater than the button of a disposable pencil

#### 11.2. BRANDING

11.2.1. The Zip Pen handle shall be gray pantone 427 with inlayed green pantone 356 TPR. The Megadyne name will be molded into the handle.

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### 11.3. TIP EXPOSURE

11.3.1. The dimension from the distal end of the electrode to the nozzle opening shall be comparable to the Ultra Vac 2110-10

### 11.4. NOZZLE CLARITY

11.4.1. The nozzle shall be clear in the area of the electrode

### 11.5. CORD CONTAINMENT

11.5.1. The Zip Pen cord shall be inside of the tubing for a minimum of the first 64 inches of tubing.

### 11.6. TUBING SWIVEL

11.6.1. The tubing will have a swivel near the pencil connection.

### 11.7. TUBING ERGONOMICS

11.7.1. The tubing shall be configurable in three different ways as shown in the IFU

### 11.8. BUTTON LOCATION

11.8.1. The yellow CUT button shall be nearer to the electrode and the blue COAG button shall be farthest from the electrode.

### 11.9. ULPA FILTER EFFICIENCY

11.9.1. The ULPA filter shall have a minimum efficiency of 99.999% for 0.1 to 0.2 micron particles.

### 11.10. ULPA FILTER FLUID TRAP

11.10.1. The ULPA filter shall contain a fluid trap for capture of fluids prior to the filtration media.

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#### 11.11. ULPA FILTER CONNECTOR

11.11.1. The ULPA filter connector shall accept the threaded proximal adapter of the Zip Pen.

#### 11.12. CHARCOAL FILTER CARBON

11.12.1. The Carbon filter shall connect to the outlet of the Mega Vac and Mega Vac Plus. The Carbon filter shall contain charcoal.

#### 11.13. ZIP ELECTRODE INSERTION

11.13.1. When installing a replacement electrode in the Zip Pen, it shall not be possible to install the electrode such that it is secure in the Zip Pen without being electrically connected to the Zip Pen Collet.

11.13.2. The electrode shall have continuity and a resistance below 50 ohms when installed.

#### 11.14. ZIP PEN PACKAGING

11.14.1. The shipping box for the Zip Pen 2525-10 and 2525-15 shall be an RSC (regular slotted container) design.

11.14.2. The shipping box for the Zip Pen 2525-10 and 2525-15 shall contain one IFU in each box.

11.14.3. The Zip Pens shall be packaged with 20 units in each box.

#### 11.15. ZIP EXTENSION NOZZLE PACKAGING

11.15.1. The shipping box for Extension Nozzles 2540 and 2560 shall be an RSC (regular slotted container) design.

11.15.2. The shipping box for the Extension Nozzles 2540 and 2560 shall contain one IFU in each box.

11.15.3. The Extension Nozzles shall be packaged with 10 units in each box

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#### 11.16. ZIP PEN AND EXTENSION NOZZLE UNIT LABELING

11.16.1. The unit labels for the Zip Pen and Extension Nozzles shall contain the following information.

11.16.1.1. Label Part Number

11.16.1.2. The label revision and date

11.16.1.3. A bar code that is unique to the device

11.16.1.4. The product catalog number preceded by the appropriate symbol

11.16.1.5. The product trade name

11.16.1.6. The symbol for “manufacturer” followed by Megadyne name with registered trade mark, address, city, state, zip code and phone number

11.16.1.7. A graphic representation of the product

11.16.1.8. The E-Z Clean logo with registered trade mark (Zip Pen only)

11.16.1.9. The product Lot Number preceded by the appropriate symbol

11.16.1.10. The product Expiration Date preceded by the appropriate symbol

11.16.1.11. The CE mark as defined by the MDD

11.16.1.12. The EC Representative information preceded by the appropriate symbol

11.16.1.13. The appropriate sterilization symbol



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11.16.1.14.The symbol for “do not reuse”

11.16.1.15.The symbol for “consult instructions for use”

11.16.1.16.The symbol for “Rx Only”

11.16.1.17.The symbol for do not use if package is damaged

11.16.1.18.The words “Open Here” located near the tabs used for opening the package (Zip Pen Only)

11.16.1.19.The statement “Refer to Instructions for Use for Patent Information” (Zip Pen Only)

11.16.1.20.A symbol indicating the maximum and minimum temperature and humidity for shipping and storage conditions

11.16.1.21.A symbol that specifies the maximum rated voltage for the device (Zip Pen only).

#### 11.17. ZIP PEN AND EXTENSION NOZZLE SHIPPER LABELING

11.17.1.The shipping labels for the Zip Pen and Extension Nozzles shall contain the following information.

11.17.1.1.Label Part Number

11.17.1.2.The label revision and date

11.17.1.3.A bar code that is unique to the device

11.17.1.4.The product catalog number preceded by the appropriate symbol

11.17.1.5.The symbol for “manufacturer” followed by Megadyne name with registered trade mark, address, city, state, zip code and phone number

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11.17.1.6.The product trade name

11.17.1.7.A graphic representation of the product

11.17.1.8.The E-Z Clean logo with registered trade mark (Zip Pen only)

11.17.1.9.The CE mark as defined by the MDD

11.17.1.10.The EC Representative information preceded by the appropriate symbol

11.17.1.11.The product Lot Number preceded by the appropriate symbol

11.17.1.12.The product Expiration Date preceded by the appropriate symbol

11.17.1.13.The appropriate sterilization symbol

11.17.1.14.The symbol for “do not reuse”

11.17.1.15.The symbol for “consult instructions for use”

11.17.1.16.The symbol for “Rx Only”

11.17.1.17.The symbol for do not use if package is damaged

11.17.1.18.A symbol indicating the maximum and minimum temperature and humidity for shipping and storage conditions

11.17.1.19.The symbol indicating the number of units in the case

## 11.18. ULPA AND CARBON FILTER UNIT LABELING

11.18.1.The unit labels for ULPA Replacement and Carbon Filters shall contain the following information.

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11.18.1.1.Label Part Number

11.18.1.2.The label revision and date

11.18.1.3.A bar code that is unique to the device

11.18.1.4.The product catalog number preceded by the appropriate symbol

11.18.1.5.The product trade name (ULPA Filter Only)

11.18.1.6.The symbol for “manufacturer” followed by Megadyne name with registered trade mark, address, city, state, zip code and phone number

11.18.1.7.A graphic representation of the product

11.18.1.8.The product Lot Number preceded by the appropriate symbol

11.18.1.9.The CE mark as defined by the MDD

11.18.1.10.The EC Representative information preceded by the appropriate symbol

11.18.1.11.The symbol for “consult instructions for use”

11.18.1.12.The symbol for “Rx Only”

11.18.1.13.A symbol indicating the maximum and minimum temperature and humidity for shipping and storage conditions

## 11.19. ULPA AND CARBON FILTER SHIPPER LABELING

11.19.1.The shipper labels for ULPA Replacement and Carbon Filters shall contain the following information.

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11.19.1.1.Label Part Number

11.19.1.2.The label revision and date

11.19.1.3.A bar code that is unique to the device

11.19.1.4.The product catalog number preceded by the appropriate symbol

11.19.1.5.The symbol for “manufacturer” followed by Megadyne name with registered trade mark, address, city, state, zip code and phone number

11.19.1.6.A graphic representation of the product

11.19.1.7.The CE mark as defined by the MDD

11.19.1.8.The EC Representative information preceded by the appropriate symbol

11.19.1.9.The product Lot Number preceded by the appropriate symbol

11.19.1.10.The symbol for “consult instructions for use”

11.19.1.11.The symbol for “Rx Only”

11.19.1.12.A symbol indicating the maximum and minimum temperature and humidity for shipping and storage conditions

11.19.1.13.The symbol indicating the number of units in the case

## **12. APPENDIX**

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**Appendix I:  
BUTTON SIZE**

Zip Pen Button Size Calculation from ENG-DWG-588

Width \_\_\_\_\_

Length \_\_\_\_\_

Calculation \_\_\_\_\_

Two Dimensional Area: \_\_\_\_\_

Disposable Pencil Button Size Calculation

Catalog Number: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Button Diameter: \_\_\_\_\_

Calculation: \_\_\_\_\_

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## **Appendix II BRANDING**

Reference ENG-DWG-650

Verify that the Pen Body has the following:

Body Color is Pantone 356: YES/NO      Initials/Date \_\_\_\_\_

TPR inlay is Pantone 427: YES/NO      Initials/Date \_\_\_\_\_

Megadyne Name: YES/NO      Initials/Date \_\_\_\_\_

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### Appendix III

#### TIP EXPOSURE

Zip Pen Catalog Number: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Ultra Vac Catalog Number: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Zip Pen Sample Number	Measurement		Ultra Vac Sample Number	Measurement
Z1			U1	
Z2			U2	
Z3			U3	
Z4			U4	
Z5			U5	
Z6			U6	
Z7			U7	
Z8			U8	
Z9			U9	
Z10			U10	
Z11			U11	

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#### **Appendix IV**

##### **NOZZLE CLARITY**

Reference Drawing ENG-DWG-594

Verify that the Nozzle meets the following:

Material is clear and not opaque:      YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

#### **Appendix V**

##### **CORD CONTAINMENT**

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

Cord is assembled inside the tube for at least the first 48 inches:

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_



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## **Appendix VI**

### **TUBING SWIVEL**

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

The assembly has a swivel component approximately 8 inches from the handle:

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

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## **Appendix VII**

### **TUBING ERGONOMICS**

Reference IFU MKT-LBL-531

Verify that the Assembly meets the following:

The Tube/Cord can be configured as shown for the three methods in the IFU. Photograph the three configurations for the test report:

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

## **Appendix VIII**

### **BUTTON LOCATION**

Reference Drawing ENG-DWG-716

Verify that the Assembly meets the following:

The Yellow CUT Button is nearest to the electrode and the Blue COAG Button is farthest from the electrode:

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

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## Appendix IX

### ULPA FILTER EFFICIENCY

Reference Assembly Drawing ENG-DWG-1017and  
Component Drawing ENG-DWG-1015

Verify that the Assembly meets the following:

The assembly has a minimum filtration efficiency of 99.999% :

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

## Appendix X

### ULPA FLUID TRAP

Reference Assembly Drawing ENG-DWG-1017

Verify that the Assembly meets the following:

The assembly has a Fluid Trap :

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

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## **Appendix XI**

### **ULPA FILTER CONNECTOR**

Reference Component Drawing ENG-DWG-1017

Verify that the Assembly meets the following:

The assembly has a threaded connector that is compatible with the Zip Pen Proximal Adapter ENG-DWG-1160:

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

## **Appendix XII**

### **CHARCOAL FILTER CARBON**

Obtain a sample of Carbon Filter 2220

Verify that the Filter meets the following:

The Filter connects to the Mega Vac and/or Mega Vac Plus

The filter contains charcoal

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

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### Appendix XIII

#### ZIP ELECTRODE INSERTION

Zip Pen Catalog Number: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Electrode Catalog Number: \_\_\_\_\_ Lot Number: \_\_\_\_\_

Zip Pen Sample Number	Insertion Correct Yes/No	Continuity (Ohms)
C1		
C2		
C3		
C4		
C5		
C6		
C7		
C8		
C9		
C10		
C11		

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#### **Appendix XIV**

#### **ZIP PEN PACKAGING**

Reference Assembly Drawings 2525-10 and 2525-15

Verify that the Assembly meets the following:

The assembly box is an RSC style box :

YES/NO      Initials/Date \_\_\_\_\_

The assembly requires and IFU in each box :

YES/NO      Initials/Date \_\_\_\_\_

The assembly requires 20 units per box :

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

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## Appendix XV

### EXTENSION NOZZLE PACKAGING

Reference Assembly Drawing 2540 and 2560

Verify that the Assembly meets the following:

The assembly box is an RSC style box :

YES/NO      Initials/Date \_\_\_\_\_

The assembly requires and IFU in each box :

YES/NO      Initials/Date \_\_\_\_\_

The assembly requires 10 units per box :

YES/NO      Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

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## Appendix XVI

### ZIP PEN AND EXTENSION NOZZLE UNIT LABELING

Reference Unit Label Drawings ENG-DWG-272, ENG-DWG-277, MKT-LBL-514 and MKT-LBL-517. Verify that the Labels meet the following:

Requirement	2525-10	2525-15	2540	2560
Label Part Number				
Label Revision and Date				
Bar code				
Catalog Number and Symbol				
Product Trade Name				
Manufacturer symbol and name				
Graphic of the product				
E-Z Clean Logo			N/A	N/A
Lot Number and Symbol				
Expiration Date and Symbol				
CE Mark				
EC Rep and symbol				
Sterilization Symbol				
Do Not Reuse Symbol				
Consult Instructions Symbol				
Rx Only Symbol				
Do Not Use if Package is Damaged Symbol				
The words "OPEN HERE"			N/A	N/A
Refer to Instructions for Use for Patent Information			N/A	N/A
Temperature and Humidity Symbol				
Rated Voltage Symbol			N/A	N/A

Acceptance YES/NO Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_



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## Appendix XVII

### ZIP PEN AND EXTENSION NOZZLE SHIPPING LABELS

Reference Shipper Label Drawings MKT-LBL-499, MKT-LBL-510, MKT-LBL-515 and MKT-LBL-516. Verify that the Labels meet the following:

Requirement	2525-10	2525-15	2540	2560
Label Part Number				
Label Revision and Date				
Bar code				
Catalog Number and Symbol				
Manufacturer symbol and name				
Product Trade Name				
Graphic of the product				
E-Z Clean Logo			N/A	N/A
CE Mark				
EC Rep and symbol				
Lot Number and Symbol				
Expiration Date and Symbol				
Sterilization Symbol				
Do Not Reuse Symbol				
Consult Instructions Symbol				
Rx Only Symbol				
Do Not Use if Package is Damaged Symbol				
Temperature and Humidity Symbol				
Quantity per box symbol				

Acceptance YES/NO Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_

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## Appendix XVIII

### ULPA AND CARBON FILTER UNIT LABELING

Reference Unit Label Drawings MKT-LBL-518 and MKT-LBL-522. Verify that the Labels meet the following:

Requirement	2221	2220
Label Part Number		
Label Revision and Date		
Bar code		
Catalog Number and Symbol		
Product Trade Name		N/A
Manufacturer symbol and name		
Graphic of the product		
Lot Number and Symbol		
CE Mark		
EC Rep and symbol		
Consult Instructions Symbol		
Rx Only Symbol		
Temperature and Humidity Symbol		

Acceptance YES/NO Initials/Date \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

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## Appendix XIX

### ULPA AND CARBON FILTER SHIPPING LABELS

Reference Shipping Label Drawings MKT-LBL-519 and MKT-LBL-523. Verify that the Labels meet the following:

Requirement	2221	2220
Label Part Number		
Label Revision and Date		
Bar code		
Catalog Number and Symbol		
Manufacturer symbol and name		
Product Trade Name		N/A
Graphic of the product		
CE Mark		
EC Rep and symbol		
Lot Number and Symbol		
Consult Instructions Symbol		
Rx Only Symbol		
Temperature and Humidity Symbol		
Quantity per box symbol		

Acceptance    YES/NO    Initials/Date    \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_