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ENG-PRT-451 Zip Rqmt Testing

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ENG-PRT-327	Shipping Test – Zip Pen 2525-15
ENG-RPT-569	Aged, Non-Aged Zip Tubing Strength Comparison Report
MKT-CMR-029	MEGADYNE Smoke Evacuation Product Line CMR
ENG-PS-007	Product Specification, Smoke Evacuation Pencil and

	Accessories
ENG-PS-010	Product Specification, Disposable Electrosurgical Pencil
MKT-US-002	Usability Requirements Specification, Smoke Evacuation Pencils, Extension Nozzles and Universal ULPA Filter
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2. APPENDIX CONTENTS

I. Cable & Tube Length, Connector Dimension, Swivel Distance Acceptance Sheet
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3. SCOPE

This protocol pertains to the Zip Pen products identified in MKT-CMR-029, including cat numbers 2525-10 (252510), 2525-10EC (252510EC), 2525-10BN (252510BN), 2525-10ECBN (252510ECBN), 2525-15EC (252515EC), and 2525-15 (252515), ME7251C, ME7251E, ME725M1C, ME725M1E. These Zip products share the same design, differing only in cord / tubing length, active electrode type, and/or packaging. This protocol also pertains to the Extension Nozzle cat numbers 2540 (2540J) and 2560 (2560J). The catalog numbers in parentheses are new catalog numbers referring to the same product, due to transition of product information from Megadyne Medical Products to Ethicon Endo Surgery. The old and new catalog numbers are interchangeable as it relates to referencing a product.

4. PURPOSE

The purpose of this test protocol is to verify requirements to show compliance with customer and marketing level (MKT-CMR-029), usability (MKT-US-002) and product specification (ENG-PS-007) requirements that are not tested under other protocols.

5. BACKGROUND

The Zip Pen is a smoke evacuation pencil for Megadyne. The ULPA Replacement Filter is an existing accessory that has been redesigned and sourced from a different supplier. These accessories have been the subject of several verification protocols. This protocol is intended to document additional evidence for verification of requirements. For all other test documentation, refer to Input/Output Conformance Test Matrix ENG-IOM-012.

6. MATERIALS

6.1. Calibrated Calipers

6.2. Calibrated Measuring Tape or Yard Stick

6.3. Competitive ESUs

6.3.1. ConMed Sabre 2400

6.3.2. Valleylab Force 2

6.3.3. Erbe ICC 350

6.3.4. Force Triad

6.3.5. Force FX

6.3.6. Erbe VIO 300D

6.3.7. ConMed System 5000

6.4. Zip-Pen (252510EC, 252515)

6.4.1. Aged Samples (Source: Lot # S160050, proof of aging and shipped testing in ENG-PRT-327, ENG-RPT-503)

6.4.2. Non-Aged Samples (Source: Pulled from Warehouse)

6.5. Extension Nozzles (2560J, 2540J)

6.5.1. Non-Aged Samples (Source: Pulled from Warehouse)

6.6. Instron Force Tester

6.7. ULPA Filter (2211J)

6.7.1. Non-Aged Samples (Source: Pulled from Warehouse)

6.8. Connector Filter/Tubing (2140)

6.8.1. Non-Aged Samples (Source: Pulled from Warehouse)

6.9. Pantone Color Chips

7. RISK ASSESSMENT

7.1. Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risk associated with these devices. The items below relate to testing here.

Line ID	Failure Mode	Cause	Mitigation	Verification
30-d	Tubing disconnects from connector	Improper tubing material specified	Test mechanical pull strength of tubing from connectors	Test Report ENG-RPT-329
24-a	User not aware of product brand	Branding not on product	Design with brand on the product	Test Report ENG-RPT-418
29-d	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 ENG-RPT-329
43-a, 44-a	Incorrect electrode to Nozzle Size	Electrode too short, cannot do surgery without removing nozzle. Electrode too long, poor smoke capture	Put compatibility statement in IFU	IFU MKT-LBL-531

8. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

8.1. There are several attributes part of this test which do not exhibit variation as it relates to the acceptance criteria. For these attributes one (1) part/device will be inspected along with the documentation controlling the presence of that attribute. For dimensional measurements, critical dimensions (as defined by diamonds on the print) are measured during incoming inspection on a sample of the product. Most components are molded and experience minimal variation relative to the specification. Therefore, the sample size for dimensional measurements is three. For comparative tests, 11 samples will be used. For functional measurements, 30 samples will be used (per QA-SOP-012). The majority of product attributes are shared between all Zip product codes, and thus a single catalog number can be used to verify the attributes of all catalog numbers previously listed, with the exception of attributes such as cable and tube length. Sterilized samples will be used. Accelerated aged products will be

used to meet ENG-PS-007 requirement PRS 2001, with justification provided if non-aged samples are used.

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

Test Description	Test Type	Sample Size	Requirement Linkage	Justification for non-aged or ship testing
Cable & Tube Length, Connector Dimension, Swivel Distance	Drawing comparison, Measurement	252510EC (3) 252515 (3)	MKT-CMR-029	Transportation and aging do not affect length
E-Z Clean Coating	Drawing comparison, Pass/Fail	252510EC (1) 252515 (1)	MKT-CMR-029	Transportation and aging do not affect presence of the coating
Holster, Plug, Cord Color	Drawing inspection, Pass/Fail	252515 Accelerated Aged (1)	MKT-CMR-029, PRS 1103, PRS 1109, URS 1002	Transportation does not affect the color
Plug Branding	Drawing inspection, Pass/Fail	252515 (1)	MKT-CMR-029, PRS 1104	Transportation and aging do not affect presence of the branding
Angled, Clarity Nozzle	Drawing inspection, Pass/Fail	252515 – Accelerated Aged (1) or 2540J – Accelerated Aged (1) or 2560J – Accelerated Aged (1)	PRS 1113	Transportation does not impact the molded angle of the nozzle or the clarity. Aging does not have an impact on the angle.
Cord Exit, Tube Containment	Drawing inspection,	252510EC (3)	MKT-CMR-	Transportation and aging

Test Description	Test Type	Sample Size	Requirement Linkage	Justification for non-aged or ship testing
Length	Measurement	252515 (3)	029, PRS 1110	do not affect length
Cord Containment	Functional Pass/Fail	252515 – Accelerated Aged and Ship Tested (11)	MKT-CMR-029, PRS 1109	N/A
ESU Physical Plug Compatibility	Pass/Fail, Statement	252515 – Accelerated Aged and Ship Tested (1)	MKT-CMR-029	N/A
Plug Extraction Force	Functional, Instron Measurement	252515 – Accelerated Aged and Ship Tested (30)	MKT-CMR-029, PRS 1310	N/A
Extension Nozzle Length	Drawing inspection, Measurement	2540J (3) 2560J (3)	MKT-CMR-029	Transportation and aging do not affect dimensions
2211 ULPA Filter Attachment	Drawing inspection, Pass/Fail	2211J (1) 2140 (1)	MKT-CMR-029	Transportation and aging do not affect molded connection dimensions
EC Connector Instron Pull Test	Functional Comparison, Instron Measurement	252510EC – Non-Aged (11)	URS 2001, PRS 1308	ENG-RPT-569; Transportation and aging do not affect tubing connections
Cable, Plug Cytotoxicity	Document	N/A	PRS 1504	N/A
2211 ULPA Filter Efficiency	Document	N/A	MKT-CMR-029, PRS 1314	N/A

9. PROCEDURE

NOTE: If operator other than originator conducts testing, ensure proper training is conducted, and documentation of training is provided in the report.

9.1. Cable & Tube Length, Connector Dimension, Swivel Distance

9.1.1. Obtain 3 samples each of 252510EC and 252515.

9.1.2. Measure the length of the cord and tubing of 252510EC and 252515 using measuring tape. Record the value in Appendix I.

9.1.3. Measure the ID of the EC 22mm Connector of the 10' Zip using calipers, at the widest point. Refer to the dimension in Figure 1. Record the value in Appendix I.

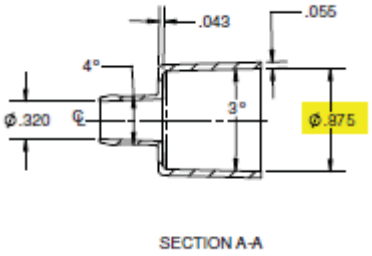

Figure 1

9.1.4. Repeat for each of the three samples.

9.2. E-Z Clean Coating

9.2.1. Obtain 1 sample each of 252510EC and 252515 and inspect the electrode

9.2.2. Verify the electrode is coated with E-Z Clean, record acceptance in Appendix II.

9.3. Holster, Plug, Cord Color.

9.3.1. Obtain 1 sample of 252510EC.

9.3.2. Verify the holster, plug, and cord are Grey Pantone 427, using Pantone color blocks.

9.3.3. Record results in Appendix III.

9.4. Plug Branding

9.4.1. Obtain 1 sample of 252510EC.

9.4.2. Verify the plug has 'Megadyne' branding per Zip Assembly Drawing 6020312-01.

9.4.3. Record results in Appendix IV.

9.5. Angled Nozzle, Clarity

9.5.1. Obtain 1 sample each of 252510EC, 2540J, 2560J

9.5.2. Verify the nozzles have angled tips, and the nozzles are clear, not opaque.

9.5.3. Record results in Appendix V.

9.6. Cord Exit, Tube Containment Length

9.6.1. Obtain 3 samples each of 252510EC and 252515

9.6.2. Measure the length of the cord exiting the tubing of 252510EC and 252515 using measuring tape (from tubing exit to plug). Record the value in Appendix VI.

9.6.3. Measure the length of the cord contained within the tubing of 252510EC and 252515 using measuring tape (from tubing exit to Zip Pen body). Record the value in Appendix VI.

9.6.4. Repeat for each of the three samples.

9.6.5. Record results in Appendix VI.

9.7. Cord Containment

9.7.1. Obtain 11 samples of accelerated aged and ship tested 252515 products (Ship Test described in ENG-RPT-503)

9.7.2. Verify the paper tape is still present and wrapped around the cable.

9.7.3. Verify the cord is still wrapped and contained within the holster.

9.7.4. Record results in Appendix VII.

9.8. ESU Plug Physical Compatibility

9.8.1. Obtain 1 aged Zip sample.

9.8.2. Insert the plug of the 252510EC into each competitive ESU listed in Materials section 6.3. NOTE: This is testing the physical fit of the standard 3 prong plug to standard monopolar ESU ports, not holistic compatibility.

9.8.3. Turn the ESU on. Ensure power settings are suitable for activation (not in standby mode).

9.8.4. Press the cut button. Press the coag button.

9.8.5. Verify the Zip Pen activates and the plug remains attached after insertion. NOTE: Should the connection become too lose for acceptance, obtain a new Zip sample. As a single use device, Zip Pens are intended to be plugged in one time.

9.8.6. Record results in Appendix VIII.

9.9. Plug Extraction Force

9.9.1. Obtain 30 samples of aged, sterilized Zip.

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

9.9.3. Place a representative Mega Power ESU connector block in the lower jaws of the Instron (Figure 3).

9.9.4. Insert the plug into the connector block (Figure 3).

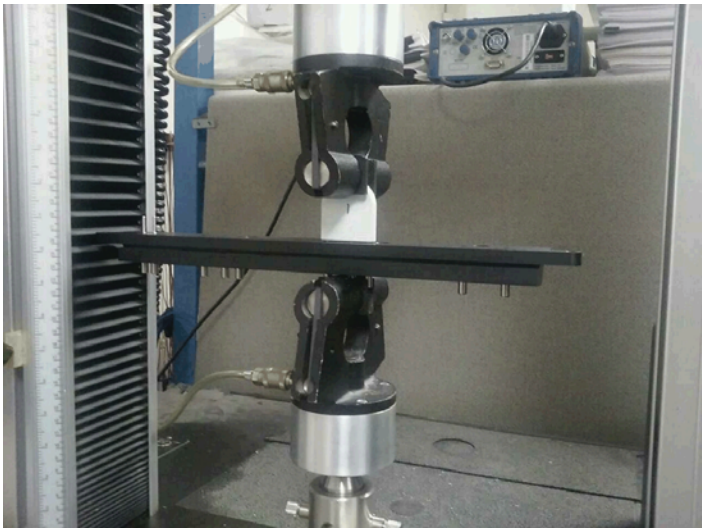

Figure 3

9.9.5. 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.

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

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

9.9.8. Pull the plug out of the connector measuring the extraction force.

9.9.9. Repeat for each of the samples.

9.9.10. Sign and date the print out of the results for use in the test report.

9.10. Extension Nozzle Length

9.10.1. Obtain 3 samples each of 2540J and 2560J.

9.10.2. Measure the longest axis of the nozzle, along centerline.

9.10.3. Repeat for each of the three samples.

9.10.4. Record results in Appendix IX.

9.11. 2211 ULPA Filter Attachment

9.11.1. Obtain 1 sample of 2211 ULPA filter and a 2140 connector. NOTE: The 2140 connector is the threaded connector component of 2110-10 / 2110-09 UltraVac Pencils. Either a standalone 2140 connector or an UltraVac can be used, as the connectors are the same components.

9.11.2. Insert the threaded 2140 connector into the ULPA filter threaded connector.

9.11.3. Record results in Appendix X.

9.12. EC Connector Instron Pull Test

9.12.1. Obtain 11 samples of 252510EC.

9.12.2. Program the Instron for a speed of 7.87 inches per minute (200 mm per minute) and a travel distance of 12 inches (2.54 mm). Use the ten pound load cell.

9.12.3. Secure a filter with a 7/8” port to the base of the Instron using straps or a large vice.

9.12.4. Securely insert the 22 mm EC connector into the 7/8” port.

9.12.5. Clamp the tubing in the upper jaws of the Instron with an approximately 10 inch gap between the upper jaws and the 22 mm connector (Figure 4)

Figure 4

9.12.6. Select “Balance Load” to zero the load cell.

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

9.12.8. Repeat for the remainder of samples.

9.12.9. Sign and date the print out the results for use in the test report.

9.13. Cable, Plug Cytotoxicity

9.13.1. Acquire documentation for past cytotoxicity testing of the cable and plug materials.

9.13.2. Include documentation in test report.

9.14. 2211 ULPA Filter Efficiency

9.14.1. Acquire documentation for past filter efficiency testing.

9.14.2. Include documentation in test report.

10. ACCEPTANCE CRITERIA

The following acceptance criteria must be met, or a sourced document demonstrating the same acceptance criteria must be provided.

10.1. Cable & Tube Length, Connector Dimension, Swivel Distance

10.1.1. Cable length shall be 10 feet for 252510EC and 15 feet for 252515, +/- 6 inches for measurement error. There is no tolerance for Zip Pen cable length on print, only called out as quantity in BOM within 6020191-01 rev 005 and 6020312 rev 007. Tolerance is therefore taken from ENG-PS-010 4.2.6.

10.1.2. Tube length should be 120 inches for 252510 +/- 2.6 inches and 176 in for 252515EC, +/- 3.6 inches per 4100058-01 rev 003 and 4100058-02 rev 003 Length and tolerance determined by adding tolerances for each tubing segment, including note to trim 8.5” tubing segment within 6020191-01 rev 005 and 6020312 rev 007.

10.1.3. The ID of the 22 mm Connector shall be 0.875in, +/- 0.005in per 5800099-01 rev 005.

10.1.4. Swivel Distance shall be approximately 8in from the Zip Pen handle, +/- 1in for measurement error.

10.2. E-Z Clean Coating

10.2.1. The blade shall be coated with proprietary E-Z Clean coating.

10.3. Holster, Plug, Cord Color.

10.3.1. The holster, plug, and cord should be gray Pantone 427.

10.4. Plug Branding

10.4.1. The Megadyne name will be molded into the plug clam shell.

10.5. Angled Nozzle, Clarity

10.5.1. Each nozzle shall have an angled end, and be clear not opaque.

10.5.2. All nozzles (Zip nozzle, 2540J, 2560J are composed of the same material per 5800104-01 rev 003, 5800308 rev 002, 5800309 rev 002). Therefore, acceptance for clarity of one aged sample signifies acceptance of all.

10.6. Cord Exit, Tube Containment Length

10.6.1. Each cord length exiting the tube shall be at least 4 feet in length.

10.6.2. Each length of cord assembled inside the tube should be at least 64 inches in length.

10.7. Cord Containment

10.7.1. The paper shall be present and wrapped around the cable.

10.7.2. The cord shall be wrapped and contained within the holster.

10.8. ESU Plug Compatibility

10.8.1. The plug shall physically fit each ESU with standard three prong monopolar ports—see specific units listed in Materials. There is no specification around specific devices that must be compatible with the exception of Megadyne ESUs which are tested elsewhere.

10.9. Plug Extraction Force

10.9.1. Plug extraction force should be at least 6.0 lbs.

10.10. Extension Nozzle Length

10.10.1. Average length of 2140J should be 2.79 inches and 2160J should be 5.29 inches, each+/- 0.02 inches per 5800309 rev 002 and 5800308 rev 002.

10.11. 2211 ULPA Filter Attachment

10.11.1. The threaded 2140 connector should be capable of being attached with the 2211 ULPA Filter. These parts are molded and designed for compatibility.

10.12. EC Connector Instron Pull Test

10.12.1. Tubing to connector strength should be at least 4.0 lb.

10.13. Cable, Plug Cytotoxicity Acceptance Sheet

10.13.1. Documentation shall be provided for past successful cytotoxicity testing of cable and plug materials.

10.14. 2211 ULPA Filter Efficiency Acceptance Sheet

10.14.1. Documentation shall be provided for past filter efficiency testing demonstrating 99.999% efficiency for particles 0.1 to 0.2 micron.

11. APPENDICES

Appendix I:
Cable & Tube Length, Connector Dimension, Swivel Distance

252510EC

Catalog Number:_____ Lot Number: _____

Sample Number	22mm Connector Diameter	Tube Length	Cord Length	Swivel Distance from Handle
1				
2				
3				

Matches Drawing 5800099-01 Rev 005, 6020312 Rev 007: YES/NO

252515

Catalog Number:_____ Lot Number: _____

Sample Number	Tube Length	Cord Length	Swivel Distance from Handle
1			
2			
3			

Matches Drawing 6020191-01 Rev 005: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

Equipment Name, Number, Cal Date, Cal Due Date: _____

_____

Appendix II
E-Z Clean Coating

252510EC

Catalog Number:_____ Lot Number: _____

Electrode is Coated with E-Z Clean: YES/NO

252515

Catalog Number:_____ Lot Number: _____

Electrode is Coated with E-Z Clean: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix III
Holster, Plug, Cord Color

252510EC

Catalog Number:_____ Lot Number: _____

Holster Color is Pantone 427: YES/NO

Plug Color is Pantone 427: YES/NO

Cord Color is Pantone 427: YES/NO

Matches Drawing 6020312 Rev 007: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix IV
Plug Branding

252510EC

Catalog Number:_____ Lot Number: _____

Plug has 'MEGADYNE' Branding: YES/NO
Matches Drawing 6020312 Rev 007: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix V
Angled Nozzle, Clarity

252510EC

Catalog Number:_____ Lot Number: _____

Nozzle is Angled: YES/NO
Nozzle is Clear and Not Opaque: YES/NO
Material Name from 5800104-01 Rev 003: _____

2540J

Catalog Number:_____ Lot Number: _____

Nozzle is Angled: YES/NO
Material Name from 5800309 Rev 002: _____

2560J

Catalog Number:_____ Lot Number: _____

Nozzle is Angled: YES/NO
Material Name from 5800308 Rev 002: _____

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix VI
Cord Exit, Tube Containment Length

252510EC

Catalog Number:_____ Lot Number: _____

Sample Number	Cord Exit Length	Cord Length Within Tubing
1		
2		
3		

252515

Catalog Number:_____ Lot Number: _____

Sample Number	Cord Exit Length	Cord Length Within Tubing
1		
2		
3		

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

Equipment Name, Number, Cal Date, Cal Due Date: _____

_____

Appendix VII
Cord Containment

252515 – Accelerated Aged and Ship Tested

Catalog Number:_____ Lot Number: _____

Sample #	Paper Wrapped: Pass/Fail	Cord Wrapped and in Holster: Pass/Fail

Matches Drawing 6020191-01 Rev 005: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix VIII
ESU Plug Compatibility

252510EC

Catalog Number:_____ Lot Number: _____

ESU Name	Serial #	Pass/Fail	Comments

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____

Appendix IX
Extension Nozzle Length

2540J

Catalog Number:_____ Lot Number: _____

Sample Number	Extension Nozzle Length
1	
2	
3	

Matches Drawing 5800309 Rev 002: YES/NO

2560J

Catalog Number:_____ Lot Number: _____

Sample Number	Extension Nozzle Length
1	
2	
3	

Matches Drawing 5800308 Rev 002: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

Equipment Name, Number, Cal Date, Cal Due Date: _____

_____

Appendix X
2211 ULPA Filter Attachment

2211

Catalog Number:_____ Lot Number: _____

2140

Catalog Number:_____ Lot Number: _____

Connector is Compatible: YES/NO

Test Conducted By (Name):_____ Date:_____

Test Conducted By (Signature):_____

Comments: _____

_____