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3 yr Real Time Aging Zip ACE Mod

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1. SCOPE

This protocol evaluates the ability of the 6-pack shipping boxes and sterile packaging (see drawing ME725M1C) to withstand the anticipated shipping environment after EO sterilization and 3-year real time aging. In addition, it evaluates the ability of the Zip Pen to meet DMR requirements post EO sterilization and 3-year real time aging. This test protocol applies to ME725M1C as well as ME725M1E.

2. PURPOSE

This protocol defines the ship testing requirements and verifies package performance of EO sterilized product after shipping and 3-year real time aging. In addition, this protocol defines the required testing to show that Zip Pens meet DMR requirements after EO sterilization. Successful completion of this protocol provides objective evidence that the packaging and Zip Pen meet DMR requirements after EO sterilization and 3-year real-time aging.

3. REFERENCES

IEC 60601-2-2 Ed. 5	Medical electrical equipment – Part 2-2: Particular requirements for the safety of high frequency surgical equipment
ASTM D4169	Performance Testing of Shipping Containers and Systems
ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-IOM-012	Test Matrix, Input/Output Conformance – ZIP Pen
ENG-WI-007	Operation of Vibration Table and Drop Test Equipment
OPER-FRM-004	Inspection Form, Peel Pouch Burst Test
ENG-PRT-229	Shipping Test – Zip Pen 2525-10
ENG-RPT-330	Shipping Test – Zip Pencil
ENG-WI-009	Real Time Aging Work Instructions
ENG-PRT-330	Zip Pen EO Compatibility
ENG-RPT-476	Zip Pen EO Compatibility
ENG-PRT-441	ZIP ACE Modified, 6-Pack Ship Test, T=0
ENG-RPT-535	ZIP ACE Modified, 6-Pack Ship Test Report, T=0
ENG-PRT-466	ZIP ACE Modified, 6-Pack Shit Test, 3 yr. Accelerated Aging

ENG-RPT-585	ZIP ACE Modified, 6-Pack Ship Test Report, 3 yr. Accelerated Aging
2010421-01	ASTM D6344 Guided Free Fall Concentrated Impact Test Equipment
ME725M1C	Zip Pen, Electrosurgical Pencil w/ ACE12, Holster, 10 ft. Tubing
2525-10	Zip Pen, Electrosurgical Pencil w/ E-Z Clean, Holster, 10 Foot Tubing
ENG-WI-001	Sterilization Chart

4. BACKGROUND

Zip Pens are currently shipped in a 20-unit shipping container (see Product Code: 2525-10) and gamma sterilized. Marketing has identified a need to distribute Zip Pens in 6-unit shipping containers in configurations that require EO sterilization.

The proposed 6-unit shipping configuration is identical to the current 20-unit shipping configuration in packaging configuration, packaging materials, and manufacturing process. The effects of EO sterilization on the Zip Pen and its packaging material are not completely understood. As such, this protocol will evaluate the Zip Pen and its packaging's integrity after three-year real time aging and EO sterilization. T=0 and T=3 Accelerated Aging ship testing after 2X EO sterilization was performed per protocol ENG-PRT-441 and ENG-PRT-466 respectively.

5. EQUIPMENT

- (6) 6-unit box/36-samples of ME725M1C
- Environmental Chamber
- LAB AccuDrop 160
- Martin Vibration Systems Vibration Table
- Metal shim 0.06 in thick, approximately 2 in wide
- Model F100-2600-3 Test-A-Pack Seal Strength Tester
- Guided Free Fall Concentrated Impact Test Equipment (PN: 2010421-01)
- Instron Force Tester

6. RISK ASSESSMENT

All components and materials of the Zip Pen were analyzed while considering the effects of EO sterilization on the device. It was determined that "EO sterilization of ZIP Pen does not present an increased risk of material failure for all materials of construction with the exception of the EVA tubing" (see Appendix I: ZIP Pen Materials of Construction and Ethylene Oxide Sterilization Exposure).

With the material analysis in mind, the FMEA for Smoke Accessories (ENG-RMF-045) was reviewed while considering the effects of EO sterilization on the Zip Pen and its packaging material over the product life time (3-years). The following line item were identified and require additional testing:

Failure Mode	Cause	Mitigation	Verification
Disconnects from fitting, tubing web tears (Line Item: 30-D)	Improper tubing material specified	Design, material selection, and product validation	Test mechanical pull strength of tubing from connectors
Disconnects from pencil or tubing (Line Item: 31-D)	Incorrect tubing design or material	Design, material and selection	Test mechanical pull strength of tubing from swivel
Does not meet DMR after 3 years (Line Item: 51-D)	Unstable product	Design for 3-year real time aging	Evaluate packaging and product after completing sterilization, 3-year accelerated aging, shipping conditions, and storage extremes.

In addition, the Zip Input-Output matrix (ENG-IOM-012) was reviewed, with the material analysis in mind, while considering the effects of EO sterilization on the Zip Pen and its packaging material over the product life time (3-years). The following product specification were identified and require additional testing.

Origin of Input (Standards – Internal/External)	Design Input
ENG-PS-007: PRS 1308 MKT-CMR-029 ENG-RMF-045	Tubing strong and pliable with adequate connection strength, will remain connected to all connection points under tensile force applied parallel to pencil body equal to 4 lbs.
ENG-PS-007: PRS 1202	Device shall be capable of being transported and stored at temperature range of -40°C to +50°C and humidity range of 15% to 95%.

After review, the following risk controls will be done to address each line item above:

- For line items 30-D, 31-D, and PRS 1308, a tubing strength test will be performed after 2X EO exposure, 3-year real time aging, thermal cycling, and ship conditioning (see ENG-RPT-329).
- For product specification PRS 1202, a bubble leak testing, dye testing, burst testing, minimum seal width testing, and visual damage inspection will be performed after 2X EO exposure and 3-year real time aging.
- For line item 51-D and PRS 2002, outstanding packaging and mechanical requirements will be verified per the aforementioned risk controls. Electrical requirements have been verified in ENG-PRT-330 and ENG-RPT-476.

7. EXPERIMENTAL DESIGN/SAMPLE SIZE JUSTIFICATION

7.1. Test Summary

1. 2x EO Sterilization
2. Real Time Aging
3. Thermal Cycling
4. Ship Conditioning
5. Bubble Leak Testing
6. Dye Testing
7. Burst Testing
8. Minimum Seal Width Testing
9. Product Damage Inspection
10. Tubing Strength Test

Test Description	ME725M1C
Product Conditioning	
EO Sterilization	35 ea.
Real Time Aging	35 ea.
Thermal Cycling	35 ea.
Ship Conditioning	35 ea.
Packaging Tests	
Bubble Leak Test	35 ea.
Dye Test	35 ea.
Burst Test	35 ea.
Minimum Seal Width Test	35 ea.
Product Damage Inspection	
Product Damage Inspection	35 ea.
Mechanical Tests	
Tubing Strength Test	35 ea.

7.2. Experimental Design

7.2.1. All testing will be performed using the 6-unit shipping configuration described in drawing ME725M1C. Product with the "C" connector will be used for testing and can be considered a representative sample for all Zip product codes as the "standard" proximal adapter (PN: 5800302-01) is bulkier than the "EC" proximal adapter (PN: 5800099-01) found in other Zip Pen configurations and thus represents a worst-case shipping scenario.

7.2.2. 2X EO Sterilization

Prior to real time aging, all test product will be subject to two routine EO cycles (Sterigenics Cycle 115).

7.2.3. Real Time Aging

Prior to ship conditioning, all test products will be subjected to 3 yr. Real Time aging according to ENG-WI-009.

7.2.4. Thermal Cycling and Ship Conditioning

Ship Conditioning will be performed according to ASTM D4169 under typical warehouse conditions, which are:

Temperature: 23°C ±5°C

Relative Humidity: 50% ±35%

These conditions are a wider range than stated in ASTM D4169. This deviation from the standard is considered acceptable because actual warehouse, transport, and storage conditions will vary greatly from the range listed in the standard.

For this test, assurance level II as described in ASTM D4169 will be used in this testing. This assurance level was chosen because it is the recommended starting level in the standard.

The test schedule for will follow Distribution Cycle 3:

1. Pre-conditioning
2. Handling
3. Vehicle Stacking
4. Loose load Vibration Vehicle Vibration
5. Concentrated Impact
6. Handling

While this product will normally be shipped on a pallet, distribution cycle 3 was chosen because the product may also be shipped as a single package without a pallet or skid. The chosen cycle (without a pallet) is considered to be a worst-case scenario and is applicable to verify shipping in all foreseeable shipping scenarios.

7.3. Sample Size Justification

Thirty-Six (36) samples will be process through EO Sterilization, Real Time Aging, Thermal Cycling, and Shipping Conditioning. This will provide adequate samples for the following tests.

7.3.1. Bubble Leak Testing

A minimum of 35 will be tested since that is how many were tested during accelerated aging (ENG-RPT-585). A minimum of 29 is required per the rationale in Appendix VIII.

7.3.2. Dye Testing

A minimum of 35 will be tested since that is how many were tested during accelerated aging (ENG-RPT-585). A minimum of 29 is required per the rationale in Appendix VIII.

7.3.3. Burst Testing

A minimum of 35 will be tested since that is how many were tested during accelerated aging (ENG-RPT-585). A minimum of 29 is required per the rationale in Appendix VIII.

7.3.4. Minimum Seal Width Testing

A minimum of 35 will be tested since that is how many were tested during accelerated aging (ENG-RPT-585). A minimum of 29 is required per the rationale in Appendix VIII.

7.3.5. Product Damage Inspection

A minimum of 35 will be tested since that is how many were tested during accelerated aging (ENG-RPT-585). A minimum of 29 is required per the rationale in Appendix VIII.

7.3.6. Tubing Strength Test

A sample size of 35 will be used in a C = 0 sampling plan. This is based on a lot size of up to 3200 and an AQL of 1.5 (per QA-SOP-012 major classification). Although the severity of broken tubing is minor (per QA-SOP-012), a classification of major will be used as 35 samples are being processed through all other tests.

8. PROCEDURE

8.1. 2X EO Sterilization Cycle

8.1.1. Expose product EO sterilization Sterigenics Cycle 115 (per ENG-WI-001 Section 7.2) or equivalent twice.

8.1.2. Attach both EO sterilization cycle data to report.

8.2. Real Time Aging

8.2.1. Perform 3-year real time aging to as outlined in ENG-WI-009.

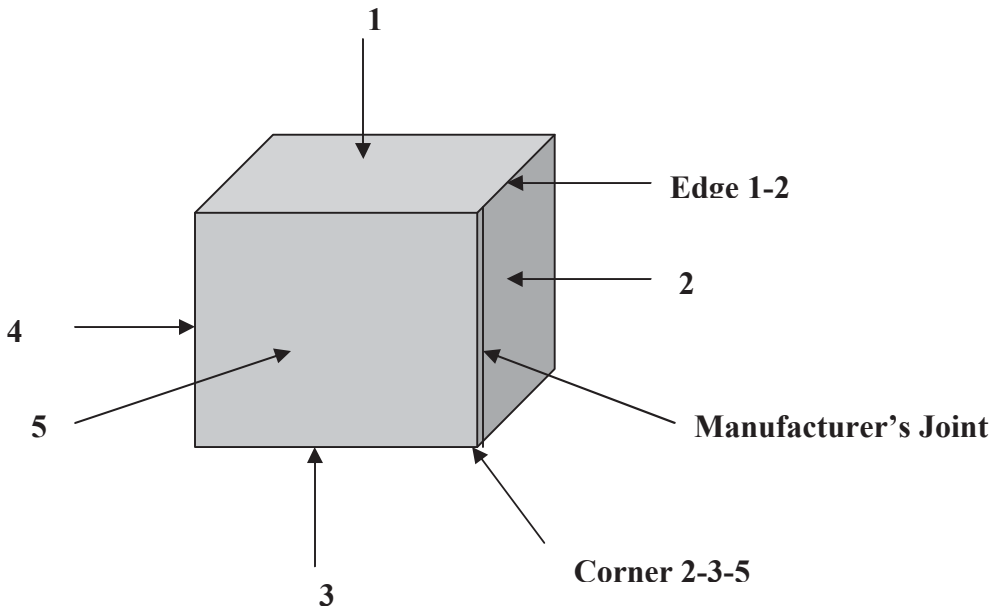
8.3. Thermal Cycling

8.3.1. Using sterile product that has received maximum EO dosage and undergone 3 yr. real time aging, condition the product following the temperature and humidity schedule listed below. Record results on the Appendix II data sheet.

CONDITIONS (± 1 ^{0}C; ± 2% RH)	DURATION (minimum durations noted)
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to 55°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 55°C to 55°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 95%RH	4 hours
Transition from 55°C and 95% RH to 55°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 55°C and 15%RH	4 hours
Transition to 23°C and 50%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH

8.4. Ship Condition Simulation

8.4.1. Use a permanent marker to identify the faces of the shipping boxes according to the following diagram.



8.4.2. Record the gross weight (M) of the shipper box containing product in pounds.

8.4.3. Record the Catalog Number of the product.

8.4.4. Record the Lot Number of the product.

8.4.5. Perform the Handling Test.

8.4.5.1. The required drop height from ASTM D4169 paragraph 10.2.3, using assurance level II, is 15 inches for packages from 0 to 20 pounds. Package weight is approximately 3.5 pounds.

8.4.5.2. Set the height on the LAB AccuDrop 160 to 15 inches. Drop the test package in the following sequence.

Drop Sequence	Orientation	Specific face, edge or corner
1	Top	Face 1
2	Edge	Edge 5-3
3	Edge	Edge 6-3
4	Corner	Corner 2-3-5
5	Corner	Corner 4-3-6
6	Bottom	Face 3

8.4.5.3. Record package drops on the data sheet in Appendix III.

8.4.6. Perform the Vehicle Stacking Test (compression test). Use ASTM D4169 section 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level II will be applied. The compression weight will be at least 200 lbs. This was calculated using the following formula:

$L = M \times J \times ((H-h)/h) \times F$

Where:

L = 200 lb. (computed load (lbf))
M = 3.5 lb. (mass of the package (lb))
J = 1 lbf/lb
H= 108 in
h = 5.5 in. (height of package (in))
F = 3.0 (see section 11.2 of ASTM D4169)

8.4.6.1. Place Face 3 of the shipper box on the ground.

8.4.6.2. Place a wood board on top of the shipper box, such that the shipper box is centered underneath the board. The wood board must extend a minimum of two inches on all sides of the box.

8.4.6.3. Place the test load (determined above) on the center of the wood board.

8.4.6.4. Allow the weight to remain on the wood board for a minimum of 3 seconds.

8.4.6.5. Inspect the package for damage. Record observed shipper box damage, if applicable.

8.4.7. Following the Vehicle Stacking test, perform the Loose Load Vibration test per ENG-WI-007. Record the information in Appendix III.

8.4.7.1. Place the shipper box containing packaged product on the vibration table so that Face 3 rests on the platform.

8.4.7.2. Start the vibration system beginning at the lowest frequency.

8.4.7.3. Slowly increase the frequency of the vibration until the shipper box begins to momentarily leave the surface of the platform.

8.4.7.4. Check the frequency using the shim.

8.3.7.4.1 Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel on the long side of the box from one end of the box to the other. At this low frequency, the movement of the shim will be interrupted movement.

8.4.7.5. Leave the box on the vibration table for a period of 40 minutes.

8.4.7.6. After 40 minutes of Loose Load Vibration, increase the frequency for the Vehicle Vibration Test.

8.4.7.7. Check the frequency using the shim.

8.3.7.7.1 Swipe the shim under the shipping box along the longest side from one of the end to the other. The shim should be able to travel uninterrupted on the long side of the box from one end of the box to the other.

8.4.7.8. If the shim does not travel uninterrupted, increase the frequency of the vibration table.

8.4.7.9. Leave the box on the vibration table for a period of 10 minutes.

8.4.8. Following the Vibration tests, perform a Concentrated Impact test.

8.4.8.1. The Impact test will be done on faces 1,2 and 3 using the Impact test equipment identified in ENG-DWG-768.

8.4.8.2. The impact energy applied to each surface will be 4.0 ft.-lbf (5.4 J). This energy will be achieved by dropping the cylinder mass defined within the 2010421-01 equipment at a height of 32 in (0.8 m).

8.4.9. Following the Concentrated Impact test, perform the second package handling (drop test). Follow the sequence listed below. Make all of the drops from 15 inches except the final drop which is from 30 inches.

Drop Sequence	Orientation	Specific face, edge or corner
1	Edge	Edge 4-6
2	Face	Face 4
3	Face	Face 6
4	Corner	Corner 2-1-5
5	Edge	Edge 2-1
6	Bottom	Face 3, Increase height to 30 inches.

8.4.10. Record completion of Shipping Test in Appendix III.

8.5. Bubble Leak Testing

8.5.1. Perform Bubble Leak Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 16.

8.5.2. Record data in Appendix IV and attach results to test report.

8.6. Dye Testing

8.6.1. Perform Dye Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 17.

8.6.2. Record data in Appendix V and attach results to test report.

8.7. Burst Testing

8.7.1. Perform Burst Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 18.

8.7.2. Record data on form OPER-FRM-004 and attach results to test report.

8.8. Minimum Seal Width Testing

8.8.1. Perform Minimum Seal Width Testing on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 19.

8.8.2. Record data in Appendix VI and attach results to test report.

8.9. Product Damage Inspection

8.9.1. Perform Product Damage Inspection on 35 samples as outlined in ENG-PRT-229 Rev. 002 Section 20.

8.9.2. Record data in Appendix VII and attach results to test report.

8.10. Tubing Strength Test

8.10.1. Program the Instron for a speed of 30 in./min. and a travel distance of 18.0 in.

8.10.2. Prepare the samples for testing.

8.10.2.1. Cut the Zip Pen just on the distal side of the first swivel

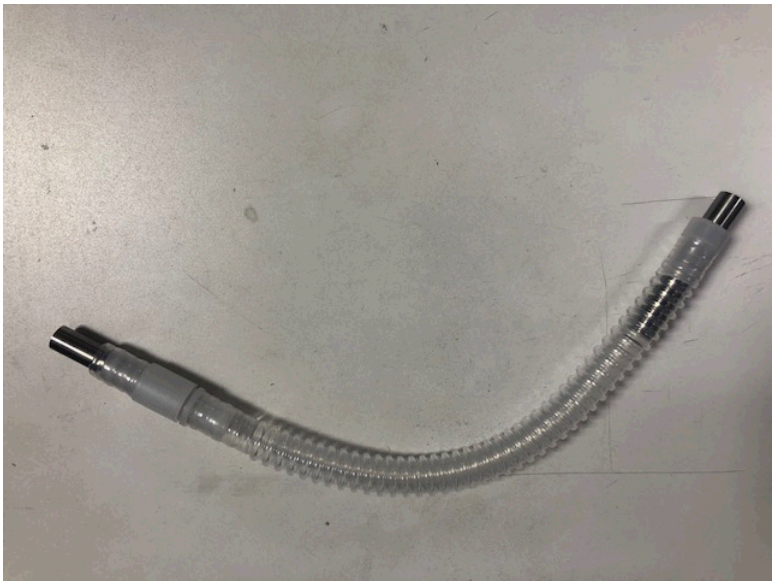
connector (see below).

8.10.2.2. Pry the tubing away from the pencil body (see below).

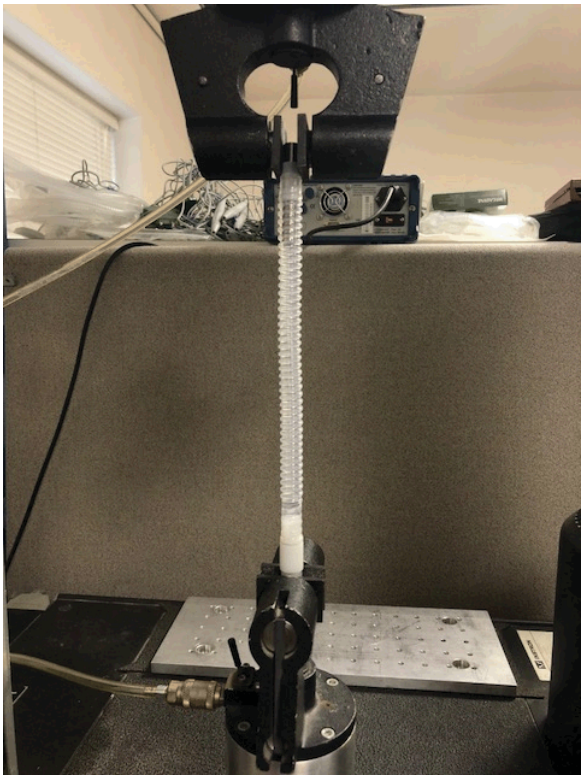
8.10.2.3. Slide the tubing along the cable to remove it from the pencil

body (see below).

8.10.2.4. Slide pin gauges into each end of the tubing. These gauges will provide structural support to the connectors when grasped by the Instron clamps (see below).



8.10.2.5. Mount the tubing segment in the Instron. Ensure each clamp is



grasping the connector and not the tubing (see below).

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

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

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

9. ACCEPTANCE CRITERIA

9.1. Shipping Test

Each box shall remain intact and not break open during the test. Indentation on edges or corners are acceptable.

9.2. Bubble Leak Testing

There shall be no tears, holes or open seals in any pouch that compromise sterility after the ship test exposure.

9.3. Dye Testing

The primary reason for the dye test is to make the seal edge more visible and to insure there are no breaches in the seal. There shall be no breaches in the seal.

9.4. Burst Testing

The minimum allowable burst value is 19 in H_2O. All package burst test values shall be above this limit.

9.5. Minimum Seal Width Testing

The minimum seal width is 0.20". All Seals shall meet or exceed this dimension.

9.6. Product Damage Inspection

There shall be no damage to the electrode or any other part of the Zip Pen on any of the samples.

9.7. Tubing Strength Test

Tubing will remain connected to all connection points and not break when subjected to at least 4 lbs. tensile force.

10. APPENDIX I – ZIP PEN MATERIAL OF CONSTRUCTION AND EHTYLENE OXIDE EXPOSURE

Megadyne Medical Products

Memo

To: ZIP ACE Project

From: Darcy Greep – Megadyne Materials SME DG. 2/8/2018

Date: 02/08/2018

Re: ZIP Pen Materials of Construction and Ethylene Oxide Sterilization Exposure

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This memo addresses the potential for damage/degradation of the materials used to create the components of the Megadyne ZIP Pen by exposure to Ethylene Oxide (EO) sterilization.

[1]Sterigenics, one of the largest Sterile Processors of Medical Devices Worldwide, employs Ethylene Oxide Sterilization as a key Medical Device method because, "Ethylene Oxide (EO) is a proven and reliable sterilization process used worldwide since the 1940s."
"EO is considered the broadest sterilization method available for medical products due to its effectiveness at lower temperatures and its general compatibility with a diversity of materials, resins and product types, including:

> Polymer resin-based products
> Single-use medical devices
> Procedure kits
> Surgical trays
> Synthetic gowns
> External terminal sterilization of sealed combination device/drug devices (filled syringes, drug coated stents)."

The following table identifies the components of the ZIP Pen device that are exposed to the EO sterilization atmosphere and identifies the potential for damage/degradation based on that exposure. This identification is made after review of material compatibility information, scientific literature, and historical use and testing of these materials in electrosurgical pencil applications.

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[1] Sterigenics Website - http://sterigenics.com/Sterilization_Technologies/Ethylene_Oxide.php?gclid=CjwKCAiAweXTBRAhEiwAmb3Xu851_U6_UHvrdTvsjeSghMg7k9fqu4ELBeiTz26g9HhT6wgmEJC4dhoCSXYQAvD_BwE

ZIP Pen Materials of Construction and EO Sensitivity

Component	Material	EO Sensitivity
Nozzle	PolyCarbonate (PC)	No to Low
Hand-piece	ABS	No to Low
Grip	TPR	No to Low
Tubing	Ethylene Vinyl Acetate (EVA)	Potential Sensitivity
Collet	Stainless Steel	No
Swivels	High Density Polyethylene (HDPE)	No
Holster	High Density Polyethylene (HDPE)	No
Cable	Poly Vinyl Chloride (PVC)	No
Domes	Stainless Steel	No
PCB Tape	PTFE	No
PCB Tape	Surlyn	No
PCB Overmold	TPR	No to Low
Button	Nylon 6-6	No
Plug Pins	Brass	No
Plug Housing	ABS	No to Low
Proximal Connector	ABS	No to Low
Proximal Connector	High Density Polyethylene (HDPE)	No

Stainless Steel and Brass metal components such as the collet, dome switches, and plug pins are completely unaffected by EO sterilization and are used in a host of reprocessable, sterilizable surgical instruments and products from many manufacturers. The chemical, moisture, and heating conditions of EO sterilization have no energy potential to affect these metals. No additional testing is required for these components.

PolyCarbonate (PC) polymer used to make the nozzle has been shown through testing and the literature to be unaffected by EO exposure.[2] No additional testing of the nozzle is required.

The ABS and TPR polymers used to make up the handle components as well as overmolding the PCB, and the ABS used for the plug housing and proximal connector have also been shown through testing and the literature to be unaffected by EO exposure.[2,3,4] No testing required post EO exposure.

Several components including the swivels, the 22mm proximal connector, and the holster are composed of HDPE. This polymer is often used in medical devices because of its inert nature and again, does not pose a risk from exposure to EO gas.[3] No testing required for EO exposure.

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[2] Medical Device & Diagnostic Industry Magazine. August 1, 1997 Column The Effects of High-Energy and EtO Sterilization on Thermoplastics. https://www.mddionline.com/effects-high-energy-and-eto-sterilization-thermoplastics

[3] ENG-PRT-330 ZIP PEN, EO Compatibility Test Protocol

[4] ENG-RPT-476 ZIP PEN, EO Compatibility Test Report

The material of most concern is the EVA tubing used to convey the smoke from the pencil to the Smoke Evac Box. EVA has been identified in the literature to be safe for EO sterilization as well as potentially damaging. Teleflex Medical identifies their EVA material as being compatible with EO sterilization[5]. Colex International (a manufacturer of liquid transfer tubing in the UK) provides information stating that EVA has poor resistance to EO[6]. Due to these conflicting reports, testing to ensure EO exposure is not detrimental to the tubing is highly recommended. Mechanical and electrical characteristics should be reviewed and compared with samples not exposed to EO.

PVC is shown in the literature to be compatible with EO sterilization, but slow to release residuals. This is addressed by the actual processing of the product with sufficient aeration time, nitrogen washes, heat application, and the load configuration. No issues are expected with the characteristics of the cable outer jacket which has been confirmed by previous cable testing of the ISOS2 pencil (uses the same cable). No further testing is required for EO exposure.

Nylon 6,6 used for the buttons, and the PTFE and Surlyn tapes used on the PCB are all identified in the literature as compatible and unaffected by exposure to EO. ISOS2 pencil buttons are composed of Nylon 6,6 even though they are a different design than ZIP pen. The ISOS2 validation efforts are adequate and no further testing is required for ZIP Pen.

EO sterilization of ZIP Pen does not present an increased risk of material failure for all materials of construction with the exception of the EVA tubing. Additional post EO exposure testing should focus on the mechanical properties of the EVA tubing to ensure proper operation of the pencil. The most accurate evaluation would include comparison of virgin EVA tubing (no sterilization exposure of any kind) with post-EO exposed EVA tubing. Mechanical testing could include tensile pull, flex repetition, or any other test appropriate for evaluating the desired characteristic.

[5] Teleflex Medical Website Materials Sterilization Guide - http://www.teleflexmedicaloem.com/guide-materials-sterilization/eva/
[6] Colex International Website Chemical Resistance Chart - http://www.colexint.com/downloads/Compliance/Chemical_Resistance_Chart_PDF.pdf

11. APPENDIX II – THERMAL CYCLE DATA

Appendix II: Thermal Cycle Data

Maximum Temperature (^{0}C):	
Minimum Temperature (^{0}C):	
Maximum Temperature (%RH):	
Minimum Temperature (%RH):	
Chamber conditions held @ -40^{o}C and no humidity control for a duration of 4 hours:	
Chamber conditions held @ 55°C and 95%RH for a duration of 4 hours:	
Chamber conditions held @ 55°C and 15%RH for a duration of 4 hours:	
Chamber conditions held @ 23^{o}C and 50%RH for a duration of 72 hours:	

Test Technician Name Signature Date

Engineer Name Signature Date

Thermotron SN Calibration Due Date

12. APPENDIX III – SHIPPING TEST

Preconditioning:

Start Date:_____ Chamber Number:_____

Completion Date:_____ Last Calibration:_____

Signature/Date:_____ Calibration due:_____

Drop Test:

Catalog Number:_____ Weight:_____ Drop Height: _____

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Top	Face 1	
2	Edge	Edge 5-3	
3	Edge	Edge 6-3	
4	Corner	Corner 2-3-5	
5	Corner	Corner 4-3-6	
6	Bottom	Face 3	

Comments:

Signature:_____ Date:_____

Compression Test:

Catalog Number:_____ Pounds Force:_____

Comments:

Signature:_____ Date:_____

Appendix III Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials:_____

High frequency 10 minutes, Initials:_____

Completion Date:_____

Signature:_____ Date:_____

Concentrated Impact Test:

Completion Date:_____

Signature:_____ Date:_____

Second Drop Test:

Catalog Number:_____ Weight:_____ Drop Height: _____

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	
2	Face	Face 4	
3	Face	Face 6	
4	Corner	Corner 2-1-5	
5	Edge	Edge 2-1	
6	Bottom	Face 3, Increase height to 30 inches.	

Comments:

Signature:_____ Date:_____

13. APPENDIX IV – BUBBLE LEAK TEST

Catalog # _____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			

Sample	Pass	Fail	Comment
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			

Signature: _____ Date: _____

14. APPENDIX V – DYE PENETRATION TEST

Catalog # _____ Lot # _____

Sample	Pass	Fail	Comment
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			

Sample	Pass	Fail	Comment
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			
33			
34			
35			

Signature: _____ Date: _____

15. APPENDIX VI – MINIMUM SEAL WIDTH TESTING

Catalog #			Lot #		
Sample	Cavity	Front	Back	Right	Left
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
19					
20					
21					
22					
23					
24					
25					
26					
27					
28					
29					
30					
31					
32					
33					
34					
35					
Signature:				Date:	

16. APPENDIX VII – PRODUCT DAMAGE INSPECTION

Inspect the product per the protocol and enter the number of units that pass or fail in the box below.

Catalog #	Pass	Fail
Damage		

Comments:

_____

_____

_____

Signature:_____ Date:_____

17. APPENDIX VIII – SAMPLE SIZE CALCULATION

Conditional probability and the binomial formula can be used to calculate a sample size which will achieve a minimum reliability or probability of success. In terms of success and failure, reliability is the probability of success of a design and failure is equal to (1 – probability of success). Design reliability takes into account the good and bad conditions of use. This is known as **Reliability Under Use Conditions**. If the probability of the bad or stress conditions is known, a **Reliability Under Stress Conditions** can be calculated using conditional probability. The Reliability Under Stress Conditions is a probability value that can then be entered into the binomial formula in order to compute a required sample size.

The probability of failure from a drop height of 15in (the smallest drop in this study) is assumed to be 10% (since the package is less than 25lbs) and can be used to calculate minimum sample size requirements for transit testing.

Table 1- Reliability Calculation Definition of Variables

R_U	**Required Reliability Under Use Conditions** Reliability under of the environmental conditions, good & bad. This is the probability of success for the product performing as intended under all the conditions (good & bad) that it will experience = 1 – Probability of Failure
R_S	**Required Reliability Under Stress Conditions** This is the probability of success for the product performing as intended under the stress conditions it will experience (such as when dropped from extreme heights).
F	**Failure** Package or Device Class 0 defect
S	**Stress** Drop at extreme height
P(F and S)	**Probability of Failure and Stress** Probability of stress occurring *and* probability of failure occurring. = 1- R_U
P(F|S)	**Probability of Failure given Stress** Probability that failure occurs given that the package is subjected to stress. = 1- Rs

A 10% drop height probability is used for **Probability of Stress, P(S)** and a target of 99% minimum **Reliability Under Use Conditions, R_U**:

Using R_U = 0.99 (99% minimum required reliability)
P(F and S) =1 – 0.99
P(F and S) = 0.01

Conditional Probability:
Using P(S) = 0.10 (10% drop height probability)
And using P(F and S) = 0.01:

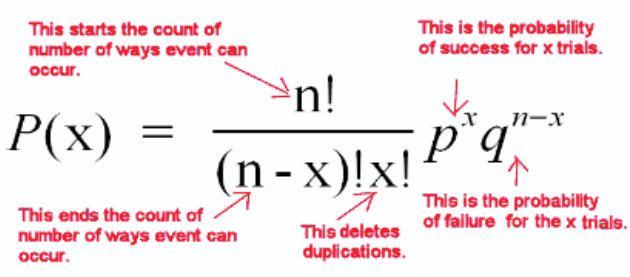
[i]P(F|S) = P(F and S) / P(S)
P(F|S) = 0.01 / 0.10
P(F|S) = 0.10

Using P(F|S)= 0.10:
R_S = 1 – P(F|S)
R_S = 1- 0.10
R_S = 0.90

We conclude that the probability that this product will perform as intended when subjected to stress is 0.90.

Package performance testing has a binomial result (pass or fail), therefore the binomial formula can be used to calculate the sample size needed in a package transit test if the reliability (probability of success) is known.

The binomial formula[ii] is used to compute the probability of ***x*** successes in ***n*** independent 2-event (success or failure) trials where ***p*** is the probability of success on a trial and ***q*** is the probability of failure on the trial.



In the calculation that follows, a value for **n** (number of trials or package samples required) is being determined for a given number of package failures. The desired failures are to be = 0 because a failure to the sterile barrier is a critical defect. ***p*** will be defined as the probability of success in realizing package failures. This can also be expressed as $p = 1 - R_S$.

In the package test we can only use the formula below for x = 0 because the formula is an exact probability and anything higher than an x of zero (e.g. 1, 2 etc), requires calculating the cumulative probability.

Table 2- Definitions of Binomial Formula Variables

x	Number of failures, assumed = 0
P(x)	Probability of success (reliability confidence)
n	Number of trials or units tested
p	Probability of success in any one trial = **$1 - R_S$** (probability of realizing package failures)
q	Probability of failure in any one trial = **$1 - p = R_S$**

$P(x) = \frac{n!}{(n-x)!\,x!} * p^x q^{n-x}$

Using P(x) = 0.05 (95% confidence (or α *risk*- reference QA-SOP-012)), x = 0, p = 0.10, q = 0.90 (The value of q comes from the above calculation for R_S):

$$0.05 = \frac{n!}{(n-0)!\,0!} * (0.10)^0 * (0.90)^{n-0}$$

$$0.05 = \frac{n!}{n!\,1} * 1 * (0.90)^n$$

$$0.05 = (0.90)^n$$

$$\ln(0.050) = n(\ln(0.90))$$

$$n = \ln(0.050) / \ln(0.90)$$

$$n = 28.4$$

Rounding up:

n = 29 samples

In conclusion, when using a 10% drop height probability at least 29 samples must be tested (with no 'critical' failures) in order to achieve a 99% *reliability under use*.

[i] Triola, Mario F. *Elementary Statistics*- 7th Edition, p. 149.
[ii] Triola, Mario F. *Elementary Statistics*- 7th Edition, p. 199.