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DOCUMENT NUMBER: ENG-PRT-441

DOCUMENT TITLE: ZIP ACE Modified Product 6-Pack Ship Test Protocol

DOCUMENT NOTES:

Verifies performance of packaging materials to protect ZIP Pencil Products in 6-Pack

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Zip ACE Mod T=0 Ship testing

Change Request

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1. SCOPE

This protocol evaluates the ability of the proposed 6-pack Zip Pen with ACE blade shipping boxes and sterile packaging (see drawing ME725M1C) to withstand the anticipated shipping environment after EO sterilization at T=0. This test protocol applies to ME725M1C and any other ZIP Pencil products EO sterilized and packaged in a 6-pack configuration with the same materials (ME725XXX).

2. PURPOSE

This protocol defines the product ship testing requirements of EO sterilized product and verifies package performance after shipping. The protocol verifies that the Tyvek pouch seal is not damaged, and that there is no product damage. Successful completion of this protocol provides evidence that the product will withstand the anticipated shipping environment and meet DMR requirements in ENG-DMR-012 after shipping at T=0.

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-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-PRT-466	ZIP ACE Modified, 6-Pack Ship Test, 3 yr. Accelerated Aging
ENG-PRT-467	ZIP ACE Modified, 6-Pack Ship Test, 3 yr. Real Time Aging
2010421-01	ASTM D6344 Guided Free Fall Concentrated Impact Test Equipment
XME725M1C	Zip Pen, Electrosurgical Pencil w/ ACE12, Holster, 10 ft. Tubing
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) after gamma sterilization. Marketing has identified a need to distribute Zip Pens in EO sterilized 6-unit shipping containers.

The proposed 6-unit shipping configuration is identical to the current 20-unit shipping configuration in packaging configuration, packaging materials, and manufacturing process. However, the effects of EO sterilization on the Zip Pen packaging material are not completely understood. As such, this protocol will be used to perform T=0 ship testing. ENG-PRT-466 will be used to perform three-year accelerated aging, and ENG-PRT-467 will be used to perform three-year real-time aging. Three-year accelerated aging will be performed prior to release; however, three-year real-time aging will be performed post release.

5. EQUIPMENT

- (6) 6-unit box/36-samples of XME725M1C
- 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)

6. RISK ASSESSMENT

The FMEA for Smoke Accessories (ENG-RMF-045) was reviewed while considering the proposed 6-unit shipping box. The following line items were found to be applicable:

Failure Mode	Cause	Mitigation	Verification
Product unsterile (sterile barrier broken) Holes in packaging Product damaged (42-D)	Ineffective packaging for this application	Material Selection	Evaluate packaging after completing sterilization, shipping conditions, and storage extremes.
Product is contaminated (43-D)	Inner bag/pouch opens unexpectedly	Design bag flap to be on the pouch side so flap stays in the package when peeled open	Evaluate packaging after completing sterilization, shipping conditions, and storage extremes.

Failure Mode	Cause	Mitigation	Verification
Damaged pencil fails in use (45-D)	Transport and storage out of accepted limits	Design, material selection, and product validation	Evaluate packaging after completing sterilization, shipping conditions, and storage extremes.
Does not meet DMR after 3 years (51-D)	Unstable product	Design for 3-year real time aging	Evaluate packaging after completing sterilization, 3-year accelerated aging, shipping conditions, and storage extremes.

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

- For line items 42-D and 43-D, Bubble leak testing, Dye testing, Burst testing, and Minimum seal width testing will be performed post ship testing.
- For line item 45-D, product visual damage inspection will be performed post ship testing. Function of the pencil after exposure to sterilization, storage, and shipping conditions were completed and documented in ENG-RMF-045.
- For line item 51-D, bubble leak testing, dye testing, burst testing, minimum seal width testing, and visual damage inspection will be performed after accelerated aging. This line item will not be addressed in this protocol; however, this will be addressed in ENG-PRT-466 and ENG-PRT-467.

7. EXPERIMENTAL DESIGN/SAMPLE SIZE JUSTIFICATION

7.1. Experimental Design

7.1.1. 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.

7.1.2. 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.

7.2. Sample Size Justification

See sample size justification in Appendix VII. A minimum of 29 samples are needed.

7.3. Test Summary

1. EO Sterilization
2. Thermal Cycling
3. Ship Conditioning
4. Bubble Leak Testing
5. Dye Testing
6. Burst Testing
7. Minimum Seal Width Testing
8. Product Damage Inspection

Tests will be performed in the following order:

Test Description	ME725M1C
Product Conditioning	
EO Sterilization	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 Test	
Product Damage Inspection	35 ea.

8. PROCEDURE

8.1. EO Sterilization Cycle

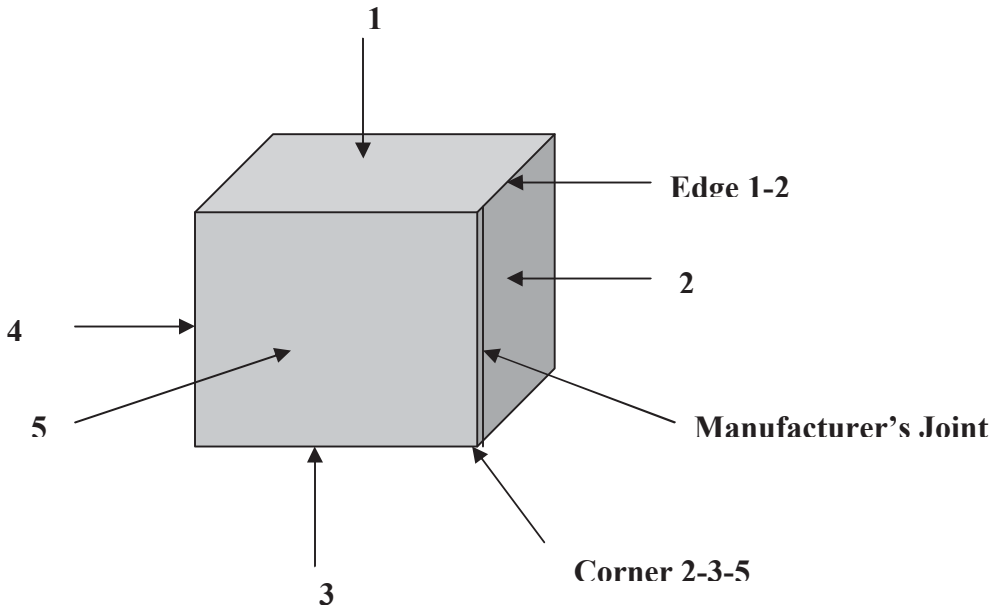
8.1.1. Expose product EO sterilization Sterigenics Cycle 115 (per ENG-WI-001 Section 7.2) or equivalent.

8.2. Using sterile product that has received maximum dosage, condition the product following the temperature and humidity schedule listed below. Record results on the Appendix I 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

8.3. Ship Condition Simulation

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



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

8.3.3. Record the Catalog Number of the product.

8.3.4. Record the Lot Number of the product.

8.3.5. Perform the Handling Test.

8.3.5.1. 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.

8.3.5.2. 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

8.3.5.3. Record package drops on the data sheet in Appendix I.

8.3.6. 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 formula for the weight of the compression is as follows:

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

Where:

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

This formula results in a testing weight (L) of 195.78 lbs.

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

8.3.6.2. 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.

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

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

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

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

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

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

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

8.3.7.4. 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.

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

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

8.3.7.7. 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.

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

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

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

8.3.8.1. The Impact test will be done on the following faces using the Impact test equipment identified in ENG-DWG-768.

8.3.8.2. 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).

8.3.9. 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.

8.3.10. Record completion of Shipping Test in Appendix I.

8.4. Bubble Leak Testing

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

8.4.2. Record data in Appendix III and attach results to test report.

8.5. Dye Testing

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

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

8.6. Burst Testing

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

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

8.7. Minimum Seal Width Testing

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

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

8.8. Product Damage Inspection

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

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

10. APPENDIX I – THERMAL CYCLE DATA

Appendix I: 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

11. APPENDIX II – 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 II 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:_____

12. APPENDIX III – 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: _____

13. APPENDIX IV – 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: _____

14. APPENDIX V – 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:	

15. APPENDIX VI – 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:_____

16. APPENDIX VII – 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**:

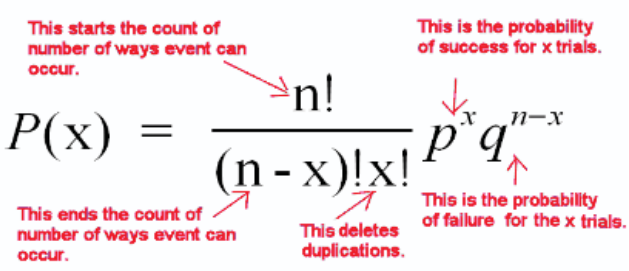
Using R_U = 0.99 (99% minimum required reliability)
P(F and S) =1 – 0.99
P(F and S) = 0.01

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.