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The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-401

DOCUMENT TITLE: Zip Pen Extension Nozzles, Three Year Accelerated Aging

DOCUMENT NOTES:

Report for Aged Extension Nozzles

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All dates and times are in Mountain Standard Time.

ENG-RPT-344 / 401 Extension Nozzles

Change Request

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Collaboration

Name/Signature	Title	Date	Meaning/Reason
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Mark Glassett (MGLASSETT)		15 Feb 2018, 07:55:49 AM	Complete
Darlene Hull (DHULL)	Regulatory	15 Feb 2018, 12:08:47 PM	Complete
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Mallory Schroeder (MSCHROEDER)	Engineer	20 Feb 2018, 09:02:00 AM	Complete

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Name/Signature	Title	Date	Meaning/Reason
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Final Release

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Lucy Richards (LRICHARDS)		21 Feb 2018, 09:47:10 AM	Approved

Authored By: Mark Glassett

TABLE OF CONTENTS **Page**

1. ABSTRACT

Zip Pen Extension Nozzle samples were tested per the requirements of XENG-PRT-239 rev 002 to show compliance with ISO 11607-1. These products were exposed to three year accelerated aging, ship cycle temperature extremes and subjected to the shipping tests required per the protocol. The Extension Nozzle's passed the requirements of the protocol.

Additional tests to show compliance to the DMR were also performed. These tests included flow rate, retention force, and nozzle pry force. The Extension Nozzles also passed these tests.

2. OBJECTIVE

The objective of this test report is to document compliance of the Zip Pen Extension Nozzle catalog items 2540 and 2560 with ISO 11607-1 requirements for sterile barrier packaging and show compliance with the DMR after three year accelerated aging and shipping extremes.

3. RESULTS

3.1. Extension Nozzle Shipping Test

Extension Nozzles are shipped to Megadyne from an outside contractor in Taiwan. They are shipped ten per unit box and the unit boxes are packed eight per case. The typical shipment from Megadyne to the customer will be unit boxes packed in a shipper by the shipping department. The test units were shipped from the contractor in order to be tested

at Megadyne. A simulation of this configuration was not repeated since it actually occurred. The ship testing for the report utilized two different configurations packed by the shipping department that are likely to occur.

3.1.1. The Extension Nozzles were subjected to the ship test specified by ASTM D4169. The samples were preconditioned with temperature and humidity extremes per the protocol to demonstrate stability for IEC 60601-1 shipping and storage extremes. The samples were also preconditioned per the requirements of ASTM D4169. The documentation for this preconditioning is shown in Appendix I.

3.1.2. Following preconditioning, the samples were subjected to shipping conditions including handling (drop test), compression, loose load vibration, vehicle vibration, and a second handling (drop test). These tests were performed by the engineering lab technician. The samples passed these tests. Documentation of these tests is shown in Appendix I.

3.1.3. The samples were then inspected for print clear and legible. Thirty samples of each catalog number were inspected. The inspection was done by the Engineering Lab Technician. None of the samples showed degradation to the print. Documentation of this inspection is shown in Appendix II.

3.1.4. Following inspection of the print, 30 samples of each catalog number were tested for package integrity using the bubble leak test specified by ASTM F2096. All of the packages passed the bubble leak test. This testing was performed by the Engineering Lab Technician. Documentation of this test is shown in Appendix III.

3.2. Flow Rate Test

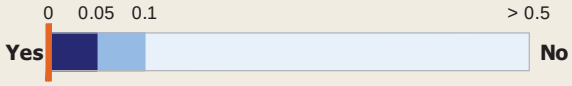
The flow rate test was performed to show equivalence of flow with the control sample. The 2540 and 2560 Extension Nozzles are two different lengths. The control sample (2110-10) has an adjustable length. Therefore, the control sample was set to the equivalent length of the Zip Pencil with the Extension Nozzle attached to the and the flow of each was measured. Eleven samples of each type were tested.

3.2.1. Zip Pencil with Extension Nozzle 2540 compared to 2110-10 extended to match the length of Zip Pencil with a 0014A electrode. The ‘t’ test shows that the flow rate of the 2540 with a Zip Pencil is greater than the 2110-10.

The 2540 passes the test. See 't' test summary report below and the raw data in Appendix IV.

2-Sample t Test for the Mean of 2540 and 2110-10/014A
Summary Report

Mean Test
Is 2540 greater than 2110-10/014A?



P = 0.000

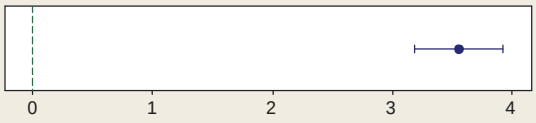
The mean of 2540 is significantly greater than the mean of 2110-10/014A (p < 0.05).

Statistics	2540	2110-10/014A
Sample size	11	11
Mean	69.464	65.9
90% CI	(69.16, 69.76)	(65.656, 66.144)
Standard deviation	0.55004	0.44721

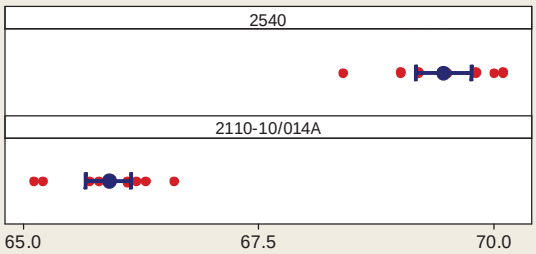
Difference between means*	3.5636
90% CI	(3.1940, 3.9332)

* The difference is defined as 2540 - 2110-10/014A.

90% CI for the Difference
Does the interval include zero?



Distribution of Data
Compare the data and means of the samples.



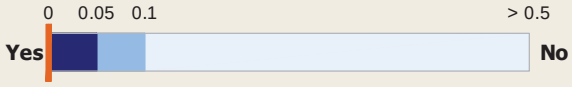
Comments

-- Test: You can conclude that the mean of 2540 is greater than 2110-10/014A at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 3.1940 and 3.9332.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

3.2.2. Zip Pencil with Extension Nozzle 2560 compared to 2110-10 extended to match the length of Zip Pencil with a 0014 electrode. The 't' test shows that the flow rate of the 2560 with a Zip Pencil is greater than the 2110-10. The 2560 passes the test. See 't' test summary report below and the raw data in Appendix IV.

2-Sample t Test for the Mean of 2560 and 2110-10/014
Summary Report

Mean Test
Is 2560 greater than 2110-10/014?



P = 0.000

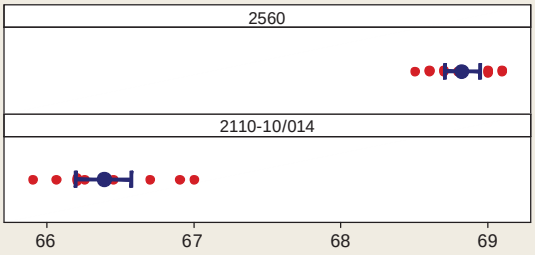
The mean of 2560 is significantly greater than the mean of 2110-10/014 ($p < 0.05$).

Statistics	2560	2110-10/014
Sample size	11	11
Mean	68.827	66.388
90% CI	(68.71, 68.95)	(66.198, 66.578)
Standard deviation	0.21950	0.34730

Difference between means* 2.4391
90% CI (2.2228, 2.6554)
* The difference is defined as 2560 - 2110-10/014.

90% CI for the Difference
Does the interval include zero?

Distribution of Data
Compare the data and means of the samples.



Comments

-- Test: You can conclude that the mean of 2560 is greater than 2110-10/014 at the 0.05 level of significance.
-- CI: Quantifies the uncertainty associated with estimating the difference from sample data. You can be 90% confident that the true difference is between 2.2228 and 2.6554.
-- Distribution of Data: Compare the location and means of samples. Look for unusual data before interpreting the results of the test.

3.3. Comparison Measurements

The comparison measurement section of the protocol was not repeated for this test. The purpose of comparison measurements was to support the fact that regulatory submissions are being made on Extension Nozzles that are not aged. These extension nozzles were aged and therefore the comparison Measurement section will be removed from the protocol.

3.4. Nozzle Retention force

The nozzle retention force of each catalog number 2540 and 2560 was tested to establish if the retention force is adequate. The findings are as follows.

Catalog Number	Average Force lbs.	Standard Deviation
2540	9.88	1.625
2560	6.09	1.584
Combined Data	9.89	1.578

Comparatively, the electrode removal increased from the non-aged product. The combined average from the non- aged nozzles was 5.63 (see ENG-RPT-344) compared with 9.89 for the aged nozzles. There is no specification for this retention force but the electrode removal force is 1.5 to 4.5 pounds. This Extension Nozzle removal force data shows that the Extension Nozzle has a higher removal force than the electrode. Therefore it has adequate retention to insure it will remain in place during use. The data from this test is shown in Appendix V

3.5. Fit With Holster

The fit with holster test was performed on non-aged components; see test report ENG-RPT-344. The size of the nozzles will not change due to aging. Therefore this test was not repeated for the aged parts in this report. The fit with holster section will be removed from the protocol.

3.6. Nozzle Pry Force Test

The nozzle pry force test was performed on 15 samples of each catalog number 2540 and 2560. The requirement for the 2540 extension Nozzle is that it withstands 10 pounds force without damage. The 2540 Extension Nozzle with Zip Pencil flexed but there was no breakage or unsnapping of the Zip Pencil snap features. Beyond 10 pounds, there was flexing of up to 0.9” when the load reached 20 pounds. The 2540 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VI.

The requirement for the 2560 Extension Nozzles is that it withstands 5 pounds force without damage. The Extension Nozzle with Zip Pencil flexed but there was no breakage or unsnapping of the Zip Pencil snap features up to 5 pounds. Beyond 5 pounds, there was flexing of up to 0.9” when the load reached about 20 pounds. The 2560 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VI

4. DISCUSSION

Extension Nozzles catalog number 2540 Lot# 140119 and 2560 Lot#140120 were used for this testing. All samples were subjected to accelerated aging at 55˚C to simulate 3 years shelf life. The aging time at this temperature is 111 days as determined by the formula in ENG-RPT-049. All samples were subjected to shipping and storage extremes of -40˚C to 70˚C and humidity of 15% to 95% to support label claims prior to testing.

4.1. Extension Nozzle Shipping Test

4.1.1. The ship testing was performed per the requirements of the protocol. There were no issues with the boxes during the ship testing.

4.1.2. The boxes and pouches all passed the inspection for print clear and legible.

4.1.3. Thirty pouches of each catalog number passed the bubble leak test.

4.2. Flow Rate Test

The flow rate test followed the requirements of the protocol. The flow rate of the Zip Pencil with the Extension Nozzles attached passes the requirements of the protocol

4.3. Nozzle Retention Force

The nozzle retention force of each catalog number 2540 and 2560 was tested for range finding of this parameter. The design of the Extension Nozzles where they attached to the Zip Pen is the same on both catalog numbers of Extension Nozzle. Therefore, looking at the data by combining the two data sets is appropriate. The average removal force of the combined data is 9.89 pounds and the standard deviation is 1.578. This equates to three sigma limits of 5.2 to 14.6 pounds. This is significantly higher than the electrode retention force and that force is adequate to retain the electrode during use. Therefore, the Extension Nozzle retention force is adequate to retain the product during use.

4.4. Nozzle Pry Force Test

The nozzle pry force test was performed on 15 samples of each catalog number 2540 and 2560. The Nozzle Extensions passed the requirements of the protocol.

5. CONCLUSIONS

This testing demonstrates that the Extension Nozzles catalog numbers 2540 and 2560 comply with the required standards referenced in section 1 after three year accelerated aging and shipping and storage conditions. The Extension Nozzles also meet the DMR requirements from the protocol.

6. RECOMMENDATIONS

This testing was performed to demonstrate compliance of the Nozzle Extensions to ISO 11607-1. The product will be marked with 3 years of expiration life. Real time age samples from the first production lot will be put aside for testing per Megadyne Protocol ENG-PRT-057.

The testing also demonstrated compliance to ISO 11607-1 after exposure to extreme shipping and storage conditions. The shipping box labels of the products will show the international symbols for shipping and storage with temperatures of 5°C to 50°C and relative humidity of 15% to 95%. The IFU will include the note “Normal storage conditions are assumed. Brief excursions to limits is allowed”.

Appendix I:
SHIPPING TEST LOG SHEET

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 17 of 25

Appendix I:
SHIPPING TEST LOG SHEET

Preconditioning:

Start Date: 8-18-2014 Chamber Number: 01095

Completion Date: 8-23-2014 Last Calibration: 5-29-2014

Signature/Date: Paul Valprede 10-20-2014 Calibration due: 5-31-2015

Drop Test: ASTM D4169 Drop Height is 15 inches for packages under 20 pounds

Catalog 2540 Lot S140119 LxWxH 12x9x6 Weight: 1 lb.

Catalog 2560 Lot S140120 LxWxH 16x10x10 Weight: 2 lbs.

Case Box LxWxH N/A Weight: N/A

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV 8-23-2014
2	Edge	Edge 5-3	PV 8-23-2014
3	Edge	Edge 6-3	PV 8-23-2014
4	Corner	Corner 2-3-5	PV 8-23-2014
5	Corner	Corner 4-3-6	PV 8-23-2014
6	Bottom	Face 3	PV 8-23-2014

Comments: _____

Signature: Paul Valprede Date: 8-23-2014

Compression Test: Perform compression test on the case box only

Catalog 2540 and 2560 Pounds Force 55 and 60 lbs.

Appendix I:
SHIPPING TEST LOG SHEET (Continued)

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 18 of 25

(Pass) / Fail Comments: _____

Signature: Paul Valpreda Date: 10-20-2014

Vibration Test: Perform vibration on all three configurations

Low Frequency, 40 minutes, Initials PV High frequency 10 minutes, Initials PV

Completion Date: 8-23-2014

Signature: Paul Valpreda Date: 10-20-2014

Second Drop Test: ASTM D4169 Drop Height is 15 with the exception of the last drop which is 30 inches. Test all three configurations

Drop	Orientation	Specific face, edge or	Initials/Date
1	Edge	Edge 4-6	PV 8-23-2014
2	Face	Face 4	PV 8-23-2014
3	Face	Face 6	PV 8-23-2014
4	Corner	Corner 2-1-5	PV 8-23-2014
5	Edge	Edge 2-1	PV 8-23-2014
6	Bottom	Face 3, Increase height to 30 inches.	PV 8-23-2014

Comments: _____

Signature: Paul Valpreda Date: 10-20-2014

Appendix II
PRINT CLEAR AND LEGIBLE

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 19 of 25

Appendix II
PRINT CLEAR AND LEGIBLE

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

Catalog 2540	Pass	Fail
Pouch Print	PASS	
Lot Number Print	PASS	

Comments:_____

_____

Catalog 2560	Pass	Fail
Pouch Print	PASS	
Lot Number Print	PASS	

Comments:_____

_____

Test Performed by: Paul Valpreda Date: 10-16-2014

Appendix III
BUBBLE LEAK TEST

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 20 of 25

Appendix III

BUBBLE LEAK TEST

Catalog 2540	Lot # S140119		
Sample #	Pass/Fail	Sample #	Pass/Fail
1	Pass	16	Pass
2	Pass	17	Pass
3	Pass	18	Pass
4	Pass	19	Pass
5	Pass	20	Pass
6	Pass	21	Pass
7	Pass	22	Pass
8	Pass	23	Pass
9	Pass	24	Pass
10	Pass	25	Pass
11	Pass	26	Pass
12	Pass	27	Pass
13	Pass	28	Pass
14	Pass	29	Pass
15	Pass	30	Pass

Test Performed by: Paul Valpreda Date: 10-16-2014

Appendix III
BUBBLE LEAK TEST (Continued)

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 21 of 25

Appendix III

BUBBLE LEAK TEST (Continued)

Catalog 2560	Lot # S140120		
Sample #	Pass/Fail	Sample #	Pass/Fail
1	Pass	16	Pass
2	Pass	17	Pass
3	Pass	18	Pass
4	Pass	19	Pass
5	Pass	20	Pass
6	Pass	21	Pass
7	Pass	22	Pass
8	Pass	23	Pass
9	Pass	24	Pass
10	Pass	25	Pass
11	Pass	26	Pass
12	Pass	27	Pass
13	Pass	28	Pass
14	Pass	29	Pass
15	Pass	30	Pass

Test Performed by: Paul Valpredo Date: 10-16-2014

Appendix IV
FLOW RATE TEST

Appendix IV

FLOW RATE TEST

Mega Vac Serial Number: I4211

Flow Meter ID#: 01272 Last Calibration Date: May 2014
Calibration Due Date: May 2015

Catalog 2540	Lot # S140119	Catalog 2560	Lot # S140120
Electrode 0014A	Lot # 143501	Electrode 0014A	Lot # 143761
Sample #	Flow Rate	Sample #	Flow Rate
1-14A	68.4	1-14	69.0
2-14A	69.2	2-14	68.5
3-14A	69.2	3-14	68.7
4-14A	70.1	4-14	68.6
5-14A	69.0	5-14	68.8
6-14A	69.0	6-14	69.0
7-14A	69.8	7-14	69.0
8-14A	69.8	8-14	69.1
9-14A	69.5	9-14	68.6
10-14A	70.1	10-14	69.1
11-14A	70.0	11-14	68.7

Appendix IV
FLOW RATE TEST (Continued)

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 23 of 25

Appendix IV (Continued)

CONTROL SAMPLES

76.7 2540 Length

Catalog 2110-10	Lot #		
Sample #	Flow Rate	Sample #	Flow Rate
1-C	65.2	7-C	66.1
2-C	66.3	8-C	66.6
3-C	66.2	9-C	65.7
4-C	65.8	10-C	65.1
5-C	65.9	11-C	65.9
6-C	66.1		

Test Performed by: Paul Valpredo Date: 10-17-2014

2110-10 LOT 5408

Appendix IV
FLOW RATE TEST (Continued)

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* 1150770-10
	Extension Nozzle	Revision: A
		Effective Date: 2014 MAY 15
		Page 23 of 25

Appendix IV (Continued)

CONTROL SAMPLES

I.C. Medical fully extended pencils.

Catalog 2110-10	Lot #		
Sample #	Flow Rate	Sample #	Flow Rate
1-C	66.06	7-C	66.2
2-C	66.2	8-C	67.0
3-C	65.9	9-C	66.7
4-C	66.20	10-C	66.26
5-C	66.9	11-C	66.45
6-C	66.4		

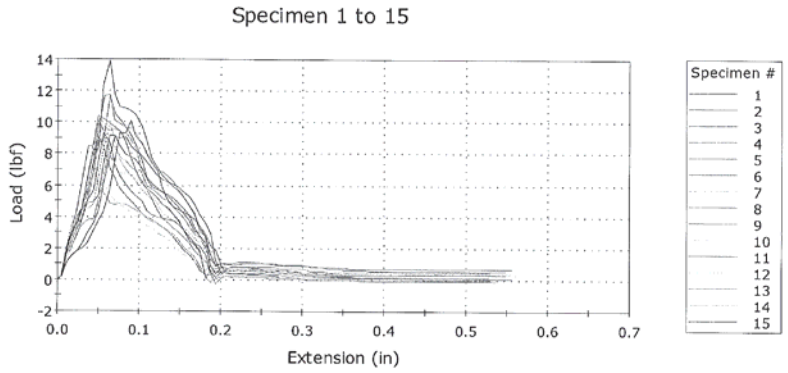
Test Performed by: Paul Valprede Date: 10-24-2014

2110-10 LOT 5408

Appendix V
Nozzle Retention Force

Tuesday, October 21, 2014

Zip nozzle extraction force on aged product.is_tens



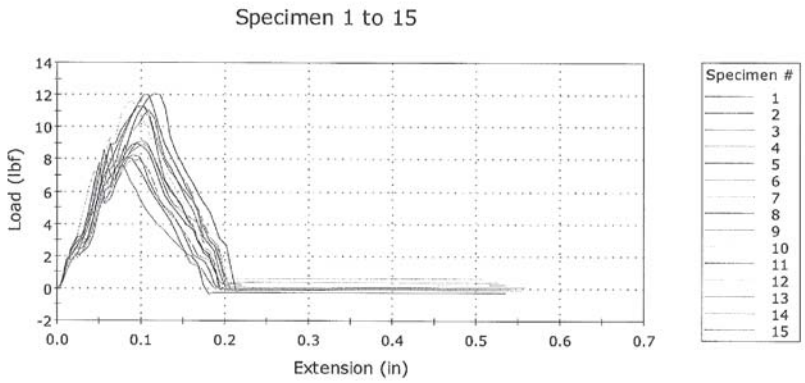
	Specimen label	Maximum Load (lbf)	Specimen note 1
1	Sample 1	11.81	2540 LOT S140119
2	Sample 2	10.12	2540 LOT S140119
3	Sample 3	9.06	2540 LOT S140119
4	Sample 4	9.70	2540 LOT S140119
5	Sample 5	9.05	2540 LOT S140119
6	Sample 6	11.60	2540 LOT S140119
7	Sample 7	10.07	2540 LOT S140119
8	Sample 8	13.91	2540 LOT S140119
9	Sample 9	10.42	2540 LOT S140119
10	Sample 10	7.81	2540 LOT S140119
11	Sample 11	9.17	2540 LOT S140119
12	Sample 12	9.93	2540 LOT S140119
13	Sample 13	8.76	2540 LOT S140119
14	Sample 14	7.44	2540 LOT S140119
15	Sample 15	9.32	2540 LOT S140119
Maximum		13.91	
Mean		9.88	
Minimum		7.44	
Standard Deviation		1.62510	

Page 1 of 1

Appendix V
Nozzle Retention Force (Continued)

Tuesday, October 21, 2014

Zip nozzle extraction force on aged product_2.is_tens



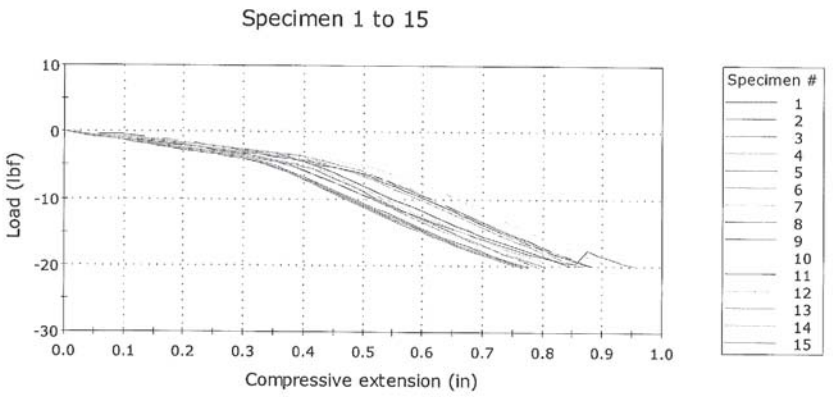
	Specimen label	Maximum Load (lbf)	Specimen note 1
1	Sample 1	11.04	2560 LOT S140120
2	Sample 2	11.31	2560 LOT S140120
3	Sample 3	9.13	2560 LOT S140120
4	Sample 4	11.34	2560 LOT S140120
5	Sample 5	12.09	2560 LOT S140120
6	Sample 6	7.96	2560 LOT S140120
7	Sample 7	10.87	2560 LOT S140120
8	Sample 8	8.97	2560 LOT S140120
9	Sample 9	12.05	2560 LOT S140120
10	Sample 10	11.60	2560 LOT S140120
11	Sample 11	8.11	2560 LOT S140120
12	Sample 12	8.93	2560 LOT S140120
13	Sample 13	8.98	2560 LOT S140120
14	Sample 14	7.98	2560 LOT S140120
15	Sample 15	8.27	2560 LOT S140120
Maximum		12.09	
Mean		9.91	
Minimum		7.96	
Standard Deviation		1.58383	

Page 1 of 1

Appendix VI
Nozzle Pry Force

Wednesday, October 22, 2014

Zip nozzle break force on aged product.is_comp



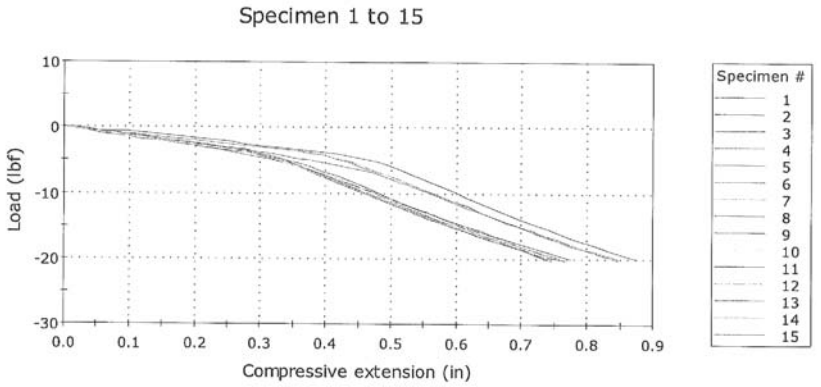
	Load at Machine Peak Load (lbf)	Notes	Comments
1	-20.74000	2540 Nozzle Extension LOT S140119	Did not break or come off
2	-20.98000	2540 Nozzle Extension LOT S140119	Did not break or come off
3	-20.98000	2540 Nozzle Extension LOT S140119	Did not break or come off
4	-21.05000	2540 Nozzle Extension LOT S140119	Did not break or come off
5	-20.72000	2540 Nozzle Extension LOT S140119	Did not break or come off
6	-20.62000	2540 Nozzle Extension LOT S140119	Did not break or come off
7	-20.71000	2540 Nozzle Extension LOT S140119	Did not break or come off
8	-20.90000	2540 Nozzle Extension LOT S140119	Did not break or come off
9	-21.01000	2540 Nozzle Extension LOT S140119	Did not break or come off
10	-20.91000	2540 Nozzle Extension LOT S140119	Did not break or come off
11	-20.62000	2540 Nozzle Extension LOT S140119	Did not break or come off
12	-20.66000	2540 Nozzle Extension LOT S140119	Did not break or come off
13	-20.64000	2540 Nozzle Extension LOT S140119	Did not break or come off
14	-20.64000	2540 Nozzle Extension LOT S140119	Did not break or come off
15	-21.02000	2540 Nozzle Extension LOT S140119	Did not break or come off
Maximum	-20.62000		
Minimum	-21.05000		
Mean	-20.81333		
Standard Deviation	0.17		

Page 1 of 1

Appendix VI
Nozzle Pry Force (Continued)

Wednesday, October 22, 2014

Zip nozzle break force on aged product_2.is_comp



	Load at Machine Peak Load (lbf)	Notes	Comments
1	-20.71000	2560 Nozzle Extension LOT S140120	Did not break or come off
2	-20.71000	2560 Nozzle Extension LOT S140120	Did not break or come off
3	-20.81000	2560 Nozzle Extension LOT S140120	Did not break or come off
4	-20.76000	2560 Nozzle Extension LOT S140120	Did not break or come off
5	-20.97000	2560 Nozzle Extension LOT S140120	Did not break or come off
6	-20.93000	2560 Nozzle Extension LOT S140120	Did not break or come off
7	-20.64000	2560 Nozzle Extension LOT S140120	Did not break or come off
8	-20.66000	2560 Nozzle Extension LOT S140120	Did not break or come off
9	-21.25000	2560 Nozzle Extension LOT S140120	Did not break or come off
10	-20.72000	2560 Nozzle Extension LOT S140120	Did not break or come off
11	-20.91000	2560 Nozzle Extension LOT S140120	Did not break or come off
12	-20.99000	2560 Nozzle Extension LOT S140120	Did not break or come off
13	-20.81000	2560 Nozzle Extension LOT S140120	Did not break or come off
14	-20.93000	2560 Nozzle Extension LOT S140120	Did not break or come off
15	-20.72000	2560 Nozzle Extension LOT S140120	Did not break or come off
Maximum	-20.64000		
Minimum	-21.25000		
Mean	-20.83467		
Standard Deviation	0.16		

Page 1 of 1