

Number: ENG-RPT-344

Version: B.3

Released: 22-May-2020

Name: Test Report, Extensions Nozzles

Windchill Signature History Report			
Signature	Role	Event Date	Vote
Kuykendall, Steve [ETHUS Non-J&J] (SKuykend)	Quality Engineering	22-May-2020 09:43:08 EDT	Approve
Brooks, Gracie [ETHUS] (gbrooks9)	Research and Development	21-May-2020 11:11:55 EDT	Approve

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	Extensions Nozzles	Revision: A Effective Date: 2014 MAY 15

MASTER DOCUMENT

Mark Glassett 13 May 2014 *Jacqueline Richards* 15 May 2014
Engineering Verification: D.C. Verification:

Authored By: Mark Glassett

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1. ABSTRACT

Extension Nozzle samples that have been exposed to shipping cycle temperature extremes were subjected to the shipping tests required for compliance to ISO 11607-01:2006. The Extension Nozzle passed the requirements of the standard.

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

Additionally, comparison measurements were made on pre and post aged Zip Pencil nozzles to support the justification for regulatory submissions of test data on non-aged Extension Nozzle samples. These measurements showed that there is no significant change to the material stability through the aging process.

2. OBJECTIVE

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

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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. Therefore, two different configurations were tested for the shipping test, the case box from the contractor and the shipper packed by the shipping department.

- 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 samples were taken from both the case box and the shipper box packed by the shipping department. The inspection was done by incoming QC. None of the samples showed any damage 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.

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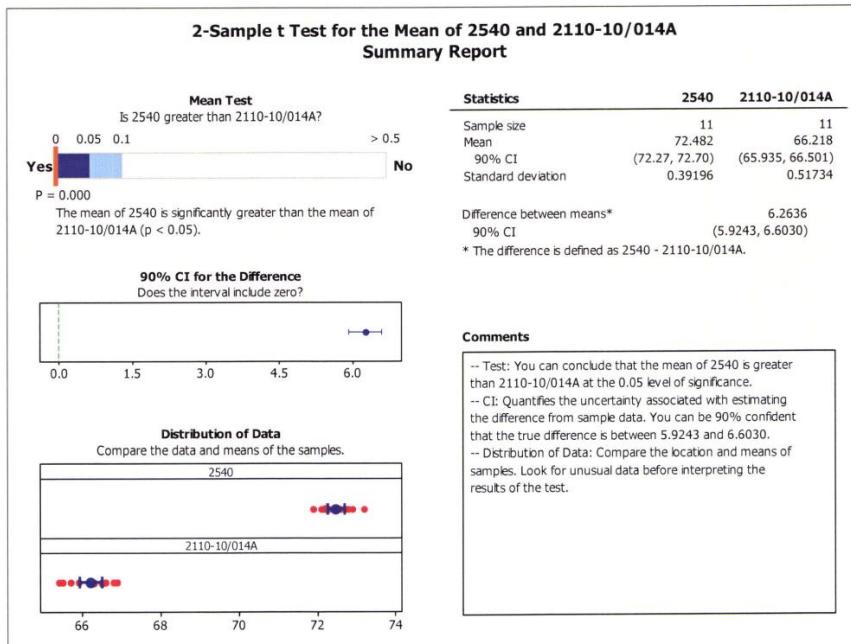
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3.2. Flow Rate Test

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.



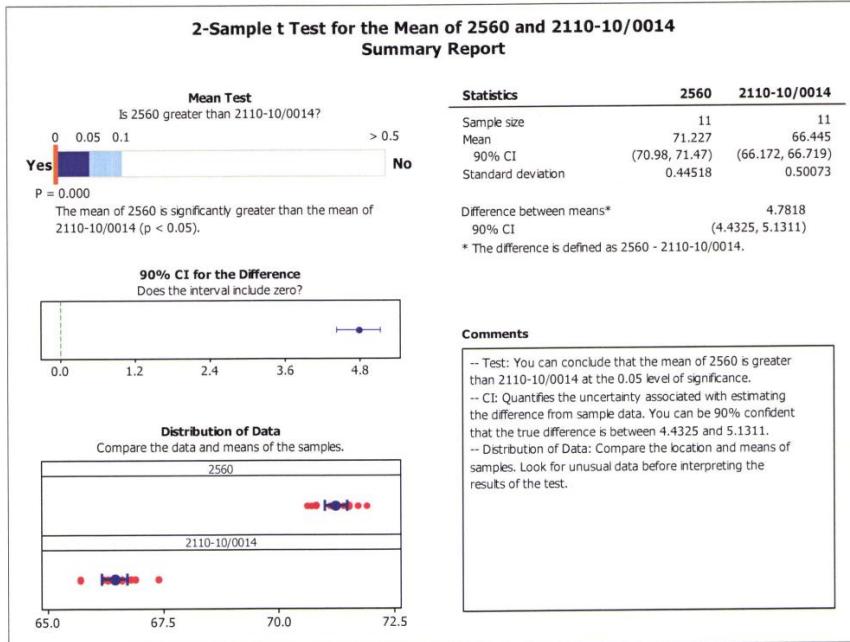
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3.2.2. Zip Pencil with Extension Nozzle 2560 compared to 2110-10 extended to match the length of Zip Pencil with a 0014 electrode. The 't' test shows that the flow rate of the 2560 with a Zip Pencil is greater than the 2110-10. The 2560 passes the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



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3.3. Comparison Measurements

The purpose of comparison measurements is to support the fact that regulatory submissions are being made on Extension Nozzles that are not aged. The nozzle of the Zip Pencil 2510-10 is the same material and has similar dimensions as the Extension Nozzles 2540 and 2560. Aged and non-aged samples of the Zip Pencil 2510-10 nozzle are available. Measurements of the Zip Pencil nozzle pre and post aging show insignificant dimension differences. Therefore it can be concluded that the measurements of the Extension Nozzles will also show insignificant change in dimension through aging. A summary of the measurements is shown below and the data shown in Appendix V.

Measurement	2525-10 Pre Age	2525-10 Post Age	Difference
O.D. Tip	0.361 inch	0.361 inch	0.000 inch
I.D. Tip	0.293 inch	0.296 inch	0.003 inch
O.D. Proximal	0.406 inch	0.406 inch	0.000 inch

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	5.17	0.704
2560	6.09	1.46
Combined Data	5.63	1.22

Comparatively, 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 VI

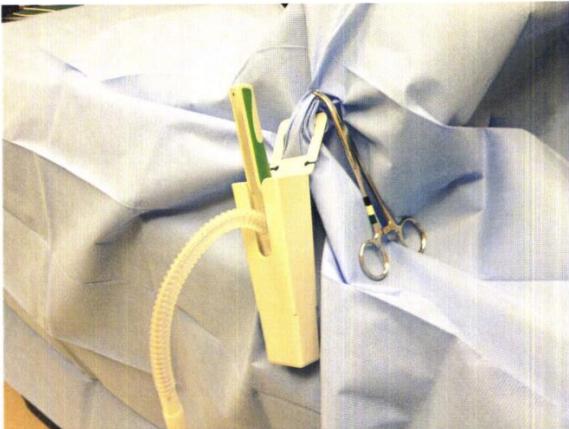
3.5. Fit With Holster

For this test, the Zip Pencil 2525-10 was set up in a simulated operating room environment. The holster was attached to the drape of a simulated sterile field. The 2525-10 Zip pencil and each length of Extension Nozzle were reviewed for fit in the holster under simulated conditions. The Marketing Product Manager and the Medical Director were present for the review. The Zip Pencil without the extension nozzle has a very secure fit in the holster; the picture below shows the fit.

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The Zip Pencil with the 2540 (0014A) extension also fits well in the holster; the picture below shows the fit.



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The Zip Pencil with the 2560 (0014) fits in the holster but can become unstable. The electrode is 6.5 inches long and the Zip Pencil in the holster is top heavy and tended to tip the holster sideways and the Zip Pencil could fall out; the picture below shows the fit.



After trying the 2560 nozzle, we tried the UltraVac 2110-10 with it fully extended. The UltraVac was equal to or less stable than the Zip Pencil with the 2560 nozzle. The reason it could be less stable is that the Zip Pencil has the option to zip the tubing down to the position shown and the UltraVac has the tubing exiting the end of the pencil which applies more torque on the pencil assembly. The consensus of the group was that the Zip Pencil with the 2560 Nozzle Extension is equal to or better than competitive pencils when they have a 6.5 inch electrode in place. The medical director was asked if he would be likely to use a holster when using a 6.5 inch electrode and he replied that he would not use it this way, he would be more likely to set the long pencil with electrode on the mayo stand.

Considering the above data, the requirement of the protocol was met for the Zip Pencil with no extension nozzle and with the 2540 extension and 0014A electrode. The Requirement of the protocol was not met for the 2560 Extension Nozzle with the 0014 electrode but the group agreed that the product is not likely to be used in this way.

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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 1.4" when the load reached 20 pounds. The 2540 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VII

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 2.5" when the load reached about 9 pounds and 3 pencils broke at near or above 9 pounds. The 2560 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VII

4. DISCUSSION

Extension Nozzles catalog number 2540 Lot# 140119 and 2560 Lot#140120 were used for this testing. 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 shipping test followed all of the requirements of the protocol for the shipping test. Note that the compression test was only done on the case box that comes from the contractor. The reason for this is that the case may be subjected to pallet stacking during transit. The shipper boxes packed by the shipping department are shipped individually and may vary in size depending on the customer order and are not likely to be stacked.

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

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4.3. Comparison Measurements

The purpose of comparison measurements is to support testing on Extension Nozzles that are not aged.

The packaging of the Extension Nozzles was also considered in the justification. The pouches used for the product is constructed of Tyvek 1073B sealed to a Polyester/Polyethylene laminated layer manufactured by Amcor. Megadyne has used this style of pouch on various products for many years. The packaging validation report for this pouch style is Nelson Lab report #41853. In this report the pouch contained a catalog #0012. This product was packaged in a pouch made of the same materials as the Extension Nozzles. The pouches for this comparable product were purchased from Beacon Converters and use the same Tyvek 1073 B and Polyester/Polyethylene laminated layer. The product in the referenced report were subjected to accelerated aging at 55°C. The accelerated aging was performed to simulate up to 5 years of shelf life and the product passed microbial barrier testing after the accelerated aging.

The package testing of aged product in equivalent pouches along with the ASTM D4169 testing presented in this test report together satisfy the requirements of ISO 11607-1:2006 requirements for terminally sterile packaging systems.

4.4. 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 5.63 pounds and the standard deviation is 1.26. This equates to three sigma limits of 2.0 to 9.4 pounds. This is 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.

4.5. Fit With Holster

The fit with holster test is a usability requirement that could not be tested previously when other usability requirements were being evaluated because Nozzle Extensions were not available. Therefore it was included in this protocol. Although the requirements of the protocol were not fully met, the findings for the fit with the holster are equivalent to the fit of existing products.

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4.6. 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 requirements of ISO 11607-01:2006 after 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 11607-01: 2006. 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 1150309-10.

The testing also demonstrated compliance to ISO 11607-01: 2006 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 excursion to limits allowed.

7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-068-01	Initial Release	2014 MAY 15

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**Appendix I:
SHIPPING TEST LOG SHEET**

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Appendix I:
SHIPPING TEST LOG SHEET

Preconditioning:

Start Date: 4-23-2014 Chamber Number: 01095
Completion Date: 4-26-2014 Last Calibration: 3-31-2014
Signature/Date: Paul Valprede 4-30-2014 Calibration due: 3-31-2015

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

Catalog 2540 Lot _____ LxWxH 12X9X6 Weight: 1.5 lbs

Catalog 2560 Lot _____ LxWxH 12X9X6 Weight: 1.5 lbs

Case Box LxWxH 12X19X8 Weight: 5 lbs

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV - 4-28-2014
2	Edge	Edge 5-3	PV - 4-28-2014
3	Edge	Edge 6-3	PV - 4-28-2014
4	Corner	Corner 2-3-5	PV - 4-28-2014
5	Corner	Corner 4-3-6	PV - 4-28-2014
6	Bottom	Face 3	PV - 4-28-2014

Comments: _____

Signature: Paul Valprede Date: 4-30-2014

Compression Test: Perform compression test on the case box only

Catalog 2540 and 2560 Pounds Force 105 lbs.

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Pass / Fail Comments: Paul Valpreda 4-30-2014

Signature: Paul Valpreda Date: 4-30-2014

Vibration Test: Perform vibration on all three configurations

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

Completion Date: 4-28-2014

Signature: Paul Valpreda Date: 4-30-2014

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 - 4-28-2014
2	Face	Face 4	PV - 4-28-2014
3	Face	Face 6	PV - 4-28-2014
4	Corner	Corner 2-1-5	PV - 4-28-2014
5	Edge	Edge 2-1	PV - 4-28-2014
6	Bottom	Face 3, Increase height to 30 inches.	PV - 4-28-2014

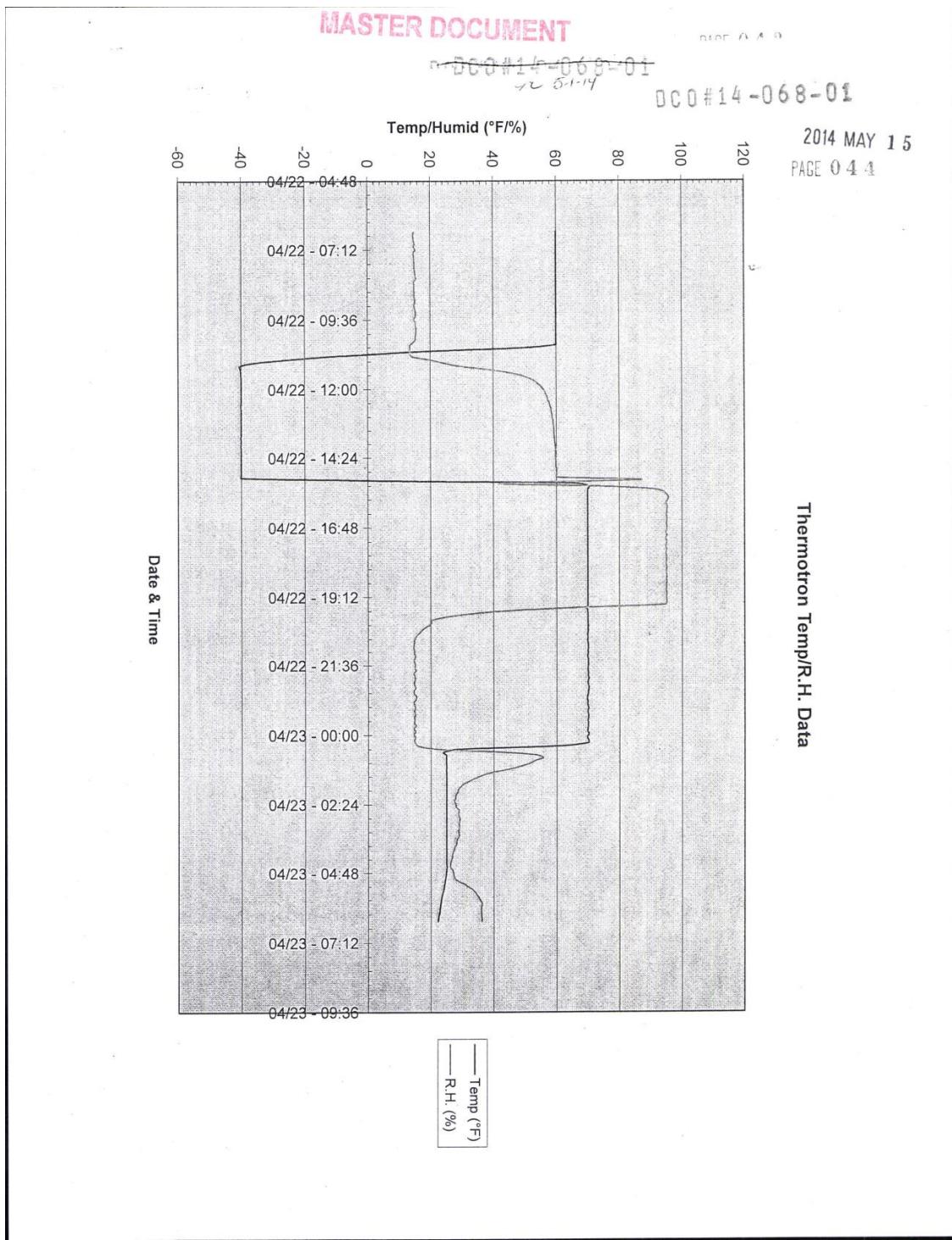
Comments: _____

Signature: Paul Valpreda Date: 4-30-2014

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Appendix II
PRINT CLEAR AND LEGIBLE

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Appendix III

BUBBLE LEAK TEST

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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	30	
Lot Number Print S14D0119	30	

Comments: _____

Catalog 2560	Pass	Fail
Pouch Print	30	
Lot Number Print S14D0120	30	

Comments: _____

Test Performed by: m. Fisher Date: 4/28/2014

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Appendix III

BUBBLE LEAK TEST (Continued)

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

Test Performed by: Paul Valpreda Date: 4-28-2014

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Appendix III
BUBBLE LEAK TEST

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

Test Performed by: Paul Valpreda Date: 4-28-2014

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Appendix IV

FLOW RATE TEST

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Appendix IV (Continued)

CONTROL SAMPLES

CD14

Catalog 2110-10	Lot # 5361	Sample #	Flow Rate
1-C	17.4	7-C	15.9
2-C	65.7	8-C	66.3
3-C	66.2	9-C	66.9
4-C	65.7	10-C	67.4 66.6 57.3 57.1 57.1 57.1
5-C	66.6	11-C	66.3
6-C	66.9		

Test Performed by: M.S. Date: 4/28/14

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Appendix IV (Continued)

CONTROL SAMPLES

Catalog 2110-10	Lot # 5361		
Sample #	Flow Rate	Sample #	Flow Rate
1-C	67.6	7-C	66.3
2-C	65.5	8-C	66.9
3-C	63.7	9-C	66.1
4-C	65.4	10-C	66.5
5-C	66.5	11-C	66.3
6-C	66.3		

Test Performed by: M. J. Date: 4/28/14

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Appendix IV

FLOW RATE TEST

Mega Vac Serial Number: J4211 File # 5364
Flow Meter ID#: 01272 Calibration Date: April 2013
short Calibration Due Date: 2014

Catalog 2540	Lot #	Catalog 2560	Lot #
Electrode 0014A	<u>540119</u>	Electrode 0014A	<u>514020</u>
<u>140831</u>		<u>141143</u>	
Sample #	Flow Rate	Sample #	Flow Rate
1-14A	<u>72.3</u>	1-14	<u>71.5</u>
2-14A	<u>71.9</u>	2-14	<u>71.7</u>
3-14A	<u>72.6</u>	3-14	<u>70.8</u>
4-14A	<u>72.8</u>	4-14	<u>71.9</u>
5-14A	<u>72.4</u>	5-14	<u>71.5</u>
6-14A	<u>72.2</u>	6-14	<u>70.8</u>
7-14A	<u>72.2</u>	7-14	<u>71.5</u>
8-14A	<u>72.7</u> <u>52/14</u>	8-14	<u>70.7</u> <u>52/14</u>
9-14A	<u>72.1</u> <u>51</u>	9-14	<u>70.6</u>
10-14A	<u>72.6</u> <u>72.9</u>	10-14	<u>71.4</u>
11-14A	<u>73.2</u>	11-14	<u>71.1</u>

11/28/14
4/28/14

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Appendix V
COMPARISON MEASUREMENTS

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Comparison Measurements

Measurement	2525-10 Pre Age	2525-10 Post Age	2540	2560
O.D. Tip - 1	0.361	0.361	0.350	0.380
O.D. Tip - 2	0.362	0.361	0.351	0.380
O.D. Tip - 3	0.361	0.362	0.350	0.382
O.D. Tip - 4	0.361	0.362	0.351	0.382
O.D. Tip - 5	0.360	0.360	0.349	0.382
O.D. Tip - 6	0.361	0.362	0.350	0.381
O.D. Tip - 7	0.359	0.363	0.349	0.382
O.D. Tip - 8	0.360	0.362	0.350	0.382
O.D. Tip - 9	0.360	0.362	0.349	0.380
O.D. Tip - 10	0.360	0.360	0.349	0.381
O.D. Tip - 11	0.362	0.361	0.349	0.381
Average	0.361	0.361	0.350	0.381
Standard Deviation	0.001	0.001	0.001	0.001

I. D. Tip - 1	0.293	0.296	0.294	0.312
I. D. Tip - 2	0.293	0.296	0.294	0.312
I. D. Tip - 3	0.293	0.296	0.294	0.312
I. D. Tip - 4	0.293	0.296	0.294	0.312
I. D. Tip - 5	0.293	0.296	0.294	0.312
I. D. Tip - 6	0.292	0.296	0.294	0.312
I. D. Tip - 7	0.293	0.296	0.294	0.312
I. D. Tip - 8	0.293	0.296	0.294	0.312
I. D. Tip - 9	0.293	0.296	0.294	0.312
I. D. Tip - 10	0.293	0.296	0.294	0.312
I. D. Tip - 11	0.293	0.296	0.294	0.312
Average	0.293	0.296	0.294	0.312
Standard Deviation	0.000	0.000	0.000	0.000

O.D. Proximal -1	0.407	0.406	0.499	0.497
O.D. Proximal -2	0.405	0.406	0.498	0.497
O.D. Proximal -3	0.406	0.406	0.499	0.498
O.D. Proximal -4	0.406	0.406	0.498	0.498
O.D. Proximal -5	0.406	0.405	0.498	0.497
O.D. Proximal -6	0.407	0.407	0.499	0.497
O.D. Proximal -7	0.406	0.406	0.497	0.497
O.D. Proximal -8	0.405	0.406	0.499	0.497
O.D. Proximal -9	0.407	0.407	0.498	0.497
O.D. Proximal -10	0.406	0.406	0.498	0.497
O.D. Proximal -11	0.407	0.405	0.498	0.497
Average	0.406	0.406	0.498	0.497
Standard Deviation	0.001	0.001	0.001	0.000

Name (Print): PAUL VALPREDA

Signature: Paul Valpreda

Date: 4-30-2014

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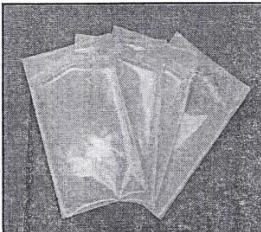
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2014 MAY 15



Chevron Pouches made with 1073B Tyvek®



Pouches are constructed of uncoated 1073B Tyvek® and a polyester/polyethylene laminate.

Pouches have a solid 0.375" side and chevron seals

Minimum Order: \$400.00 (Full case quantity only)

Pricing Effective: July 1, 2013

Item No.	CATALOG NUMBER	OUTSIDE DIMENSIONS (width x length)	Product Code	CASE QTY.	PRICE 1-2 CASES	PRICE 3-4 CASES	PRICE 5+ CASES
027708C	30307PN	3" x 7"	TLP-031	1000	\$298.004	\$217.028	\$175.795
027707C	30409PN	4" x 9"	TLP-031	1000	\$306.115	\$225.124	\$182.360
027708C	30412PN	4" x 12"	TLP-031	1000	\$328.778	\$244.566	\$198.102
027709C	30610PN	6" x 10"	TLP-031	1000	\$330.403	\$247.802	\$200.716
027710D	30812PN	8" x 12"	TLP-031	1000	\$398.421	\$317.445	\$257.135
027790D	31015PN	10" x 15"	TLP-031	500	\$369.273	\$288.283	\$233.508
027791C	31218PN	12" x 18"	TLP-031	400	\$383.855	\$299.628	\$242.701

Materials: 1073B Uncoated Tyvek® Vent
2.75 Mil PE/PET Lamination

Printing: None

PRICING: Pricing is effective January 1, 2013 and can change without notice

TERMS: All AMCOR Flexibles Terms and Conditions apply, including the following:

Net 30 days upon credit approval
FOB AMCOR Flexibles Facility
Our Terms and Conditions of Sale include limitations on warranty and limitations on remedies.
For a complete listing of Terms and Conditions see the Amcor Flexibles web site at
www.amcor.com/flexibles-healthcare

PRICING: Pricing method is by quantity ordered per individual part number.

OTHER: Artwork, die, engravings, plate and/or tooling charges are invoiced separately and are not included in the price
Pricing is preliminary pending review and acceptance of formal customer specification.

Tyvek® is a registered trademark of DuPont for its brand of protective material

Amcor Customer Service 1-800-447-0049

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Technical Datasheet

Tyvek® Pouches

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Description

Product Code : TLP-031

Structure : HEAT SEAL POUCH, 1073B Tyvek® (PTU-002)//12.2 µ PET/Adh/ 57.2 µ LDPE-EVA (RLA-069)
HEAT SEAL POUCH, 1073B Tyvek® (PTU-002)//48 ga PET/Adh/2.25 mil
LDPE-EVA (RLA-069)

General Description

- Incorporates an adhesive lamination of polyester and polyethylene
- Suitable for radiation and EO sterilization for wide range of medical devices
- Uncoated Tyvek® provides breathability and microbial barrier
- Film portion of pouch has excellent clarity and strength properties
- Consistent peelable seal is feature of pouch

Technical Data 48 ga PET/Adh/2.25 mil LDPE-EVA (RLA-069)

Property	Metric	Value		Method
		US	ASTM	
Basis Weight	72.8 g/m ²	44.7 lbs/3000 ft ²		
Thickness	69.9 µm	2.75 mil		ASTM F2251
Yield	13.7 m ² /kg	9,660 in ² /lb		TAPPI T410
Tensile Strength (film)				ASTM D882
MD	42 MPa	6,020 psi		
TD	42 MPa	6,100 psi		
Percent Elongation at Break				ASTM D882
MD	110 %	110 %		
TD	100 %	100 %		
Tear Strength (Elmendorf)				ASTM D1922
MD	280 mN	29 grams force		
TD	340 mN	35 grams force		
Puncture Strength (1/8" probe)				FTMS 101C
	41.4 N	9.3 pounds force		
Haze	7.0 %	7.0 %		ASTM D1003

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Technical Datasheet

Tyvek® Pouches

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Technical Data 1073B Tyvek® (PTU-002)

Property	Metric	Value	Method
		US	
Substrate Weight	74.5 g/m ²	45.8 lbs/3000 ft ²	TAPPI T410
Yield	13.4 m ² /kg	9430 in ² /lb	TAPPI T410
Tensile MD	110 N/15mm	42 lb/in	ASTM D 5035
Tensile CD	124 N/15mm	47 lb/in	ASTM D 5035
Elmendorf Tear MD	2.1 N force	0.82 lb force	ASTM D 1922
Elmendorf Tear CD	2.2 N force	0.84 lb force	ASTM D 1922
Porosity (Gurley)	22 sec/100cc	22 sec/100cc	TAPPI T460

Disclaimer

The above figures are indicative only. No guarantee, warranty, or responsibility on the part of Amcor is implied. The customer is responsible for determining whether Amcor products are fit for a particular purpose, as well as ensuring any proprietary rights, legislation, and existing laws are observed.

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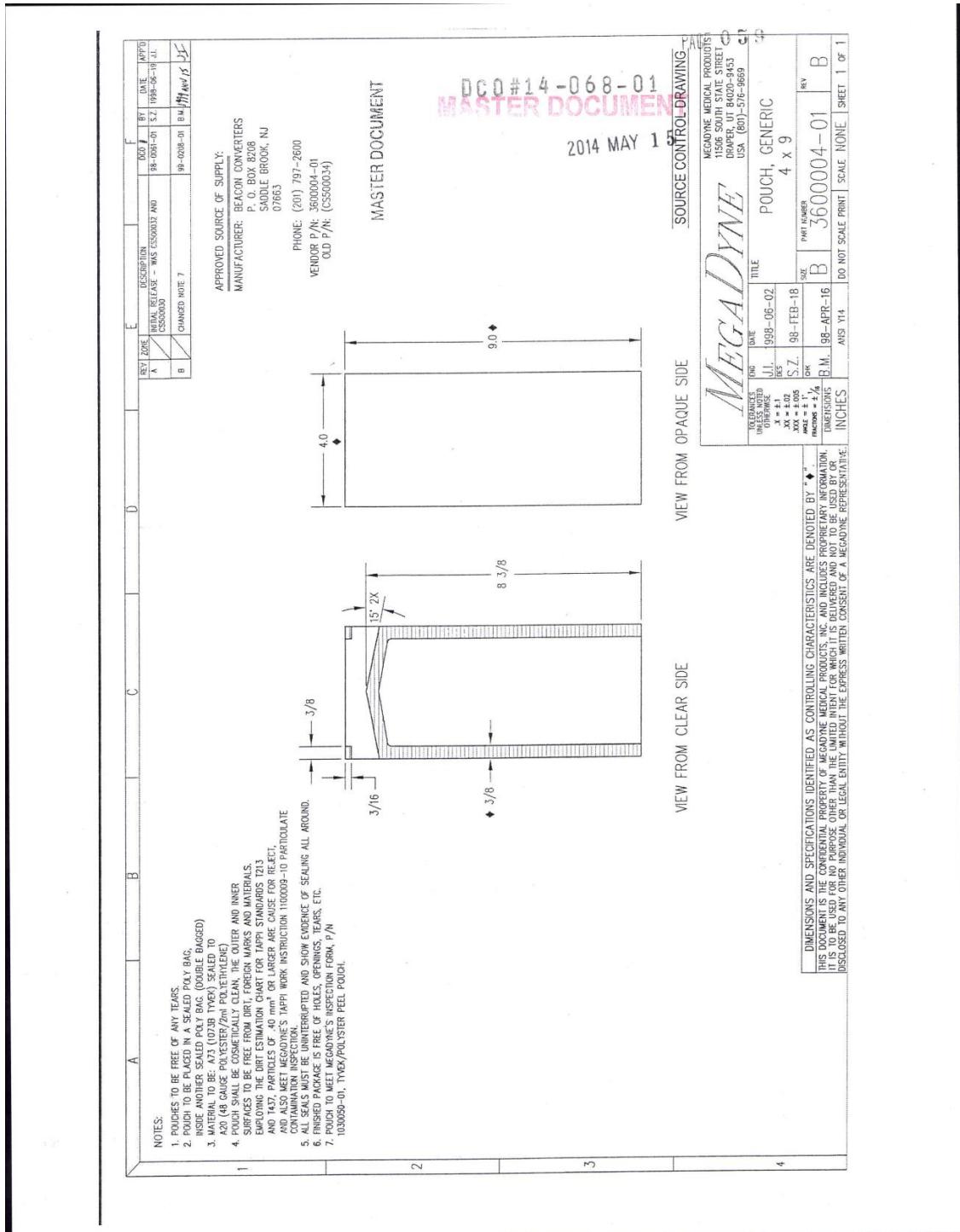
Rev Date: 09-21-2011

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Appendix VI

Nozzle Retention Force

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Nozzle Removal force

2014 MAY 15

Sample	2540	2560
1	3.430	3.930
2	5.820	5.340
3	5.650	4.380
4	4.400	6.860
5	4.850	5.390
6	4.600	8.180
7	4.920	5.890
8	4.920	5.540
9	5.490	6.740
10	4.870	5.910
11	5.720	4.830
12	5.790	7.970
13	5.870	6.730
14	6.030	8.920
15	5.220	4.750
Average	5.172	6.091
Standard Deviation	0.704	1.457
Combined Average		5.631
Combined Standard Deviation		1.218

Name (Print): PAUL VALPREDA

Signature: Paul Valpreda Date: 4-30-2014

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Appendix VII

Nozzle Pry Force

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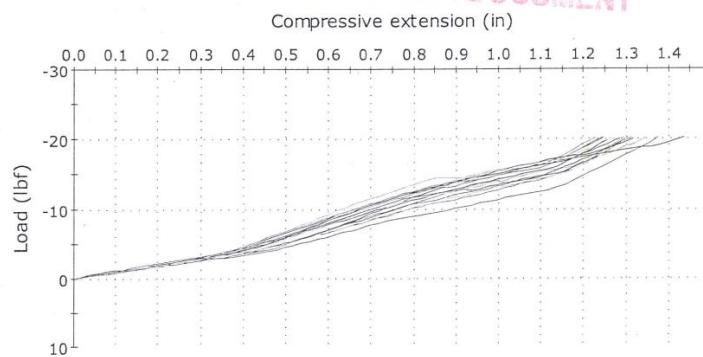
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Specimen 1 to 15 #14-068-01

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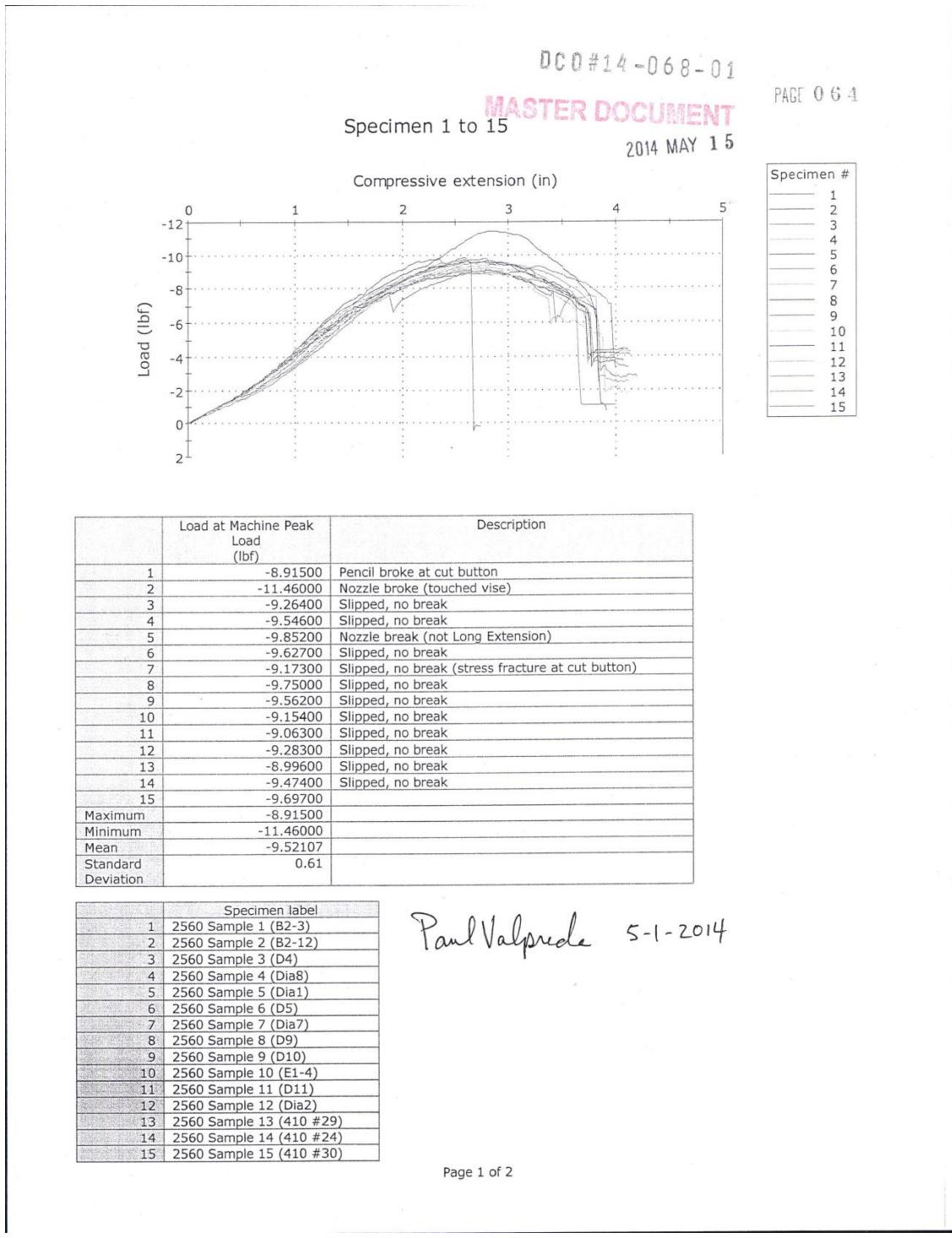


Specimen #
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

	Load at Machine Peak Load (lbf)	Description	Specimen label
1	-21.09000	Did not break or come loose	2540 Sample 1
2	-20.51000	Did not break or come loose	2540 Sample 2
3	-20.83000	Did not break or come loose	2540 Sample 3
4	-20.85000	Did not break or come loose	2540 Sample 4
5	-21.25000	Did not break or come loose	2540 Sample 5
6	-20.86000	Did not break or come loose	2540 Sample 6
7	-20.98000	Did not break or come loose	2540 Sample 7
8	-20.64000	Did not break or come loose	2540 Sample 8
9	-20.93000	Did not break or come loose	2540 Sample 9
10	-20.81000	Did not break or come loose	2540 Sample 10
11	-20.91000	Did not break or come loose	2540 Sample 11
12	-20.82000	Did not break or come loose	2540 Sample 12
13	-20.94000	Did not break or come loose	2540 Sample 13
14	-20.83000	Did not break or come loose	2540 Sample 14
15	-20.98000	Did not break or come loose	2540 Sample 15
Maximum	-20.51000		
Minimum	-21.25000		
Mean	-20.88200		
Standard Deviation	0.17		

Paul Valpred 5-1-2014

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1. NOTE ON TEST PROTOCOL

ENG-RPT-344 was tested to ENG-PRT-239 rev 001. Subsequent revisions were written for the testing of aged samples. ENG-RPT-401 contains the 3-year accelerated aging results.

The Device Master Record for this device is ENG-DMR-012.

The pencil collet must meet IEC standards. Therefore, the pencil collet will be tested in accordance with IEC 60601-2-2: Edition 5, section 201.15.4.1.102 Retention of detachable active electrodes. This section requires inserting an electrode into the pencil 10 times. Following the tenth insertion, the collet must demonstrate that it can maintain its hold on an electrode when a weight of 10 times the electrode is applied along its axis of insertion for 1 minute.

2. REVISION HISTORY

Revision	DCO Number	Description of Change	Effective Date
A	14-068-01	Initial report	2014-05-14
001	See Master Control	Initial upload of hard copy to Master Control	See Master Control
002	See Master Control	Specifying test protocol. No changes made to original report revision A.	See Master Control
B	See Windchill	Added notes for clarification	See Windchill

3. ORIGINAL TEST REPORT

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Mark Glassett 13 May 2014 Lucy Richards 15 May 2014
Engineering Verification: D.C. Verification:

Authored By: Mark Glassett

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3. RESULTS	1
4. DISCUSSION.....	8
5. CONCLUSIONS.....	10
6. RECOMMENDATIONS.....	10
7. REVISION HISTORY.....	10

1. ABSTRACT

Extension Nozzle samples that have been exposed to shipping cycle temperature extremes were subjected to the shipping tests required for compliance to ISO 11607-01:2006. The Extension Nozzle passed the requirements of the standard.

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

Additionally, comparison measurements were made on pre and post aged Zip Pencil nozzles to support the justification for regulatory submissions of test data on non-aged Extension Nozzle samples. These measurements showed that there is no significant change to the material stability through the aging process.

2. OBJECTIVE

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

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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. Therefore, two different configurations were tested for the shipping test, the case box from the contractor and the shipper packed by the shipping department.

- 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 samples were taken from both the case box and the shipper box packed by the shipping department. The inspection was done by incoming QC. None of the samples showed any damage 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.

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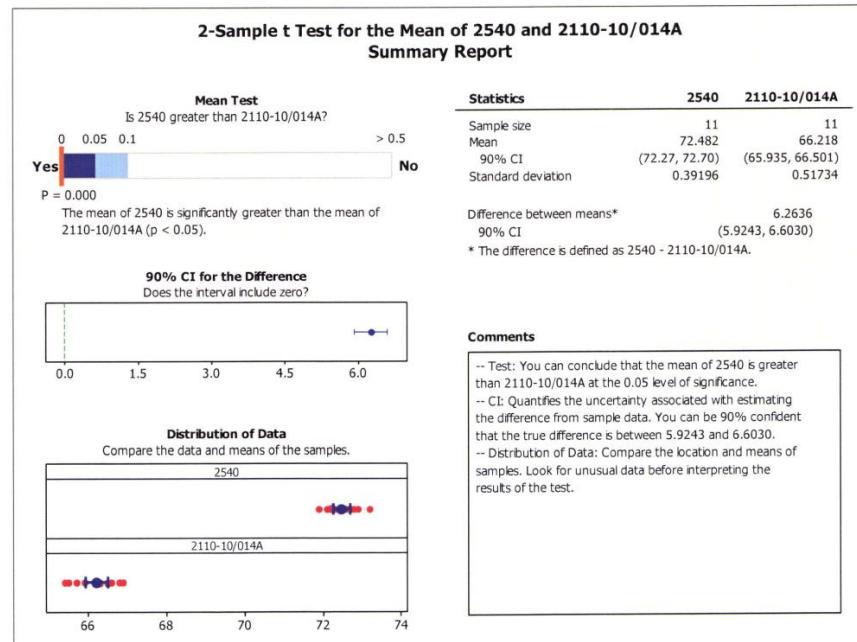
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3.2. Flow Rate Test

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 end 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.

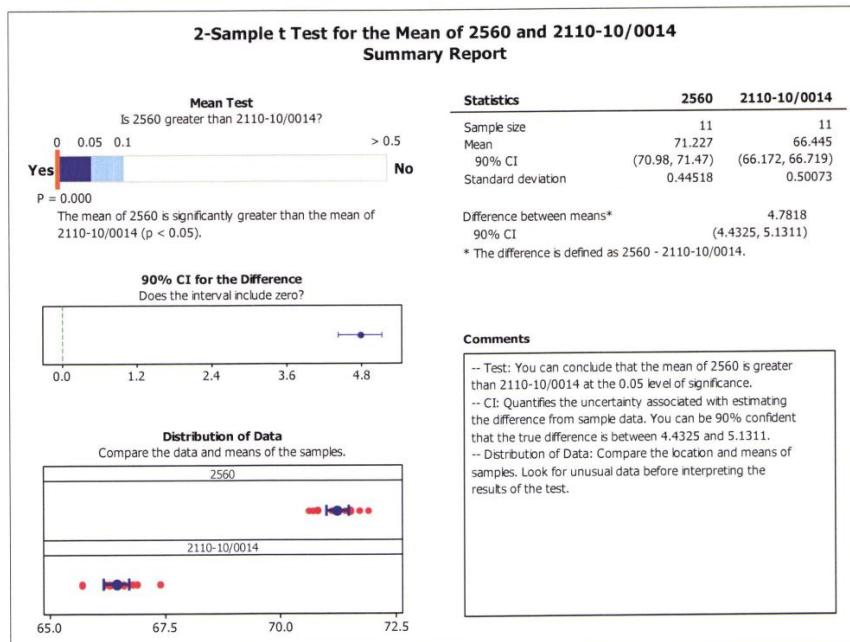


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3.2.2. Zip Pencil with Extension Nozzle 2560 compared to 2110-10 extended to match the length of Zip Pencil with a 0014 electrode. The 't' test shows that the flow rate of the 2560 with a Zip Pencil is greater than the 2110-10. The 2560 passes the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



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3.3. Comparison Measurements

The purpose of comparison measurements is to support the fact that regulatory submissions are being made on Extension Nozzles that are not aged. The nozzle of the Zip Pencil 2510-10 is the same material and has similar dimensions as the Extension Nozzles 2540 and 2560. Aged and non-aged samples of the Zip Pencil 2510-10 nozzle are available. Measurements of the Zip Pencil nozzle pre and post aging show insignificant dimension differences. Therefore it can be concluded that the measurements of the Extension Nozzles will also show insignificant change in dimension through aging. A summary of the measurements is shown below and the data shown in Appendix V.

Measurement	2525-10 Pre Age	2525-10 Post Age	Difference
O.D. Tip	0.361 inch	0.361 inch	0.000 inch
I.D. Tip	0.293 inch	0.296 inch	0.003 inch
O.D. Proximal	0.406 inch	0.406 inch	0.000 inch

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	5.17	0.704
2560	6.09	1.46
Combined Data	5.63	1.22

Comparatively, 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 VI

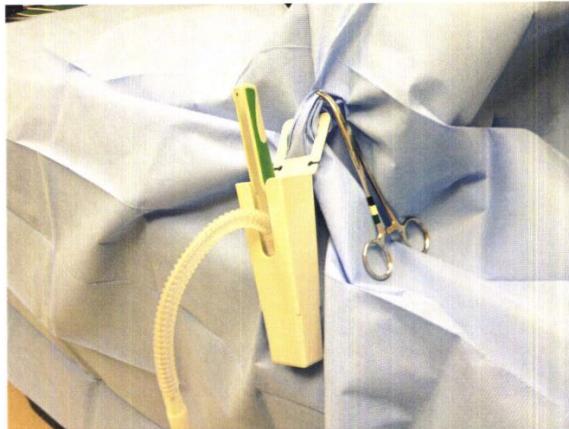
3.5. Fit With Holster

For this test, the Zip Pencil 2525-10 was set up in a simulated operating room environment. The holster was attached to the drape of a simulated sterile field. The 2525-10 Zip pencil and each length of Extension Nozzle were reviewed for fit in the holster under simulated conditions. The Marketing Product Manager and the Medical Director were present for the review. The Zip Pencil without the extension nozzle has a very secure fit in the holster; the picture below shows the fit.

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The Zip Pencil with the 2540 (0014A) extension also fits well in the holster; the picture below shows the fit.



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The Zip Pencil with the 2560 (0014) fits in the holster but can become unstable. The electrode is 6.5 inches long and the Zip Pencil in the holster is top heavy and tended to tip the holster sideways and the Zip Pencil could fall out; the picture below shows the fit.



After trying the 2560 nozzle, we tried the UltraVac 2110-10 with it fully extended. The UltraVac was equal to or less stable than the Zip Pencil with the 2560 nozzle. The reason it could be less stable is that the Zip Pencil has the option to zip the tubing down to the position shown and the UltraVac has the tubing exiting the end of the pencil which applies more torque on the pencil assembly. The consensus of the group was that the Zip Pencil with the 2560 Nozzle Extension is equal to or better than competitive pencils when they have a 6.5 inch electrode in place. The medical director was asked if he would be likely to use a holster when using a 6.5 inch electrode and he replied that he would not use it this way, he would be more likely to set the long pencil with electrode on the mayo stand.

Considering the above data, the requirement of the protocol was met for the Zip Pencil with no extension nozzle and with the 2540 extension and 0014A electrode. The Requirement of the protocol was not met for the 2560 Extension Nozzle with the 0014 electrode but the group agreed that the product is not likely to be used in this way.

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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 1.4" when the load reached 20 pounds. The 2540 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VII

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 2.5" when the load reached about 9 pounds and 3 pencils broke at near or above 9 pounds. The 2560 Extension Nozzles passed the requirements of the protocol. The data is shown in Appendix VII

4. DISCUSSION

Extension Nozzles catalog number 2540 Lot# 140119 and 2560 Lot#140120 were used for this testing. 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 shipping test followed all of the requirements of the protocol for the shipping test. Note that the compression test was only done on the case box that comes from the contractor. The reason for this is that the case may be subjected to pallet stacking during transit. The shipper boxes packed by the shipping department are shipped individually and may vary in size depending on the customer order and are not likely to be stacked.

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

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4.3. Comparison Measurements

The purpose of comparison measurements is to support testing on Extension Nozzles that are not aged.

The packaging of the Extension Nozzles was also considered in the justification. The pouches used for the product is constructed of Tyvek 1073B sealed to a Polyester/Polyethylene laminated layer manufactured by Amcor. Megadyne has used this style of pouch on various products for many years. The packaging validation report for this pouch style is Nelson Lab report #41853. In this report the pouch contained a catalog #0012. This product was packaged in a pouch made of the same materials as the Extension Nozzles. The pouches for this comparable product were purchased from Beacon Converters and use the same Tyvek 1073 B and Polyester/Polyethylene laminated layer. The product in the referenced report were subjected to accelerated aging at 55°C. The accelerated aging was performed to simulate up to 5 years of shelf life and the product passed microbial barrier testing after the accelerated aging.

The package testing of aged product in equivalent pouches along with the ASTM D4169 testing presented in this test report together satisfy the requirements of ISO 11607-1:2006 requirements for terminally sterile packaging systems.

4.4. 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 5.63 pounds and the standard deviation is 1.26. This equates to three sigma limits of 2.0 to 9.4 pounds. This is 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.

4.5. Fit With Holster

The fit with holster test is a usability requirement that could not be tested previously when other usability requirements were being evaluated because Nozzle Extensions were not available. Therefore it was included in this protocol. Although the requirements of the protocol were not fully met, the findings for the fit with the holster are equivalent to the fit of existing products.

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4.6. 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 requirements of ISO 11607-01:2006 after 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 11607-01: 2006. 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 1150309-10.

The testing also demonstrated compliance to ISO 11607-01: 2006 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 excursion to limits allowed.

7. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-068-01	Initial Release	2014 MAY 15

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**Appendix I:
SHIPPING TEST LOG SHEET**

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Appendix I:
SHIPPING TEST LOG SHEET

Preconditioning:

Start Date: 4-23-2014 Chamber Number: 01095
Completion Date: 4-26-2014 Last Calibration: 3-31-2014
Signature/Date: Paul Valpreda 4-30-2014 Calibration due: 3-31-2015

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

Catalog 2540 Lot 12x9x6 Weight: 1.5 lbs
Catalog 2560 Lot 12x9x6 Weight: 1.5 lbs
Case Box 12x19x8 Weight: 5 lbs

Drop	Orientation	Specific face, edge or	Initials/Date
1	Top	Face 1	PV - 4-28-2014
2	Edge	Edge 5-3	PV - 4-28-2014
3	Edge	Edge 6-3	PV - 4-28-2014
4	Corner	Corner 2-3-5	PV - 4-28-2014
5	Corner	Corner 4-3-6	PV - 4-28-2014
6	Bottom	Face 3	PV - 4-28-2014

Comments: _____

Signature: Paul Valpreda Date: 4-30-2014

Compression Test: Perform compression test on the case box only

Catalog 2540 and 2560 Pounds Force 105 lbs.

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Pass / Fail Comments: Paul Valpreda 4-30-2014

Signature: Paul Valpreda Date: 4-30-2014

Vibration Test: Perform vibration on all three configurations

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

Completion Date: 4-28-2014

Signature: Paul Valpreda Date: 4-30-2014

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 - 4-28-2014
2	Face	Face 4	PV - 4-28-2014
3	Face	Face 6	PV - 4-28-2014
4	Corner	Corner 2-1-5	PV - 4-28-2014
5	Edge	Edge 2-1	PV - 4-28-2014
6	Bottom	Face 3, Increase height to 30 inches.	PV - 4-28-2014

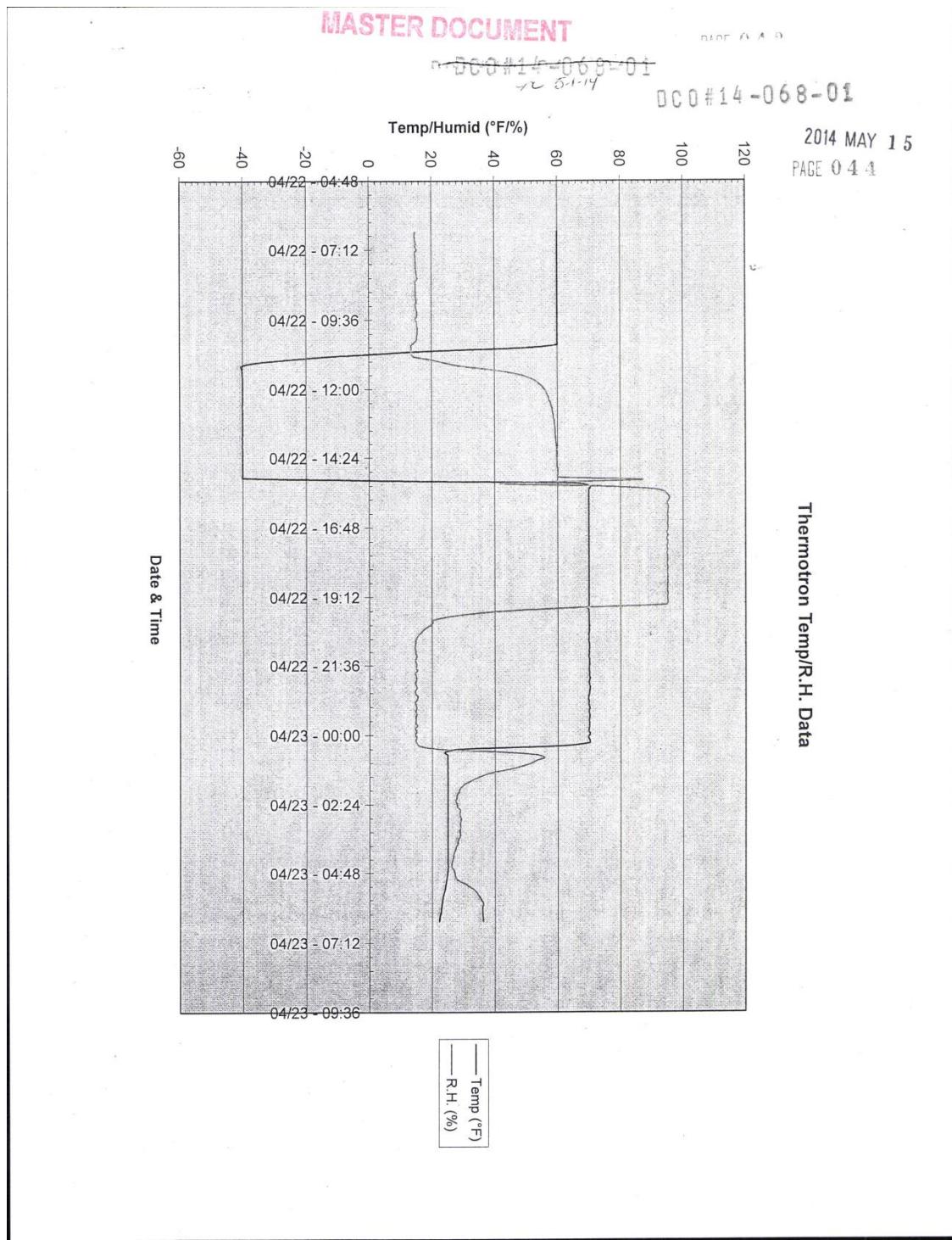
Comments: _____

Signature: Paul Valpreda Date: 4-30-2014

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Appendix II
PRINT CLEAR AND LEGIBLE

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Appendix III
BUBBLE LEAK TEST

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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	30	
Lot Number Print S14D0119	30	

Comments: _____

Catalog 2560	Pass	Fail
Pouch Print	30	
Lot Number Print S14D0120	30	

Comments: _____

Test Performed by: m. Fisher Date: 4/28/2014

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Appendix III

BUBBLE LEAK TEST (Continued)

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

Test Performed by: Paul Valpreda Date: 4-28-2014

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Appendix III
BUBBLE LEAK TEST

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

Test Performed by: Paul Valpreda Date: 4-28-2014

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Appendix IV

FLOW RATE TEST

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CONTROL SAMPLES

CD14

Catalog 2110-10	Lot # 5361	Sample #	Flow Rate
1-C	17.4	7-C	14.4
2-C	65.7	8-C	66.3
3-C	66.2	9-C	16.9
4-C	65.7	10-C	67.4 66.6 54.3 21.4
5-C	66.6	11-C	66.3
6-C	66.9		

Test Performed by: M.S. Date: 4/28/14

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CONTROL SAMPLES

Catalog 2110-10	Lot # 5361	Sample #	Flow Rate
1-C	67.6 4/28/14	7-C	66.3
2-C	65.5	8-C	66.9
3-C	65.7	9-C	66.4
4-C	65.4	10-C	66.5
5-C	66.5	11-C	66.3
6-C	66.3		

Test Performed by: M. J. Date: 4/28/14

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Appendix IV

FLOW RATE TEST

Mega Vac Serial Number: J4211 *F.17-5364*
Flow Meter ID#: 01272 *calibration 4/2015*
Last Calibration Date: April 2015
Calibration Due Date: 2014

Catalog 2540	Lot #	Catalog 2560	Lot #
Electrode 0014A	Lot # 140831	Electrode 0014A	Lot # 141193
Sample #	Flow Rate	Sample #	Flow Rate
1-14A	72.3	1-14	71.5
2-14A	71.9	2-14	71.7
3-14A	72.6	3-14	70.8
4-14A	72.8	4-14	71.9
5-14A	72.4	5-14	71.5
6-14A	72.2	6-14	70.8
7-14A	72.2	7-14	71.3
8-14A	72.7 <i>5/21/14</i>	8-14	70.7 <i>5/21/14</i>
9-14A	72.1 <i>5/21/14</i>	9-14	70.6
10-14A	72.6 <i>5/21/14</i>	10-14	71.4
11-14A	73.2	11-14	71.1

MJF 4/28/14

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Appendix V
COMPARISON MEASUREMENTS

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Comparison Measurements

Measurement	2525-10 Pre Age	2525-10 Post Age	2540	2560
O.D. Tip - 1	0.361	0.361	0.350	0.380
O.D. Tip - 2	0.362	0.361	0.351	0.380
O.D. Tip - 3	0.361	0.362	0.350	0.382
O.D. Tip - 4	0.361	0.362	0.351	0.382
O.D. Tip - 5	0.360	0.360	0.349	0.382
O.D. Tip - 6	0.361	0.362	0.350	0.381
O.D. Tip - 7	0.359	0.363	0.349	0.382
O.D. Tip - 8	0.360	0.362	0.350	0.382
O.D. Tip - 9	0.360	0.362	0.349	0.380
O.D. Tip - 10	0.360	0.360	0.349	0.381
O.D. Tip - 11	0.362	0.361	0.349	0.381
Average	0.361	0.361	0.350	0.381
Standard Deviation	0.001	0.001	0.001	0.001
I. D. Tip - 1	0.293	0.296	0.294	0.312
I. D. Tip - 2	0.293	0.296	0.294	0.312
I. D. Tip - 3	0.293	0.296	0.294	0.312
I. D. Tip - 4	0.293	0.296	0.294	0.312
I. D. Tip - 5	0.293	0.296	0.294	0.312
I. D. Tip - 6	0.292	0.296	0.294	0.312
I. D. Tip - 7	0.293	0.296	0.294	0.312
I. D. Tip - 8	0.293	0.296	0.294	0.312
I. D. Tip - 9	0.293	0.296	0.294	0.312
I. D. Tip - 10	0.293	0.296	0.294	0.312
I. D. Tip - 11	0.293	0.296	0.294	0.312
Average	0.293	0.296	0.294	0.312
Standard Deviation	0.000	0.000	0.000	0.000
O.D. Proximal -1	0.407	0.406	0.499	0.497
O.D. Proximal -2	0.405	0.406	0.498	0.497
O.D. Proximal -3	0.406	0.406	0.499	0.498
O.D. Proximal -4	0.406	0.406	0.498	0.498
O.D. Proximal -5	0.406	0.405	0.498	0.497
O.D. Proximal -6	0.407	0.407	0.499	0.497
O.D. Proximal -7	0.406	0.406	0.497	0.497
O.D. Proximal -8	0.405	0.406	0.499	0.497
O.D. Proximal -9	0.407	0.407	0.498	0.497
O.D. Proximal -10	0.406	0.406	0.498	0.497
O.D. Proximal -11	0.407	0.405	0.498	0.497
Average	0.406	0.406	0.498	0.497
Standard Deviation	0.001	0.001	0.001	0.000

Name (Print): PAUL VALPREDA

Signature: Paul Valpreda

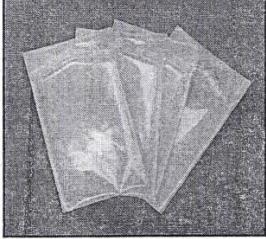
Date: 4-30-2014

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DCO #14-068-01
2014 MAY 15

Chevron Pouches made with 1073B Tyvek®



Pouches are constructed of uncoated 1073B Tyvek® and a polyester/polyethylene laminate.

Pouches have a solid 0.375" side and chevron seals

Minimum Order: \$400.00 (Full case quantity only)

Pricing Effective: July 1, 2013

Item No.	Catalog Number	Outside Dimensions (width x length)	Product Code	Case Qty.	Price 1-2 Cases	Price 3-4 Cases	Price 5+ Cases
027706C	30307PN	3" x 7"	TLP-031	1000	\$298.004	\$217.028	\$175.795
027707C	30409PN	4" x 9"	TLP-031	1000	\$306.115	\$225.124	\$182.360
027708C	30412PN	4" x 12"	TLP-031	1000	\$328.778	\$244.566	\$198.102
027709C	30610PN	6" x 10"	TLP-031	1000	\$330.403	\$247.802	\$200.716
027710D	30812PN	8" x 12"	TLP-031	1000	\$398.421	\$317.445	\$257.135
027790D	31015PN	10" x 15"	TLP-031	500	\$369.273	\$288.283	\$233.508
027791C	31218PN	12" x 18"	TLP-031	400	\$383.855	\$299.628	\$242.701

Materials: 1073B Uncoated Tyvek® Vent
2.75 Mil PE/PET Lamination

Printing: None

PRICING: Pricing is effective January 1, 2013 and can change without notice

TERMS: All AMCOR Flexibles Terms and Conditions apply, including the following:
Net 30 days upon credit approval
FOB AMCOR Flexibles Facility
Our Terms and Conditions of Sale include limitations on warranty and limitations on remedies.
For a complete listing of Terms and Conditions see the Amcor Flexibles web site at
www.amcor.com/flexibles-healthcare.

PRICING: Pricing method is by quantity ordered per individual part number.

OTHER: Artwork, die, engravings, plate and/or tooling charges are invoiced separately and are not included in the price
Pricing is preliminary pending review and acceptance of formal customer specification.

Tyvek® is a registered trademark of DuPont for its brand of protective material

Amcor Customer Service 1-800-447-0049

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Technical Datasheet

Tyvek® Pouches

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Description

Product Code : TLP-031

Structure : HEAT SEAL POUCH, 1073B Tyvek® (PTU-002)//12.2 μ PET/Adh/57.2 μ LDPE-EVA (RLA-069)
HEAT SEAL POUCH, 1073B Tyvek® (PTU-002)//48 ga PET/Adh/2.25 mil LDPE-EVA (RLA-069)

General Description

- Incorporates an adhesive lamination of polyester and polyethylene
- Suitable for radiation and EO sterilization for wide range of medical devices
- Uncoated Tyvek® provides breathability and microbial barrier
- Film portion of pouch has excellent clarity and strength properties
- Consistent peelable seal is feature of pouch

Technical Data 48 ga PET/Adh/2.25 mil LDPE-EVA (RLA-069)

Property	Metric	Value		Method
		US	SI	
Basis Weight	72.8 g/m ²	44.7 lbs/3000 ft ²		
Thickness	69.9 μ m	2.75 mil		ASTM F2251
Yield	13.7 m ² /kg	9,660 in ² /lb		TAPPI T410
Tensile Strength (film)				ASTM D882
MD	42 MPa	6,020 psi		
TD	42 MPa	6,100 psi		
Percent Elongation at Break				ASTM D882
MD	110 %	110 %		
TD	100 %	100 %		
Tear Strength (Elmendorf)				ASTM D1922
MD	280 mN	29 grams force		
TD	340 mN	35 grams force		
Puncture Strength (1/8" probe)				FTMS 101C
	41.4 N	9.3 pounds force		
Haze	7.0 %	7.0 %		ASTM D1003

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Tyvek® Pouches

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Technical Data 1073B Tyvek® (PTU-002)

Property	Value		Method
	Metric	US	
Substrate Weight	74.5 g/m ²	45.8 lbs/3000 ft ²	TAPPI T410
Yield	13.4 m ² /kg	9430 in ² /lb	TAPPI T410
Tensile MD	110 N/15mm	42 lb/in	ASTM D 5035
Tensile CD	124 N/15mm	47 lb/in	ASTM D 5035
Elmendorf Tear MD	2.1 N force	0.82 lb force	ASTM D 1922
Elmendorf Tear CD	2.2 N force	0.84 lb force	ASTM D 1922
Porosity (Gurley)	22 sec/100cc	22 sec/100cc	TAPPI T460

Disclaimer

The above figures are indicative only. No guarantee, warranty, or responsibility on the part of Amcor is implied. The customer is responsible for determining whether Amcor products are fit for a particular purpose, as well as ensuring any proprietary rights, legislation, and existing laws are observed.

Tyvek® is a registered trademark of DuPont

Rev Date: 09-21-2011

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<p>NOTES:</p> <p>1. POUCHES TO BE FREE OF ANY TEARS. 2. POUCH TO BE PLACED IN A SEALED POLY BAG, INSIDE ANOTHER SEALED POLY BAG (DOUBLE BAGGED) 3. MATERIAL TO BE: A.7 (1073B TYVEK) TAPE TO A20 (A GAUGE POLYESTER/ZIN POLYETHYLENE) 4. POUCH SHALL BE COSMETICALLY CLEAN, THE OUTER AND INNER SURFACES TO BE FREE FROM DIRT, FOREIGN MATTER, AND MATERIALS, EARNING THE DIRT ESTIMATION CHART FOR TAPPI STANDARDS T213 AND T457. PARTICLES OF .40 mm³ OR LARGER ARE CAUSE FOR REJECT, AND ALSO MEET MEGADYNE'S TAPPI WORK INSTRUCTION 100000-10 PARTICULATE CONTAMINATION INFECTION.</p> <p>5. ALL SEALS MUST BE UNINTERRUPTED AND SHOW EVIDENCE OF SEALING ALL AROUND. 6. FINISHED PACKAGE IS FREE OF HOLES, OPENINGS, TEARS, ETC. 7. POUCH TO MEET MEGADYNE'S INSPECTION FORM, P/N 103000-01, TYVEK/POLYSTER PEEL POUCH.</p>	<p style="text-align: center;">MASTER DOCUMENT</p> <p style="text-align: center;">DOD #14-068-01 MASTER DOCUMENT</p> <p style="text-align: center;">2014 MAY 15</p> <p style="text-align: center;">MASTER DOCUMENT</p>	<p>SOURCE CONTROL DRAWING</p> <p>MEGADYNE</p> <p>MEGADYNE MEDICAL PRODUCTS 1156 SOUTH STATE STREET DRAPE, UT 84020-9453 USA (801)-576-9869</p> <p>REV: J</p> <p>DATE: 1998-06-02 TITLE: POUCH, GENERIC</p> <p>UNCLASSIFIED XX = ± .005 X = ± .1 S.Z. 98-FEB-18 OK</p> <p>4 x 9</p> <p>PART NUMBER: 3600004-01</p> <p>DRAWINGS: B.M. 98-APR-16 INCHES: INCHES</p> <p>DO NOT SCALE PRINT SCALE HONE SHEET 1 OF 1</p> <p>DIMENSIONS AND SPECIFICATIONS IDENTIFIED AS CONTROLLING CHARACTERISTICS ARE DENOTED BY ♦ THIS DOCUMENT IS THE CONFIDENTIAL PROPERTY OF MEGADYNE MEDICAL PRODUCTS INC. AND INCLUDES PROPRIETARY INFORMATION. IT IS TO BE USED FOR NO PURPOSE OTHER THAN THE LIMITED INTENT FOR WHICH IT IS DELIVERED AND NOT TO BE USED BY OR DISCLOSED TO ANY OTHER INDIVIDUAL OR LEGAL ENTITY WITHOUT THE EXPRESS WRITTEN CONSENT OF A MEADORE REPRESENTATIVE.</p>

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Appendix VI

Nozzle Retention Force

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Nozzle Removal force		
Sample	2540	2560
1	3.430	3.930
2	5.820	5.340
3	5.650	4.380
4	4.400	6.860
5	4.850	5.390
6	4.600	8.180
7	4.920	5.890
8	4.920	5.540
9	5.490	6.740
10	4.870	5.910
11	5.720	4.830
12	5.790	7.970
13	5.870	6.730
14	6.030	8.920
15	5.220	4.750
Average	5.172	6.091
Standard Deviation	0.704	1.457
Combined Average	5.631	
Combined Standard Deviation	1.218	

Name (Print): PAUL VALPREDA

Signature: Paul Valpreda Date: 4-30-2014

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Appendix VII

Nozzle Pry Force

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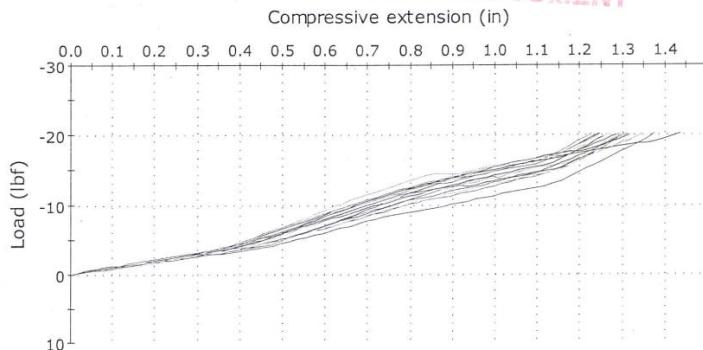
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Specimen 1 to 15 #14-068-01

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Specimen #
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15

	Load at Machine Peak Load (lbf)	Description	Specimen label
1	-21.09000	Did not break or come loose	2540 Sample 1
2	-20.51000	Did not break or come loose	2540 Sample 2
3	-20.83000	Did not break or come loose	2540 Sample 3
4	-20.85000	Did not break or come loose	2540 Sample 4
5	-21.25000	Did not break or come loose	2540 Sample 5
6	-20.86000	Did not break or come loose	2540 Sample 6
7	-20.98000	Did not break or come loose	2540 Sample 7
8	-20.64000	Did not break or come loose	2540 Sample 8
9	-20.93000	Did not break or come loose	2540 Sample 9
10	-20.81000	Did not break or come loose	2540 Sample 10
11	-20.91000	Did not break or come loose	2540 Sample 11
12	-20.82000	Did not break or come loose	2540 Sample 12
13	-20.94000	Did not break or come loose	2540 Sample 13
14	-20.83000	Did not break or come loose	2540 Sample 14
15	-20.98000	Did not break or come loose	2540 Sample 15
Maximum	-20.51000		
Minimum	-21.25000		
Mean	-20.88200		
Standard Deviation	0.17		

Paul Valpredo 5-1-2014

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