MEGADYNE® Est. 1985
The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-RPT-585

DOCUMENT TITLE: ZIP ACE Modified, 6-Pack Ship Test, 3 yr. Accelerated Aging

DOCUMENT NOTES:

Document Information

Revision: 001	Vault: MEG-Rel
Status: Release	Document Type: ENG-RPT

Date Information

Effective Date: 22 Jun 2018	Expiration Date:
Release Date: 22 Jun 2018	Next Review Date:

Control Information

Author: TSKINNER	Owner: TSKINNER
Previous Number:	Change Number: 2018-ENG-DCO-111

Signature Manifest

Document Number: ENG-RPT-585 **Revision:** 001
Title: ZIP ACE Modified, 6-Pack Ship Test, 3 yr. Accelerated Aging

All dates and times are in Mountain Standard Time.

ZIP ACE Mod 3 yr Acc Aging RPT

Change Request

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		10 May 2018, 08:24:24 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	30 May 2018, 04:42:39 PM	Complete
Paul Borgmeier (PBORGMEIER)		01 Jun 2018, 01:05:00 PM	Complete
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	19 Jun 2018, 06:04:18 PM	Complete
Tyler Skinner (TSKINNER)	Project Engineer	20 Jun 2018, 09:21:52 AM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		20 Jun 2018, 02:22:23 PM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Darlene Hull (DHULL)	Regulatory	20 Jun 2018, 03:06:31 PM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
Joni Stegeman (JSTEGEMAN)	Ethicon Quality	20 Jun 2018, 04:50:07 PM	Approved

ENG-Approval

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		21 Jun 2018, 03:31:06 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Stacey Castaneda (SCASTANEDA)	Associate Complaint Analyst		
Lucy Richards (LRICHARDS)		22 Jun 2018, 09:15:45 AM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)		22 Jun 2018, 09:15:58 AM	Approved

Authored By: Tyler Skinner

1. ABSTRACT

Test Protocol ENG-PRT-466 was completed successfully. Testing included 2x EO Sterilization, Accelerated Aging, Thermal Cycling, Ship Conditioning, Bubble Leak testing, Dye testing, Burst testing, Minimum Seal Width testing, Product Damage Inspection and Tubing Strength Testing. All testing was completed successfully.

These results demonstrate that the proposed 6-Pack shipping configuration (ME725M1C and ME725M1E) does not damage the Tyvek pouch seal and protects the product from damage. The results also provide confidence that the product will withstand the anticipated shipping environment and meet DMR requirements in ENG-DMR-012 after EO Sterilization and 3 yr. Real Time Aging.

2. REFERENCES

ENG-DMR-012	DMR, Smoke Evacuation Pencil and Accessories
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-PRT-466	ZIP ACE Modified, 6-Pack Ship Test, 3 yr. Accelerated Aging Protocol
ME725M1C	Ace Blade 700, 2.5” Zip Pen, “C” Connector, 10 ft. Tubing
ME725M1E	Ace Blade 700, 2.5” Zip Pen, EC Connector, 10 ft. Tubing

3. OBJECTIVE

This Test Report provides confidence that Zip ACE Modified product packaged in the proposed 6-Pack shipping configuration (ME725M1C and ME725M1E) will withstand the anticipated shipping environment and meet DMR requirements in ENG-DMR-012 after EO Sterilization and 3 yr. Real Time Aging.

4. APPENDICIES

Appendix I – 2X EO Sterilization
Appendix II – Accelerated Aging
Appendix III – Thermal Cycling
Appendix IV – Ship Conditioning
Appendix V – Bubble Leak Testing
Appendix VI – Dye Testing
Appendix VII – Burst Testing
Appendix VIII – Minimum Seal Width Testing
Appendix IX – Product Damage Inspection
Appendix X – Tubing Strength Testing

5. RESULTS

5.1. 2X EO Sterilization

36 Zip Pen samples (6 boxes) SKU: ME725M1C Lot # 170323 were EO sterilized twice per Sterigenics Cycle 115. See Appendix I for EO sterilization documentation.

5.2. Accelerated Aging

36 Zip Pen samples (6 boxes) SKU: ME725M1C Lot # 170323 were subjected to accelerated aging per ENG-PRT-049 to simulate 3 years aging. The aging temperature was 55°C and the aging duration per the protocol was 111 days. See Appendix II for Accelerated Aging documentation.

5.3. Thermal Cycling

36 Zip Pen samples (6 boxes) SKU: ME725M1C Lot # 170323 were subjected to Thermal Cycling per ENG-PRT-466 and followed the schedule below. See Appendix III for Thermal Cycling Data.

5.4. Shipping Conditioning

CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to55°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
Hold 23°C and 50%RH	72 hours

36 Zip Pen Samples (6 boxes) SKU: ME725M1C Lot # 170323 were ship conditioned/tested as outlined in ENG-PRT-466. See Appendix IV for a complete summary of testing.

It should be noted that tests were performed under typical warehouse conditions, which are:

Temperature: 23°C ±5°C
Relative Humidity: 50% ±35%

5.4.1. Manual Handling - Manual (Drop Test)

The Manual Handling (Drop Test) was performed using a drop height of 15 in as outlined in ENG-PRT-466.

5.4.2. Vehicle Stacking (Compression Test)

The Vehicle Stacking (Compression Test) was performed using a computed load (L) of 210 lb as outlined in ENG-PRT-466.

5.4.3. Loose Load Vibration and Vehicle Vibration Tests

The Loose Load Vibration Test was performed for 40 min as outlined in ENG-PRT-466. Following the Loose Load Vibration test, the Vehicle Vibration test was performed for 10 min as outlined in ENG-PRT-466.

5.4.4. Concentrated Impact Test

The Concentrated Impact Test was performed as outlined in ENG-PRT-466.

5.4.5. Manual - Handling (2nd Drop Test)

The Manual Handling (2^{nd} Drop Test) was performed using a drop height of 15 in with the final drop at a height of 30 in as outlined in ENG-PRT-466.

5.4.6. Each box remained intact and did not break open during the test.

5.5. Bubble Leak Testing

The Bubble Leak test was performed on 35 samples as outlined in ENG-PRT-466. There were no tears, holes, or open seals in any pouch. See Appendix V for Bubble Leak Testing Raw Data.

5.6. Dye Testing

The Dye Test was performed on 35 samples as outlined in ENG-PRT-466. There were no breaches in the seal and no signs of separation or degradation. See Appendix VI for Dye Testing Raw Data.

5.7. Burst Testing

The Burst Test was performed on 36 samples as outlined in ENG-PRT-466. All samples burst pressure exceeded the passing criteria of 19 in. H_2O with a minimum of 23.7 in. H_2O. See Appendix VII for Burst Testing Raw Data.

5.8. Minimum Seal Width Testing

The Minimum Seal Width Test was performed on 35 samples as outlined in ENG-PRT-466. The minimum seal width of all edges exceeded the passing criteria of 0.20” with a minimum of 0.26”. See Appendix VIII for Minimum Seal Width Testing Raw Data.

5.9. Product Damage Inspection

Product Damage Inspection was performed on 35 samples as outlined in ENG-PRT-466. No damage to the electrode, coating, or any other part of the Zip Pen was observed. See Appendix IX for Product Damage Inspection Raw Data.

5.10. Tubing Strength Test

The Tubing Strength Test was performed on 35 samples as outlined in ENG-PRT-466. All samples tubing strength exceeded the passing criteria of 4 lbs. tensile force with a minimum of 5.66 lbs. See Appendix X for Tubing Strength Testing Raw Data.

6. DISCUSSION

6.1. 2X EO Sterilization

Product was 2X EO Sterilized as outlined by ENG-PRT-466.

6.2. Accelerated Aging

Product was Accelerated Aged as outlined by ENG-PRT-466.

6.3. Thermal Cycling

Due to chamber and availability restraints the product was moved between several environmental chambers. Despite the product being moved, it was successfully exposed to all chamber conditions for the appropriate duration. As such product was thermally cycled as outlined by ENG-PRT-466.

6.4. Ship Conditioning

The acceptance criteria per ENG-PRT-466 were satisfied.

6.5. Bubble Leak Testing

The acceptance criteria per ENG-PRT-466 were satisfied.

6.6. Dye Testing

The acceptance criteria per ENG-PRT-466 were satisfied.

6.7. Burst Testing

The acceptance criteria per ENG-PRT-466 were satisfied.

6.8. Minimum Seal Width Testing

The acceptance criteria per ENG-PRT-466 were satisfied.

6.9. Product Damage Inspection

The acceptance criteria per ENG-PRT-466 were satisfied.

6.10. Tubing Strength Test

The acceptance criteria per ENG-PRT-466 were satisfied.

7. CONCLUSIONS

7.1. 2X EO Sterilization

Product was successfully 2X EO Exposed

7.2. Accelerated Aging

Product was successfully 3 yr. Accelerated Aged.

7.3. Thermal Cycling

Product was successfully Thermal Cycled.

7.4. Ship Conditioning

The 2x EO Sterilized, 3 yr. Accelerated Aged, Thermally Cycled, and Ship Conditioned 6-Pack shipping configuration meets ASTM D4169.

7.5. Bubble Leak Testing

The 6-Pack shipping configuration does not add additional risk of leaks in the product packaging post 3 yr. Accelerated Aging.

7.6. Dye Testing

The 6-Pack shipping configuration does not add additional risk of breaches in the seal of the product packaging post 3 yr. Accelerated Aging.

7.7. Burst Testing

The 6-Pack shipping configuration does not add additional risk to bursts in the seal of the product packaging post 3 yr. Accelerated Aging.

7.8. Minimum Seal Width Testing

The 6-Pack shipping configuration does not reduce the seal width of the product packaging post 3 yr. Accelerated Aging.

7.9. Product Damage Inspection

The 6-Pack shipping configuration does not add additional risk of damage to the product post 3 yr. Accelerated Aging.

7.10. Tubing Strength Test

The Tubing Tensile Strength remains acceptable post 2x EO Sterilization, 3 yr. Accelerated Aging, Thermal Cycling, and Ship Conditioning. Tubing meets DMR requirements post 2X EO Sterilization and 3 yr. Accelerated aging.

8. RECOMMENDATIONS

It is recommended that product codes ME725M1C and ME725M1E be released for distribution in the 6-Pack shipping configuration. Additionally, data gathered for ME725M1C and ME725M1E was found to meet all DMR requirements after EO sterilization and 3 yr. Accelerated Aging and should be considered substantial evidence to support a shelf life of 3 years post EO Sterilization upon release.

9. APPENDIX I – 2X EO STERILIZATION

NELSON LABORATORIES

Sponsor:
Christian Crook
MegaDyne Medical Products, Inc.
11506 S. STATE ST.
DRAPER, UT 84020-9453

Ethylene Oxide (EO) Exposure (BIER Vessels and STERIS® EO Sterilizers) Final Report

Test Article:	Ref: ME725M1C Lot: S170323 Description: Megadyne Ace Blade 700
Purchase Order:	29299
Study Number:	992275-S01
Study Received Date:	26 Sep 2017
Testing Facility:	Nelson Laboratories, LLC, a Business Unit of Sterigenics International 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0107 Rev 08 Customer Specification Sheet (CSS) Number: 201703061 Rev 01
Deviation(s):	None

Summary: This report describes the exposure of the above mentioned test article(s) to EO. The sterilizer was programmed using the set points below. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820. Following the exposure process, the test articles were picked up by the sponsor.

The exposed test articles are not for human use. Because the sterilization of the test articles has not been validated using additional fractional or half cycles, the delivered sterility assurance level (SAL) cannot be determined. The test articles should only be used for functionality, biocompatibility or other physical evaluations not involving human patients.

Procedure: The six boxes submitted for EO exposure were processed twice using the following set points:

Preconditioning Phase:

Temperature:	43.3°C
Relative Humidity (RH):	60%
Time:	66 hours 7 minutes (Cycle 1) 25 hours 19 minutes (Cycle 2)

Conditioning Phase:

Temperature:	48.9°C
RH:	50%
Vacuum Set Point:	1.0 pounds per square inch absolute (psia)
Humidity Set Point:	1.8 psia
Conditioning Time:	60 minutes
Vacuum Ramp Rate:	25 psia/minute

Study Director Tori Dieffenbacher — Study Completion Date 11 Oct 2017

992275-S01

tzb FRT0107-0001 Rev 7
Page 1 of 2

P.O. Box 571830 | Murray, UT 84157-1830 USA • 6280 South Redwood Road | Salt Lake City, UT 84123-6600 USA
www.nelsonlabs.com • Telephone 801 290 7500 • Fax 801 290 7998 • sales@nelsonlabs.com

NELSON LABORATORIES

EO Exposure Phase:

Gas Type:	100% EO
Gas Concentration:	804 mg/L
Temperature:	48.9°C
Sterilant Set Point:	8.9 psia
Exposure Time:	240 minutes
Vacuum Ramp Rate:	25 psia/minute

Aeration Phase:

Temperature:	43.3 ± 5°C
Time:	41 hours 52 minutes (Cycle 1) 88 hours 32 minutes (Cycle 2)

10. APPENDIX II – ACCELERATED AGING

Accelerated Aging In Process
Owner: Christian Crook ext. 807
Product to be removed on: January 28, 2018

ME725MIC TS 1-29-18

Product: ~~ME7251C~~, ACE 700

Lot Number(s): S170323

Quantity: 6 box, 6 ea.

Aging Temperature: 55°C

Humidity: Ambient

Total Time Required: 111 days

Expected Completion: 09 Oct 2017

Additional Description: Product to be removed at 3 years accelerated aging.

Record any time lost to removing product from chamber or cycle interruption below.

Start	Time	Initials	Stop	Time	Total	Initials
09 Oct. 2017	6:43	CC	Jan 29 2018	13:32	111 days	TS
~~24 Jan 2018~~ TS 1-29-18	~~13:32~~	~~TS~~			20 Hrs 49 min	

Thermotron ID Number	2810 T-Serial #
Last Calibration Date	11 May 2017
Calibration Due Date	31 May 2018

If this aging needs to be interrupted for any reason,
Contact Christian Crook at ext. 807

11. APPENDIX III – THERMAL CYCLING

11. APPENDIX II – THERMAL CYCLE DATA

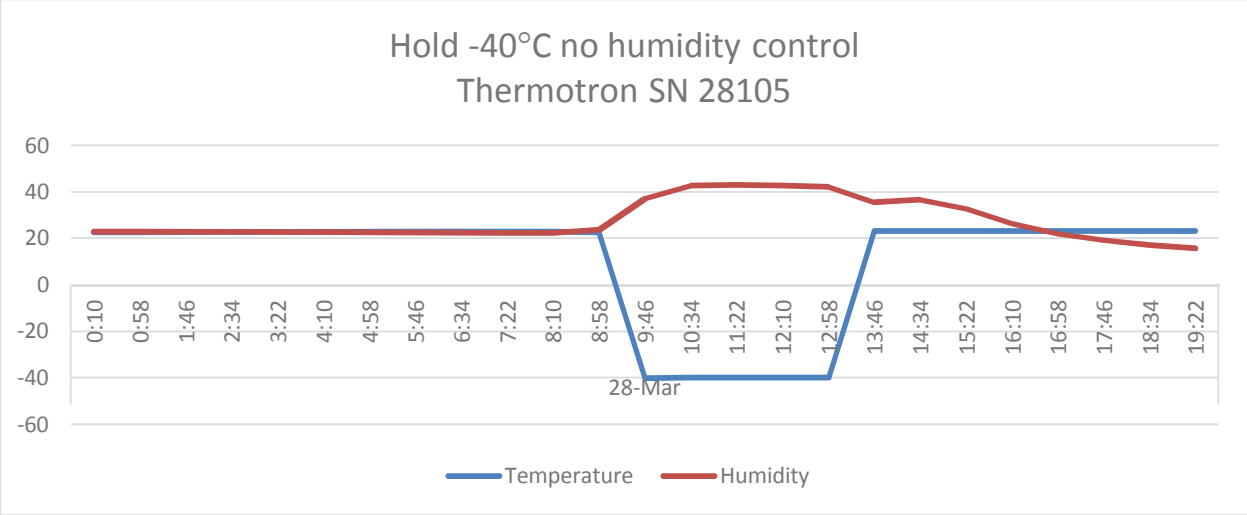
Appendix II: Thermal Cycle Data

Maximum Temperature (°C):	55C
Minimum Temperature (°C):	-40.1
Maximum Temperature (%RH):	95.1
Minimum Temperature (%RH):	42.9
Chamber conditions held @ -40°C and no humidity control for a duration of 4 hours:	yes - PV
Chamber conditions held @ 55°C and 95%RH for a duration of 4 hours:	yes - PV
Chamber conditions held @ 55°C and 15%RH for a duration of 4 hours:	yes - PV
Chamber conditions held @ 23°C and 50%RH for a duration of 72 hours:	yes - PV

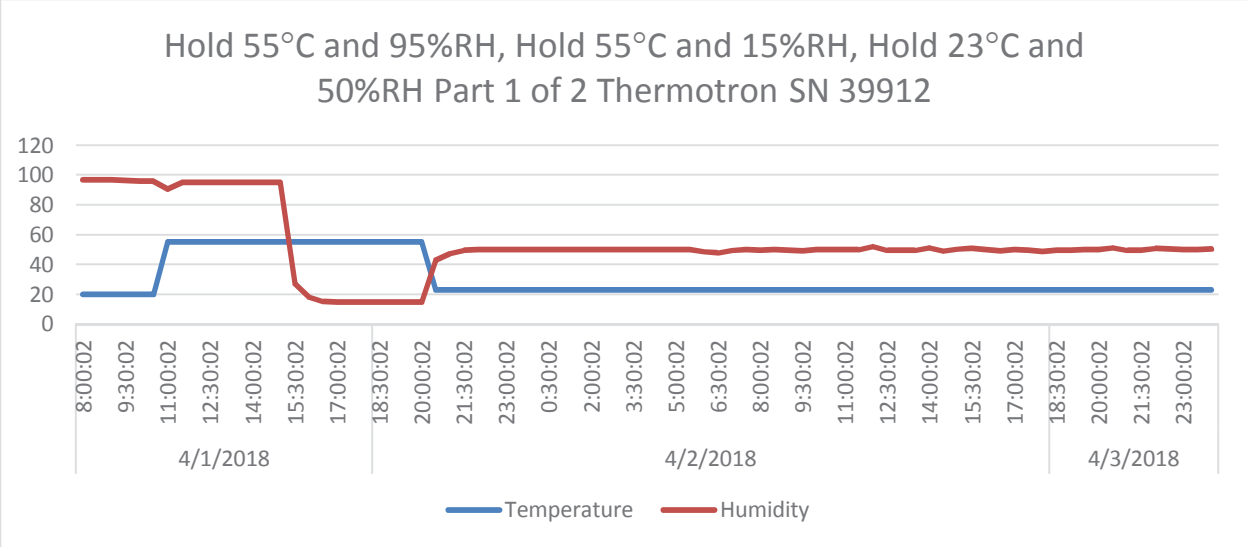
Paul Valpreda — Paul Valpreda — 4-17-2018
Test Technician Name — Signature — Date

(Tyler Skinner) — 4.30.18
Engineer Name — Signature — Date

28105 - Due on 5-31-2018, 39912 - Due on 2-28-2019
Thermotron SN — Calibration Due Date



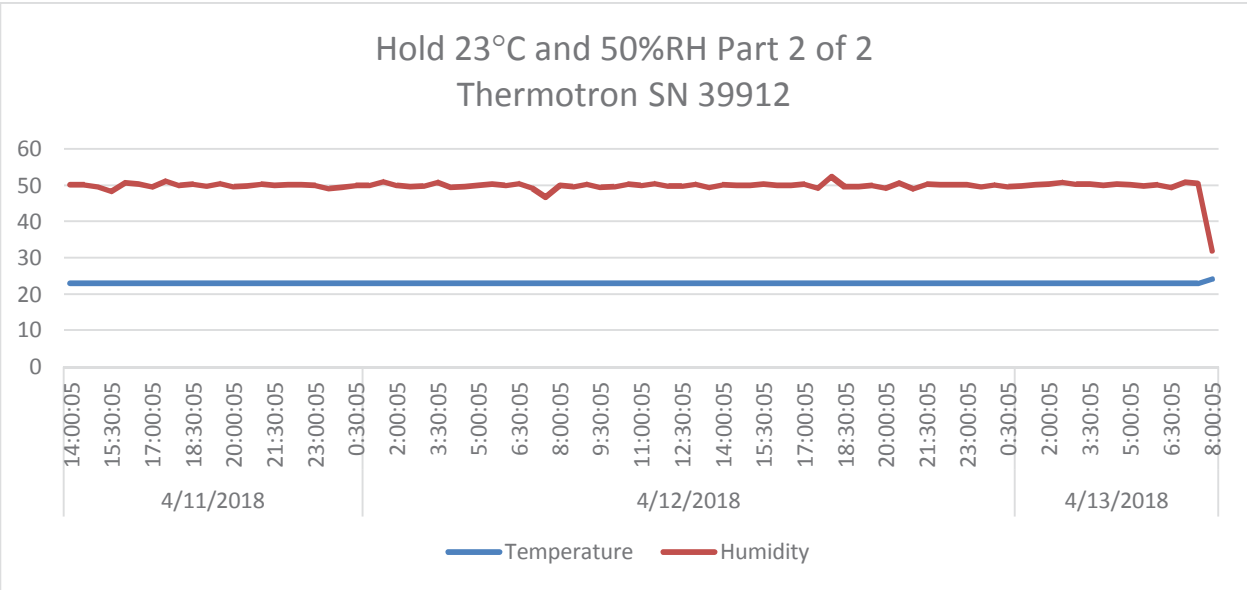
Date	Time	Temperature	Humidity
28-Mar	0:10	22.6	22.9
	0:58	22.6	22.8
	1:46	22.6	22.8
	2:34	22.6	22.7
	3:22	22.7	22.6
	4:10	22.8	22.5
	4:58	22.8	22.4
	5:46	22.8	22.4
	6:34	22.9	22.3
	7:22	22.9	22.3
	8:10	22.9	22.3
	8:58	22.6	23.6
	9:46	-40.1	37
	10:34	-40	42.7
	11:22	-40	42.9
	12:10	-40	42.6
	12:58	-40	42.2
	13:46	23.1	35.4
	14:34	23	36.6
	15:22	23	32.6
	16:10	23.1	26.4
	16:58	23	21.9
	17:46	23	19.1
	18:34	23	17
	19:22	23	15.6



Date	Time	Air Temp	Humidity
4/1/2018	8:00:02	19.9	96.8
	8:30:02	20	96.8
	9:00:02	20.1	96.6
	9:30:02	20.1	96.4
	10:00:02	20.1	96.1
	10:30:02	20.2	95.9
	11:00:02	55	90.6
	11:30:02	55	95.1
	12:00:02	55	95.1
	12:30:02	55	95
	13:00:02	55	94.9
	13:30:02	55	94.9
	14:00:02	55	95
	14:30:02	55	95
	15:00:02	55	95
	15:30:02	55	27.5
	16:00:02	55	18.5
	16:30:02	55	15.2
	17:00:02	55	14.9
	17:30:02	55	14.9
	18:00:02	55	15
4/2/2018	18:30:02	55	14.9
	19:00:02	55	14.8

	19:30:02	55	14.7
	20:00:02	55	14.7
	20:30:02	23	43.3
	21:00:02	23	47.4
	21:30:02	23	49.7
	22:00:02	23	50.1
	22:30:02	23	49.9
	23:00:02	23	49.9
	23:30:02	23	50.1
	0:00:02	23	50.1
	0:30:02	23	50.1
	1:00:02	23	50
	1:30:02	23	50
	2:00:02	23	50.2
	2:30:02	23	50
	3:00:02	23	50
	3:30:02	23	50.1
	4:00:02	23	50
	4:30:02	23	50.1
	5:00:02	23	50
	5:30:02	23	50
	6:00:02	23	48.9
	6:30:02	23	47.7
	7:00:02	23	49.5
	7:30:02	23	50.1
	8:00:02	23	49.5
	8:30:02	23	50.2
	9:00:02	23	49.6
	9:30:02	23	49.3
	10:00:02	23	50
	10:30:02	23	49.9
	11:00:02	23	49.9
	11:30:02	23	50
	12:00:02	23	52.2
	12:30:02	23	49.7
	13:00:02	23	49.8
	13:30:02	23	49.6
	14:00:02	23	51.3

	14:30:02	23	49.2
	15:00:02	23	50.3
	15:30:02	23	50.9
	16:00:02	23	49.9
	16:30:02	23	49.3
	17:00:02	23	50.2
	17:30:02	23	49.6
	18:00:02	23	48.8
4/3/2018	18:30:02	23	49.8
	19:00:02	23	49.8
	19:30:02	23	49.9
	20:00:02	23	50.2
	20:30:02	23	51.3
	21:00:02	23	49.7
	21:30:02	23	49.4
	22:00:02	23	50.7
	22:30:02	23	50.4
	23:00:02	23	50.1
	23:30:02	23	50
	0:00:02	23	50.3



Date	Time	Air Temp	Humidity
4/11/2018	14:00:05	23	50.1
	14:30:05	23	50.1
	15:00:05	23	49.5
	15:30:05	23	48.4
	16:00:05	23	50.7
	16:30:05	23	50.2
	17:00:05	23	49.6
	17:30:05	23	51.2
	18:00:05	23	49.9
	18:30:05	23	50.3
	19:00:05	23	49.8
	19:30:05	23	50.5
	20:00:05	23	49.5
	20:30:05	23	49.8
	21:00:05	23	50.2
	21:30:05	23	49.9
	22:00:05	23	50.1
	22:30:05	23	50.1
	23:00:05	23	50
	23:30:05	23	49.1
	0:00:05	23	49.4
	0:30:05	23	50
4/12/2018	1:00:05	23	49.9
	1:30:05	23	51
	2:00:05	23	50
	2:30:05	23	49.5
	3:00:05	23	49.8
	3:30:05	23	50.8
	4:00:05	23	49.4
	4:30:05	23	49.6
	5:00:05	23	49.9
	5:30:05	23	50.2
	6:00:05	23	50
	6:30:05	23	50.5
	7:00:05	23	49.3
	7:30:05	23	46.8

	8:00:05	23	49.9
	8:30:05	23	49.6
	9:00:05	23	50.3
	9:30:05	23	49.4
	10:00:05	23	49.5
	10:30:05	23	50.3
	11:00:05	23	50
	11:30:05	23	50.5
	12:00:05	23	49.8
	12:30:05	23	49.7
	13:00:05	23	50.2
	13:30:05	23	49.4
	14:00:05	23	50.1
	14:30:05	23	49.9
	15:00:05	23	50
	15:30:05	23	50.2
	16:00:05	23	49.9
	16:30:05	23	50
	17:00:05	23	50.3
	17:30:05	23	49.3
	18:00:05	23	52.4
	18:30:05	23	49.6
	19:00:05	23	49.5
	19:30:05	23	49.9
	20:00:05	23	49.3
	20:30:05	23	50.6
	21:00:05	23	49.1
	21:30:05	23	50.2
	22:00:05	23	50.1
	22:30:05	23	50.1
	23:00:05	23	50.1
	23:30:05	23	49.5
	0:00:05	23	50.1
	0:30:05	23	49.5
4/13/2018	1:00:05	23	49.8
	1:30:05	23	50.1
	2:00:05	23	50.3
	2:30:05	23	50.8

	3:00:05	23	50.3
	3:30:05	23	50.2
	4:00:05	23	50
	4:30:05	23	50.2
	5:00:05	23	50.1
	5:30:05	23	49.8
	6:00:05	23	50.1
	6:30:05	23	49.4
	7:00:05	23	50.8
	7:30:05	23	50.4
	8:00:05	24.1	32

12. APPENDIX IV – SHIP CONDITIONING

12. APPENDIX III – SHIPPING TEST

Preconditioning:

Start Date: 3-28-2018 Chamber Number: 01095 and 01514

Completion Date: 4-13-2018 Last Calibration: 5-23-2017 and 2-20-2018

Signature/Date: Paul Valpreda 4-17-2018 Calibration due: 5-31-2018 and 2-28-2019

Drop Test:

Catalog Number: ME725MIC Weight: 3.5 lbs. Drop Height: 15"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Top	Face 1	PV 4-17-18
2	Edge	Edge 5-3	PV 4-17-18
3	Edge	Edge 6-3	PV 4-17-18
4	Corner	Corner 2-3-5	PV 4-17-18
5	Corner	Corner 4-3-6	PV 4-17-18
6	Bottom	Face 3	PV 4-17-18

Comments: All six identical boxes passed. - PV

Signature: Paul Valpreda Date: 4-17-2018

Compression Test: All six identical boxes passed. - PV

Catalog Number: ME725MIC Pounds Force: 210

Comments: All passed. - PV

Signature: Paul Valpreda Date: 4-17-2018

Appendix III Continued
Shipping Test Log Sheet

Vibration:

Low Frequency, 40 minutes, Initials: PV

High frequency 10 minutes, Initials: PV

Completion Date: 4-17-2018

Signature: Paul Valpreda Date: 4-17-2018

Concentrated Impact Test:

Completion Date: 4-17-2018

Signature: Paul Valpreda Date: 4-17-2018

Second Drop Test:

Catalog Number: ME725MIC Weight: 3.5 lbs. Drop Height: 15"+30"

Drop Sequence	Orientation	Specific face, edge or corner	Initials/Date
1	Edge	Edge 4-6	PV 4-17-18
2	Face	Face 4	PV 4-17-18
3	Face	Face 6	PV 4-17-18
4	Corner	Corner 2-1-5	PV 4-17-18
5	Edge	Edge 2-1	PV 4-17-18
6	Bottom	Face 3, Increase height to 30 inches.	PV 4-17-18

Comments:

Signature: Paul Valpreda Date: 4-17-2018

13. APPENDIX V – BUBBLE LEAK TESTING

13. APPENDIX IV – BUBBLE LEAK TEST

Catalog # ME725M1C Lot # 5170323

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

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

Signature: Paul Valpreda Date: 4-18-2018

14. APPENDIX VI – DYE TESTING

14. APPENDIX V – DYE PENETRATION TEST

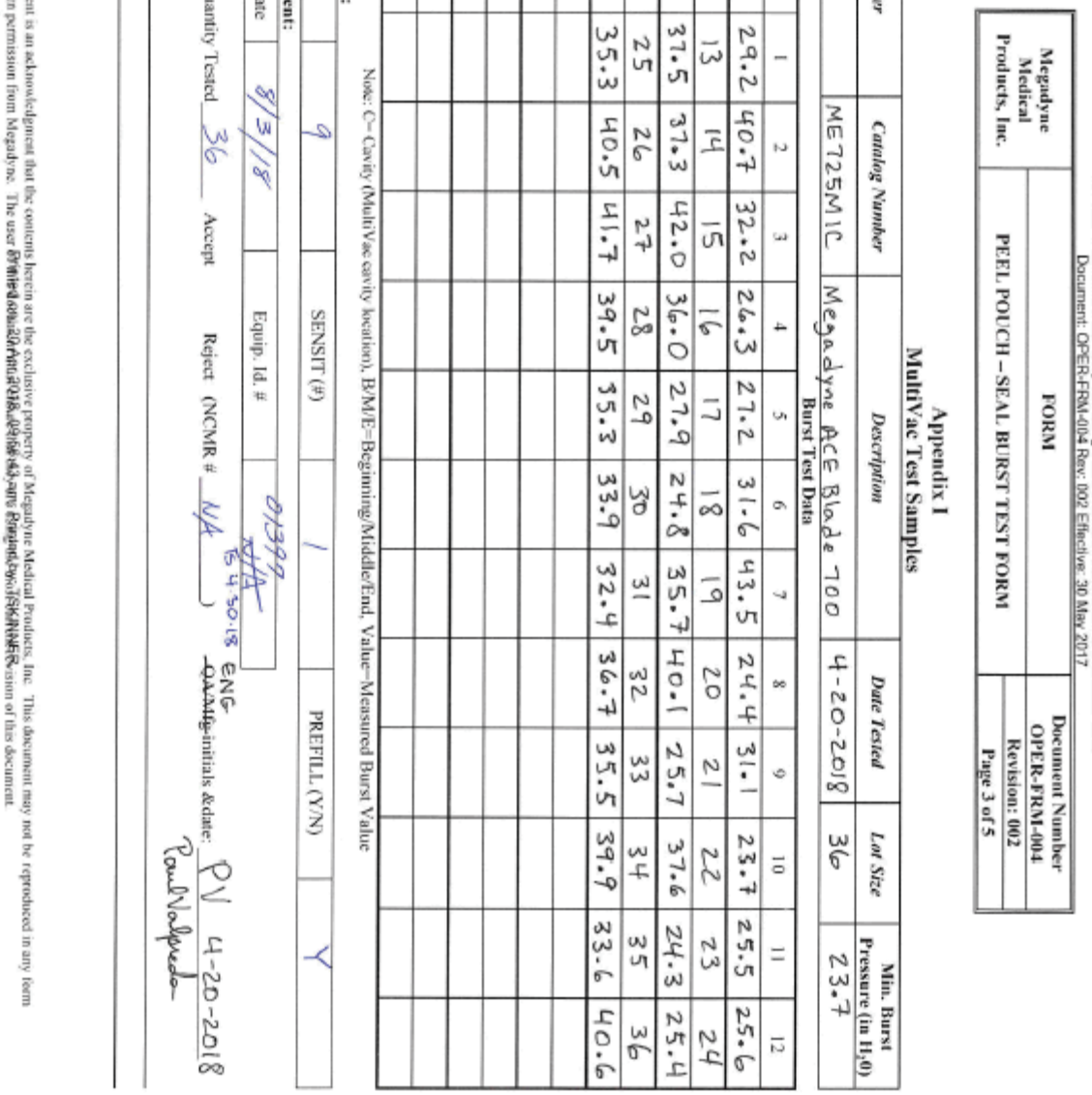
Catalog # ME725M1C Lot # S170323

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

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

Signature: Paul Valprode Date: 4-23-2018

15. APPENDIX VII – BURST TESTING



The user must ensure that they are using the correct/current revision of this document.
Document: OPER-FRM-004 Rev: 002 Effective: 30 May 2017

Megadyne Medical Products, Inc.	FORM	Document Number OPER-FRM-004
	PEEL POUCH – SEAL BURST TEST FORM	Revision: 002
		Page 3 of 5

Appendix I
MultiVac Test Samples

Lot Number	Catalog Number	Description	Date Tested	Lot Size	Min. Burst Pressure (in H_2O)
S170323	ME725M1C	Megadyne ACE Blade 700	4-20-2018	36	23.7

Burst Test Data

B/M/E	C #	1	2	3	4	5	6	7	8	9	10	11	12
	Value	29.2	40.7	32.2	26.3	27.2	31.6	43.5	24.4	31.1	23.7	25.5	25.6
B/M/E	C #	13	14	15	16	17	18	19	20	21	22	23	24
	Value	37.5	37.3	42.0	36.0	27.9	24.8	35.7	40.1	25.7	37.6	24.3	25.4
B/M/E	C #	25	26	27	28	29	30	31	32	33	34	35	36
	Value	35.3	40.5	41.7	39.5	35.3	33.9	32.4	36.7	35.5	39.9	33.6	40.6
B/M/E	C #												
	Value												
B/M/E	C #												
	Value												
B/M/E	C #												
	Value												

Note: C=Cavity (MultiVac cavity location), B/M/E=Beginning/Middle/End, Value=Measured Burst Value

Burst Test Settings:

FLOW (#)	SENSIT (#)		PREFILL (Y/N)
9	1		Y

Burst Test Equipment:

Calibration Due Date	Equip. Id. #
8/3/18	013992

Lot disposition: Quantity Tested 36 Accept Reject (NCMR # N/A) QA/RE initials &date: PV 4-20-2018

Comments: Paul Valladares

Possession of this document is an acknowledgment that the contents herein are the exclusive property of Megadyne Medical Products, Inc. This document may not be reproduced in any form whatsoever without written permission from Megadyne. The user of this document must ensure that they are using the most current revision of this document.

16. APPENDIX VIII – MINIMUM SEAL WIDTH TESTING

15. APPENDIX VI – MINIMUM SEAL WIDTH TESTING

Catalog # ME725MIC Lot # 5170323

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

- Burst Side

Signature: Paul Valpreda Date: 4-27-2018

- Burst Side

17. APPENDIX IX – PRODUCT DAMAGE INSPECTION

16. APPENDIX VII – PRODUCT DAMAGE INSPECTION

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

Catalog # ME725M1C	Pass	Fail
Damage None visible	36	ø

Comments:
All packages looked good. Only one had a very minimal amount of smeared text. The product looked good as well with no visible damage.

Signature: Paul Valprede Date: 4-17-2018

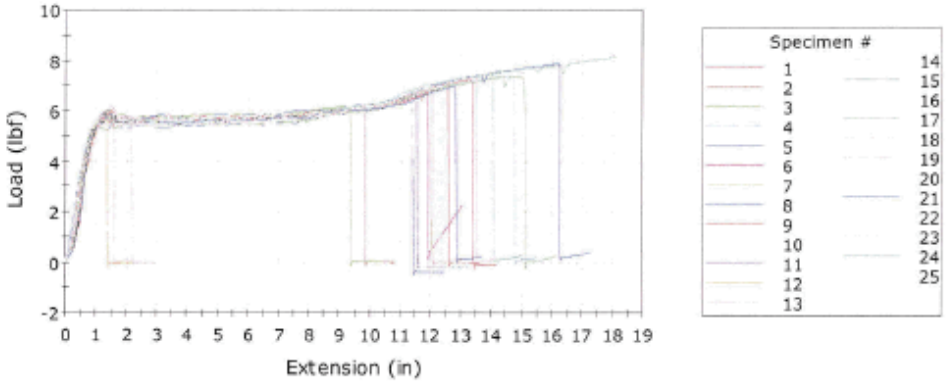
18. APPENDIX X – TUBING STRENGTH TESTING

Tuesday, May 01, 2018 ME725M1C LOT S170323 Tubing Strength.is_tens

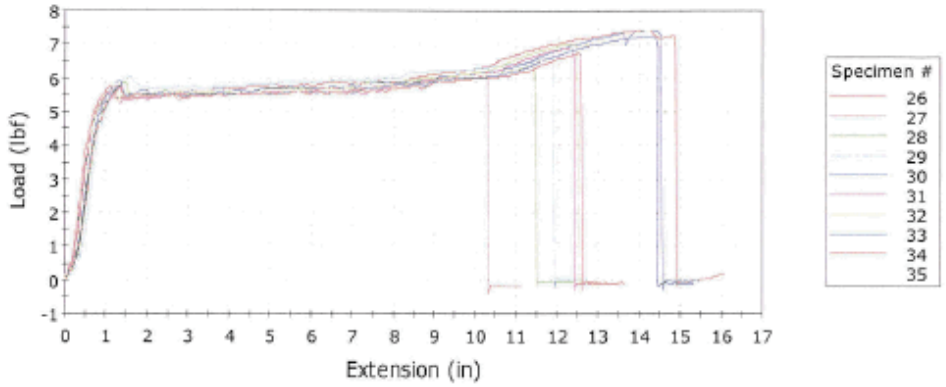
Testing performed by Paul Valpreda on 5/1/2018

Paul Valpreda 5-1-2018

Specimen 1 to 25



Specimen 26 to 35



	Specimen label	Maximum Load (lbf)	Load at Break (Standard) (lbf)	Peak to peak
1	Sample 1	> 7.24	< -0.07	> 7.31
2	Sample 2	> 6.20	> 0.01	> 6.19
3	Sample 3	> 6.17	> 0.02	> 6.15
4	Sample 4	> 7.39	> 0.20	> 7.20
5	Sample 5	> 7.90	> 0.41	> 7.49
6	Sample 6	> 6.69	> 2.24	> 4.46
7	Sample 7	> 6.87	< -0.18	> 7.04

Page 1 of 3

Tuesday, May 01, 2018

ME725M1C LOT S170323 Tubing Strength.is_tens

	Specimen label	Maximum Load (lbf)	Load at Break (Standard) (lbf)	Peak to peak
8	Sample 8	> 6.54	< -0.36	> 6.90
9	Sample 9	> 6.92	< -0.01	> 6.93
10	Sample 10	> 6.51	< -0.27	> 6.77
11	Sample 11	> 6.67	< -0.14	> 6.81
12	Sample 12	> 5.66	< -0.02	> 5.68
13	Sample 13	> 6.15	< -0.05	> 6.20
14	Sample 14	> 6.94	< -0.18	> 7.12
15	Sample 15	> 8.13	> 8.12	> 0.00
16	Sample 16	> 6.98	< -0.20	> 7.18
17	Sample 17	> 7.40	> 0.26	> 7.14
18	Sample 18	> 5.95	> 0.01	> 5.94
19	Sample 19	> 6.84	> 0.19	> 6.65
20	Sample 20	> 6.54	< -0.18	> 6.72
21	Sample 21	> 6.96	> 0.25	> 6.71
22	Sample 22	> 7.00	< -0.06	> 7.06
23	Sample 23	> 7.36	> 0.17	> 7.19
24	Sample 24	> 7.50	> 0.27	> 7.23
25	Sample 25	> 6.41	< -0.15	> 6.56
26	Sample 26	> 7.44	> 0.19	> 7.25
27	Sample 27	> 6.06	< -0.18	> 6.23
28	Sample 28	> 6.37	< -0.05	> 6.43
29	Sample 29	> 6.60	> 0.04	> 6.56
30	Sample 30	> 7.42	< -0.04	> 7.46
31	Sample 31	> 6.87	< -0.12	> 6.99
32	Sample 32	> 7.01	< -0.09	> 7.09
33	Sample 33	> 7.25	< -0.09	> 7.34
34	Sample 34	> 6.73	< -0.08	> 6.81
35	Sample 35	> 7.48	> 0.33	> 7.15
Maximum		8.13	8.12	7.49
Mean		6.86	0.29	6.57
Minimum		5.66	-0.36	0.00
Standard Deviation		0.55779	1.42560	1.28906

	Description
1	Tubing came off connector - lower
2	Tubing came off connector - upper
3	Tubing came off connector - upper
4	Tubing broke just above lower connection
5	Tubing broke just above lower connection
6	Tubing broke just above lower connection
7	Tubing came off connector - upper
8	Tubing came off connector - upper
9	Tubing came off connector - upper
10	Tubing came off connector - upper
11	Tubing came off connector - upper
12	Tubing came off connector - upper
13	Tubing came off connector - upper
14	Tubing came off connector - lower
15	Tubing came off connector - lower
16	Tubing came off connector - lower
17	Tubing broke just above lower connection
18	Tubing came off connector - upper
19	Tubing broke just above lower connection
20	Tubing broke just above lower connection
21	Tubing broke just below upper connection
22	Tubing came off connector - upper
23	Tubing broke just above lower connection
24	Tubing broke just above lower connection
25	Tubing came off connector - lower
26	Tubing broke just above lower connection
27	Tubing came off connector - lower

Page 2 of 3

Tuesday, May 01, 2018

ME725M1C LOT S170323 Tubing Strength.is_tens

	Description
28	Tubing came off connector - upper
29	Tubing came off connector - upper
30	Tubing came off connector - lower
31	Tubing came off connector - lower
32	Tubing came off connector - lower
33	Tubing came off connector - lower
34	Tubing came off connector - upper
35	Tubing broke just above lower connection
Maximum	
Mean	
Minimum	
Standard Deviation	

Page 3 of 3