MEGADYNE® Est. 1985
The Electrosurgical Authority®

DOCUMENT NUMBER: ENG-PRT-239

DOCUMENT TITLE: Extension Nozzle

DOCUMENT NOTES:

Initial release into MasterControl

Document Information

Revision: 002	Vault: MEG-Rel
Status: Release	Document Type: ENG-PRT

Date Information

Effective Date: 08 Dec 2014	Expiration Date:
Release Date: 08 Dec 2014	Next Review Date:

Control Information

Author: PBORGMEIER	Owner: ENG-APPR
Previous Number: 1150770-10	Change Number: 2014-ENG-DCO-058

Signature Manifest

Document Number: ENG-PRT-239 **Revision:** 002
Title: Extension Nozzle

All dates and times are in Mountain Standard Time.

Zip Pen 3 Year Age Test

Change Request

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		30 Oct 2014, 09:12:40 AM	Approved

Collaboration

Name/Signature	Title	Date	Meaning/Reason
Jill Skoczen (JTRASAMAR)	Ethicon Marketing	10 Nov 2014, 11:30:08 AM	Complete
Dave Shimkus (DSHIMKUS)		10 Nov 2014, 04:00:14 PM	Complete
Darcy Greep (DGREEP)		11 Nov 2014, 12:19:01 PM	Complete
Julie Barber (JBARBER)		11 Nov 2014, 05:37:03 PM	Complete
Mark Glassett (MGLASSETT)		12 Nov 2014, 04:23:30 PM	Complete
Tara Rogers (TROGERS)		14 Nov 2014, 11:01:22 AM	Complete
Balaji Sudabattula (BSUDABATTULA)		20 Nov 2014, 09:10:53 AM	Complete
Ronda Magneson (RMAGNESON)	RA DIrector	21 Nov 2014, 03:03:43 PM	Complete

Document Review

Name/Signature	Title	Date	Meaning/Reason
Mark Glassett (MGLASSETT)		01 Dec 2014, 01:53:21 PM	Complete
Lucy Richards (LRICHARDS)	Document Specialist	02 Dec 2014, 09:58:08 AM	Complete

RA-Approval

Name/Signature	Title	Date	Meaning/Reason
Ronda Magneson (RMAGNESON)	RA DIrector	08 Dec 2014, 10:09:29 AM	Approved

QA-Approval

Name/Signature	Title	Date	Meaning/Reason
Balaji Sudabattula (BSUDABATTULA)		03 Dec 2014, 03:29:45 PM	Approved

ENG-Approval

Name/Signature	Title	Date	Meaning/Reason
Paul Borgmeier (PBORGMEIER)		04 Dec 2014, 04:06:52 PM	Approved

Training Review

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)	Document Specialist	08 Dec 2014, 10:33:37 AM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)	Document Specialist	08 Dec 2014, 10:33:49 AM	Approved

Authored By: Mark Glassett

TABLE OF CONTENTS **Page**

1. REFERENCES

IEC 60601-2-2:2009	Medical Electrical Equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
XENG-DMR-012	Device Master Record, Smoke Evacuation Pencil and Accessories
ISO 11607-01	Packaging for terminally sterilized devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

ASTM F2096	Standard test method for detecting gross leaks in porous medical packaging by internal pressurization (Bubble test)
ENG-WI-076	Operation of Vibration Table and Drop Test Equipment
ENG-RMF-045	Risk Analysis, Smoke Evacuation Accessories
ENG-PRT-049	Accelerated Aging of Packaged Product
QA-SOP-012	Sampling and Statistical Techniques
ENG-WI-009	Real Time Age Work Instruction

2. APPENDIX

I. **Shipping Test Log Sheet**
II. **Print Clear and Legible Log Sheet**
III. **Bubble Leak Test Log Sheet**
IV. **Flow Test Log Sheet**

3. SCOPE

This protocol pertains to the Zip Pen Extension Nozzles Catalog numbers 2540 and 2560.

4. PURPOSE

The purpose of this test protocol is to specify testing required on the Extension Nozzles to show compliance with IEC 60601-2-2: 2009, ISO 11607-1 and DMR XENG-DMR-012.

5. BACKGROUND

The Zip Pen and Extension Nozzles are a new design of smoke evacuation pencil for Megadyne. The Zip Pen testing is addressed in other protocols. This protocol is specifically for the Extension Nozzles. The Extension Nozzles are attachments to the Zip Pen for use when extended length electrodes are used.

6. DEFINITIONS AND ACRONYMS

ESU	Electrosurgical Unit

7. APPARATUS

7.1.1. Instron Force Tester

7.1.2. Calibrated TSI 4000 Series Flow Meter

7.1.3. Mega Vac Plus Smoke Evacuator

7.1.4. Environmental Chamber

7.1.5. LAB AccuDrop 160

7.1.6. Martin Vibration Systems Vibration Table

7.1.7. Metal shim 0.06 in thick, approximately 2 in wide

8. RISK ASSESSMENT

8.1. A review of the Risk Analysis Document ENG-RMF-045 (Risk Analysis, Smoke Evacuation Accessories) identifies the risks associated with Extension Nozzles. The highest severity rating is 10 attributable to compromised sterile barrier. The following is a list of failure modes, causes, mitigations and verifications.

Failure Mode	Cause	Mitigation	Verification
Hole in package, sterile barrier broken	Ineffective packaging for this application	Material selection, Process control, labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test, Test Report 1150770-01
Hole in package, sterile barrier broken	Damaged during processing, wrong material thickness	Material selection, Process control, labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test, Test Report 1150770-01
Product damaged	Ineffective packaging for this application	Labeling includes caution to discard package if pouch is damaged	ASTM D4169 shipping test, Test Report 1150770-01

Incorrect Electrode to Nozzle size	User error, not following IFU	Put compatibility statement in IFU	IFU 3000189-01
Nozzle loose or falls off	Nozzle not correctly installed or fully installed	Visual and audible confirmation of correct placement	Test Report 1150770-01
Installed upside down or incorrectly	Nozzle not correctly installed or fully installed	Visual and audible confirmation of correct placement	Test Report 1150770-01

9. EXPERIMENT DESIGN / SAMPLE SIZE JUSTIFICATION:

9.1. Prior to testing, all test samples will be sterilized with Gamma Irradiation to a minimum dose of 50 kGy.

9.2. After sterilization, samples will be subjected to accelerated aging. The aging temperature will be 55°C. The time for aging to simulate 3 years shelf life is 111 days.

9.3. All samples will be subjected to a shipping and storage cycle. This cycle includes temperatures from -40°C to 70°C and humidity's from 15% to 95%. This temperature and humidity cycling will be documented in the test report.

9.4. For variables data, a sample size of 30 will be used for this test protocol. The use of 30 samples has statistical significance as identified in QA-SOP-012, Sampling and Statistical Techniques. Where there is variables data that is being compared to control samples, the sample size will be 11. This number is adequate for performing a 'T' test comparison of means.

9.5. For Pass/Fail tests, 30 samples will be used. The use of 30 samples has statistical significance as identified in QA-SOP-012, Sampling and Statistical Techniques.

9.6. A summary of the experimental design is as follows:

Test Description	Test Type	Sterile Samples 2540 Nozzle	Sterile Samples 2560 Nozzle
Shipping and Storage	Pass/Fail	30 ea.	30 ea.
Flow Rate	Measurement	11 ea. [1]	11 ea. [1]
Retention Force	Measurement	15 ea. [2]	15 ea. [2]
Nozzle Pry force	Measurement	15 ea. [2]	15 ea. [2]

[1] Eleven samples plus 11 control samples
[2] Sample set combined between the two catalog numbers

9.1. Tests shall be performed under typical warehouse conditions. Typical warehouse conditions are:

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

Note that these conditions are a wider range than is called out in ASTM D4169. This deviation from standards is considered acceptable because actual warehouse, transport and storage conditions will vary greatly from the range listed in the standard.

9.2. The ASTM D4169 standard requires the choice of an assurance level. For this test assurance level II will be used. This is the recommended starting level in the standard.

9.3. The schedule for this test will follow Distribution Cycle 3. This cycle has six elements performed in the following order; Pre-conditioning, Handling, Vehicle Stacking, Loose load Vibration, Vehicle Vibration, and Handling. This cycle is followed by evaluation of the packaging and the product.

10. ACCELERATED AGING

10.1. These products will be labeled with a three year expiration date. The products used for testing per this protocol have been subjected to accelerated aging to simulate three years. The aging temperature is 55°C and the aging time is a minimum of 111 days. Refer to ENG-PRT-049 for the time calculation at this temperature. Accelerated aging is used to show package and product stability for product launch. Product will be submitted for real time age per Megadyne Work Instruction ENG-WI-009 for real time shelf life verification.

11. SHIPPING AND STORAGE CYCLE AND PRECONDITIONING

11.1. Pre-Conditioning prior to testing will follow the temperature and humidity schedule listed below. This test range exceeds the shipping and storage range listed on the product to insure that the product label is justified.

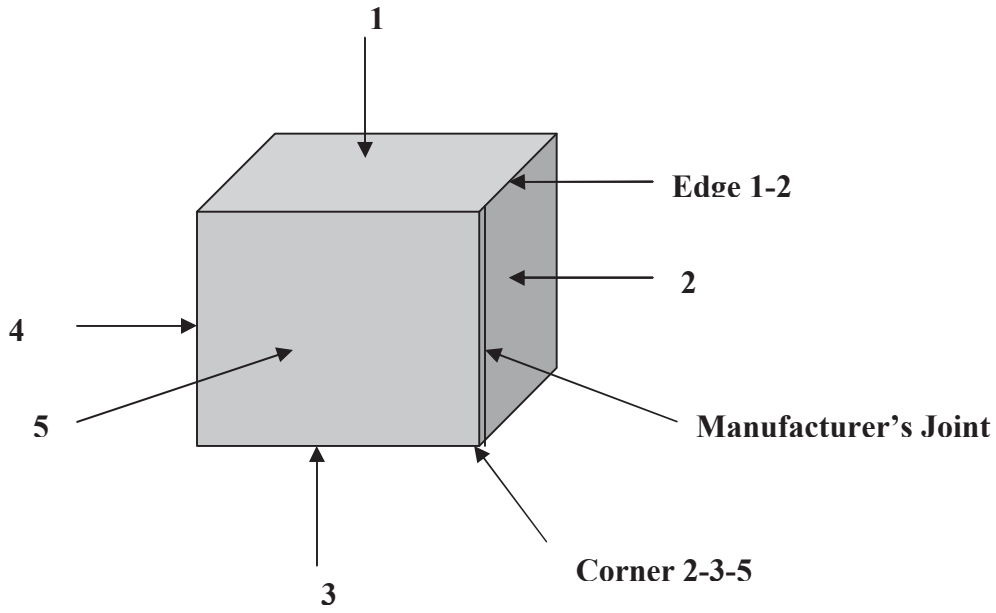
CONDITIONS	DURATION
Transition from ambient to -40°C	Based on Chamber Capability
Hold -40°C no humidity control	4 hours
Transition from -40°C to 70°C	Set time to 0:00 and set the standard deviation to 1°C
Transition from 70°C to 70°C and 95%RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°C and 95%RH	4 hours
Transition from 70°C and 95% RH to 70°C and 15% RH	Set time to 0:00 and set the standard deviation to 1°C and 2% RH
Hold 70°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

12. SHIPPING TEST

12.1. For the shipping portion of the protocol, divide the samples as follows and test each configuration:

CONFIGURATION	QUANTITY
Box packed by shipping department	20 ea. 2540
Box packed by shipping department	10 ea. 2540, 30 ea. 2560

12.2. Prepare each configuration shown above for the shipping test. Using a permanent marker and identify the faces of each shipping box according to the following diagram.



12.3. Record the gross weight (wt.) of each shipper box containing product in pounds on the data sheet in Appendix I.

12.4. Record the length, width, and height (L x W x H) in inches of each shipper box on the data sheet in Appendix I.

12.5. Perform the Handling test (drop test) as follows.

12.5.1. The required drop height from ASTM D4169 paragraph 10.2.3 using assurance level II is 15 inches for packages from 0 to 20 pounds.

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

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

4	Corner	Corner 2-3-5
5	Corner	Corner 4-3-6
6	Bottom	Face 3

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

12.6. Perform the compression test on the shipping box only (eight unit boxes in a case). Note that the case box is equivalent for the 2540 and 2560 products. The reason for testing only the case box is that the unit box is small and will never be stacked individually during transport or storage. For the compression test, use ASTM D4169 paragraph 11.3 for warehouse stacking made up of identical shipping units. For this test, the parameters for assurance level III will be applied. The justification for this adjustment is that the Extension Nozzle unit boxes will be in a case box and shipped from the supplier in large Gaylord boxes. The Gaylord box itself carries a portion of the load when they are stacked for overseas shipment. The maximum stack is four boxes high (7.5 inches per box) in each of two Gaylord's, therefore a height of 60 inches will be used in the formula. The formula for the weight of the compression is as follows:

$L = M \times Jx((H-h)/h)xF$

Where the mass M =5 lbs., J = 1 lbf/lb, H=60 inches, and h= 7.5 inches and F = 3.0, a factor to account for the combined effect of the individual factors taken from paragraph 11.2 of ASTM D4169.

Catalog Number	Shipper Weight (lbs.)	Stack Height (in.)	Compression (lbs.)
Two unit boxes	1	72	55
Four unit boxes	2	72	60

Note: Shipper weight is the actual shipper box weight rounded up to the nearest pound.

12.6.1. Place *Face 3* of the shipper box on the ground.

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

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

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

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

12.6.6. Record information on the data sheet in Appendix I.

12.7. Following the compression test perform the Loose Load Vibration test, record information in Appendix I.

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

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

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

12.7.4. Check the frequency using the shim.

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

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

12.7.6. After 40 minutes of Loose Load Vibration, increase the frequency for the Vehicle vibration.

12.7.7. Check the frequency using the shim.

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

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

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

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

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

12.1. Inspect the exterior of each box and note any damage.

12.2. Following the shipping test, evaluate the packaging and product as listed below in paragraphs 13 and 14.

13. PRINT CLEAR AND LEGIBLE

13.1. Remove 3 unit boxes of each catalog number from the overshipper. Open each unit box and remove the pouches one at a time from the unit box. Visually inspect each pouch for clarity of print on the label. Also inspect the lot number and expiration date on the label for clarity of print. Record pass/fail results in Appendix II.

13.2. All visual inspections are to be performed using no magnification, under normal, diffused (indirect) fluorescent lighting, at a distance of 16 - 18 inches, with a maximum of 5-second time limit for visual inspection.

14. BUBBLE LEAK TEST

14.1. Select 30 pouches from each catalog number. Number each pouch with a unique identifier.

14.2. Perform the bubble leak test per ASTM F2096 in a plastic tub or sink that is deep enough to submerge the entire pouch.

14.3. Test the pouches one at a time. Pierce the pouch on the clear poly side with the test needle. It is acceptable to reinforce the puncture area with a piece of clear tape if needed. Submerge the pouch under water. Pump the pouch up and look for bubbles. Record pass/fail results in Appendix III.

14.4. If bubbles are observed, circle the area with a marker and set the pouch aside for evaluation by Engineering.

15. FLOW RATE

15.1. For the flow rate test, obtain 11 samples of Zip Pen 2525-10, 11 each electrodes 0014 and 11 each electrodes 0014A. Use 11 ea. samples of Extension Nozzles 2540 and 2560 from the above testing. Also obtain a sample of 11 ea. REF 2110-10 for controls.

15.2. Number each Extension Nozzles sample and each 2110-10 sample with unique identification numbers.

15.3. Record the lot number of the pencils and electrodes for the test on data collection sheet in Appendix IV.

15.4. Use a current MegaVac Plus Smoke Evacuation device with a new filter. Record the MegaVac Serial number on the data Sheet in Appendix IV

15.5. Use the calibrated TSI 4000 Series flow meter attached to the MegaVac filter. Record the identification number, last calibration date, and calibration due date of the flow meter on the data sheet in Appendix IV

15.6. For the test samples, attach the 2525-10 Zip Pen to the flow meter and lay the tubing out on the table. Be sure that there are no kinks in the tubing. Attach the flow meter to the smoke filter on the smoke evacuation device.

15.7. Attach the Extension nozzle to the 2525-10 with the appropriate electrode in place. Use the 0014A with the 2540 and the 0014 with the 2560. Remove the cap from the electrode. .

15.8. For the control samples use the 2110-10 Pencil with the nozzle extended to the approximate length to match the 2540 or 2560. Attach the proximal connector to the flow meter and lay the tubing out on the table. Be sure that there are no kinks in the tubing. Attach the flow meter to the smoke evacuation filter on the smoke evacuation device.

15.9. Set the MegaVac to maximum flow in Open mode. Record the settings on the data sheet.

15.10. Activate the MegaVac for 5 seconds.

15.11. Observe the maximum reading on the flow meter and record the value on the data collection sheet in Appendix IV.

15.12. Repeat the flow test for each of the Extension Nozzles and 2110-10 control samples. Record the values on the data sheet in Appendix IV.

16. NOZZLE RETENTION FORCE TEST

16.1. Obtain a sample size of 15 each 2540 and 2560 Extension Nozzles and 30 each 2525-10 Zip Pen.

16.2. Number each Extension Nozzle sample with unique identification numbers as required.

16.3. Use the 100 lb. load cell in the Instron.

16.4. Install the Extension Nozzle onto the Zip Pen without an electrode.

16.5. Place an Engineering supplied holding fixture in the lower jaws of the Instron carefully aligning it vertically.

16.6. Place a sample pencil vertically in the holding fixture.

16.7. Place a steel pin or other suitable rod shaped part in the nozzle tip to prevent full collapse of the nozzle under pressure from the clamp.

16.8. Lower the upper jaws of the Instron so that they can grasp the initial 0.5" of the Extension Nozzle, actuate the jaws to grasp the Extension Nozzle.

16.9. Program the Instron for a speed of 7.87 inches per minute (200 mm per minute).

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

16.11. Press Start to perform the test to measure the removal force.

16.12. Repeat this test for each of the 30 samples.

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

17. FIT WITH HOLSTER

18. NOZZLE PRY FORCE TEST

18.1. Obtain 15 samples of each Extension Nozzle 2540 and 2560. Use of the samples from previous tests is acceptable as long as they haven't been damaged. Note that this test itself is a destructive test and therefore needs to be done last.

18.2. Install the 100 pound load cell in the Instron. Set the cross head speed to 12.0 inches per minute.

18.3. Insert a test pin suitable for Nozzle force testing in the load cell mounting socket.

18.4. Use Engineering supplied holding fixture in the vise. Insert the Zip Pen with the Extension Nozzle attached in the holding fixture with the Nozzle distal end directly below the test pin in the load cell.

18.5. Identify the sample in the Instron test software.

18.6. Balance the load to zero the Instron.

18.7. Apply a force of up to 20 pounds to the tip of the E-Z clear Extension Nozzle. Apply the force until either the Extension Nozzle or the E-Z Clear Pencil breaks or the 20 pound load is reached.

18.8. Repeat the above test for the remaining samples.

18.9. Provide the test data to Engineering for use in the Test Report.

19. ACCEPTANCE CRITERIA

19.1. Shipping and Storage

19.1.1. The Extension Nozzle boxes shall not break open during drop tests or compression test

19.1.2. The print of the labels including the lot number and expiration date shall be clear and legible after the shipping simulation.

19.1.3. There shall be no leaks in any of the pouches during the bubble leak test.

19.2. Flow Rate

19.2.1. The flow rate of the Zip Pen with the Extension Nozzle shall be equal to or greater than the flow rate of the 2110-10 with the electrode extended as determined by the “t test”.

19.3. Nozzle Retention Force

19.3.1. The Nozzle retention force does not have a specification at this time. The nozzle removal force is being characterized to establish this specification. Therefore, Marketing and Engineering judgment will be used to determine if the retention force is adequate and this will be reported in the test report.

19.4. Nozzle Pry Force

19.4.1. The nozzle pry force test is being performed to determine if the Zip Pen has adequate mechanical strength with the nozzle attached. Adequate strength is 10 pounds. The Zip Pen with Extension Nozzle shall not break or the snap features come unsnapped before 10 pounds is applied.

19.4.2. The force is being applied up to 20 pounds to determine where breakage or disassembly actually occurs.

20. REVISION HISTORY

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A		Initial release	2014 May 15
001	N/A	Released to Master control, No change	2014 May 15
See Master Control info card for revision history.			

Appendix I:
SHIPPING TEST LOG SHEET

Preconditioning:

Start Date: _____ Chamber Number:_____

Completion Date: _____ Last Calibration:_____

Signature/Date: _____ Calibration due:_____

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

Catalog 2540 Lot _____ LxWxH _____Weight: _____

Catalog 2560 Lot _____ LxWxH _____Weight: _____

Case Box LxWxH _____Weight: _____

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

Comments: _____

Signature: _____ Date: _____

Compression Test: Perform compression test on the case box only

Catalog 2540 and 2560 Pounds Force _____

Pass / Fail Comments: _____

Signature: _____ Date: _____

Vibration Test: Perform vibration on all three configurations

Low Frequency, 40 minutes, Initials_____ High frequency 10 minutes, Initials _____

Completion Date: _____

Signature: _____ Date: _____

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

Comments: _____

Signature: _____ Date: _____

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		
Lot Number Print		

Comments:_____

_____

Catalog 2560	Pass	Fail
Pouch Print		
Lot Number Print		

Comments:_____

_____

Test Performed by: _____ Date: _____

Megadyne Medical Products, Inc.	TEST PROTOCOL	*Document Number* ENG-PRT-239
	Extension Nozzle	Revision: 002
		Page 19 of 22

Appendix III

BUBBLE LEAK TEST

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

Test Performed by: _____ Date: _____

Appendix III

BUBBLE LEAK TEST (Continued)

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

Test Performed by: _____ Date: _____

Appendix IV

FLOW RATE TEST

Mega Vac Serial Number: _____

Flow Meter ID#: _____ **Last Calibration Date:** _____
Calibration Due Date: _____

Catalog 2540	Lot #	Catalog 2560	Lot #
Electrode 0014A	Lot #	Electrode 0014A	Lot #

Sample #	Flow Rate	Sample #	Flow Rate
1-14A		1-14	
2-14A		2-14	
3-14A		3-14	
4-14A		4-14	
5-14A		5-14	
6-14A		6-14	
7-14A		7-14	
8-14A		8-14	
9-14A		9-14	
10-14A		10-14	
11-14A		11-14	

Appendix IV (Continued)

CONTROL SAMPLES

Catalog 2110-10	Lot #		
Sample #	**Flow Rate**	**Sample #**	**Flow Rate**
1-C		7-C	
2-C		8-C	
3-C		9-C	
4-C		10-C	
5-C		11-C	
6-C			

Test Performed by: _____ Date: _____