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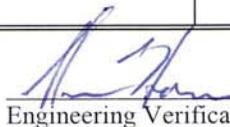
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Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A Effective Date: 2014 APR 07 Page 1 of 17



4/4/14

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TABLE OF CONTENTS

1.	REFERENCES	1
2.	SCOPE.....	1
3.	PURPOSE.....	1
4.	RISK ANALYSIS	2
5.	EXPERIMENT DESIGN AND SAMPLE SIZE JUSTIFICATION	3
6.	ULPA FILTER TESTING.....	4
7.	CARBON / MUFFLER TESTING	10
8.	ULPA FILTER ACCEPTANCE CRITERIA.....	10
9.	CARBON / MUFFLER ULPA FILTER ACCEPTANCE CRITERIA	11
10.	REVISION HISTORY	11

1. References

- 1150095-01 Rev B IEC Shipping/Storage Conditions
- ASTM D4169-05 Performance testing of shipping containers and systems
- 1300020-01 Smoke Evacuation Risk Analysis
- ICM-470-9024 IFU for Mega Vac Plus Smoke Evacuation Unit

2. Scope

- Catalog # 2211 – ULPA Filter & Fluid Trap– Test Group
- Catalog # 2210 – IC Med ULPA Filter – Control Group
- Catalog # 2220 – Carbon/Muffler (Vendor PN DF-0) – Test Group

3. Purpose

- 3.1. The purpose of this test is to qualify Catalog # 2211 ULPA Filter & Fluid trap for use with the Mega Vac™ and Mega Vac Plus™ Smoke evaluation system. This testing is intended to show that Catalog #2211 is equivalent to or better than the current # 2210.

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Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 2 of 17

- 3.2. The #2220 Carbon/Muffler is expected to be purchased from the same point source, Koby Filter, that our current vendor purchases these units from. Since this is the same filter/muffler, the only testing associated with this product is ship testing, as the box size will be different from the current shipping method.

4. Risk Analysis

This filter qualification gives engineering the opportunity to review current requirements.

4.1. ULPA Filter Review of 1300020-01 Rev E Risk Analysis

- 4.1.1. Item #54 & 55 – ULPA Filter connection to Smoke Box
- 4.1.2. Item #56 – 58 – ULPA Filter inability to capture smoke due to various conditions (examples: Seal Leak, Broken Exhaust Port, Unable to draw air through filter media)
- 4.1.3. Based on this review, the following is a list of failure modes identified:

Failure mode	Cause	Mitigation	Verification
ULPA Filter unable to insert into port on Smoke Box	Incorrect sizing of exhaust port	Design for fit with the MegaVac / Plus	Part Dimension comparison
	High Force to connect to Smoke Box	Design for fit with the MegaVac / Plus	Force to insert
Inability to Capture Smoke	Exhaust port broken	Materials, Part design	Shear Force test on exhaust port
	Ultrasonic weld not sealed	Materials, Part weld design	Pressure testing of weld joint
	Unable to draw air through filter	Media Design	Air Flow testing

4.2. Carbon / Muffler Review of 1300020-01 Rev E Risk Analysis

- 4.2.1. Item #59 – 61 – Muffler unable to attach or detach from Smoke box, unable to pass air through filter and unable to scrub smoke from air.
- 4.2.2. Based on this review, the following is a list of failure modes identified:

Failure mode	Cause	Mitigation	Verification
Unable to attach/detach	Incorrect sizing of	Part purchased from	Current product

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Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 3 of 17

Muffler	exhaust port	the same primary source	history
Odor detected from smoke box	Muffler life exceeded	IFU to state replace if odor occurs	Current product history

5. Experiment Design and Sample Size Justification

All product tested to be thermal cycled and ship tested prior test # B – E.

5.1. ULPA Filter Testing

- 5.1.1. The Interfacing feature measurement (Test A) will be a comparison between the 2211 and 2210 designs. Since both designs are molded, the features should be consistent from one unit to the next, therefore 3 units of each design will be measured.
- 5.1.2. Tests B (Force to insert Filter, C (Flow Test), E (Shear Force Test) all relate to base unit design, material selection and results in variable data output. These filter comparison tests will use a T-test to evaluate the data. Therefore, the sample size can be 11 units.
- 5.1.3. Test D (Weld Joint Seal Pressure Test) is a Pass/Fail test. Therefore a large sample size of 32 will be used.
- 5.1.4. Test F (Thermal Conditioning / Ship Test) only requires a representative sample size for ship testing. Since the individual case box is the worst case condition, 1 case will be required for test. Any other type of shipping method would ship less than a case, which would require additional over-shipping and protection which is not worst case.

ULPA FILTER TESTING

Test #	A	B	C	D	E	F
Catalog	Feature Measurement	Force to insert Filter	Flow Test	Weld Joint Seal Pressure Test	Shear Force Test	Thermal Conditioning /Ship Test
2211-New	3	11	11	32	11	1 Case -10 units
2210-IC Med	3	11	11	N/A	11	N/A

5.2. Carbon Muffler Testing

- 5.2.1. Test A (Thermal Conditioning / Ship Test) only requires a representative sample size for ship testing. Since the individual case box is the worst case condition, 1 case will be tested. Any other type of shipping method would ship less than a case, which would require additional over-shipping and protection.

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Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 4 of 17

CARBON MUFFLER TESTING

Test #	A
Catalog	Thermal Conditioning /Ship Test
2220 (DF-0)	1 Case -10 units

6. ULPA Filter Testing

6.1. Feature Measurements (Test A)

- 6.1.1. Using Calipers perform a dimension comparison on the exhaust ports of the two designs. See Figure #1 for a drawing of inspection points required. If the dimensions are somewhat different the final test is: Does the filter insert and lock into the port? The dimensional comparison will assist in supporting this. Use the first article report form to write measurement results on.

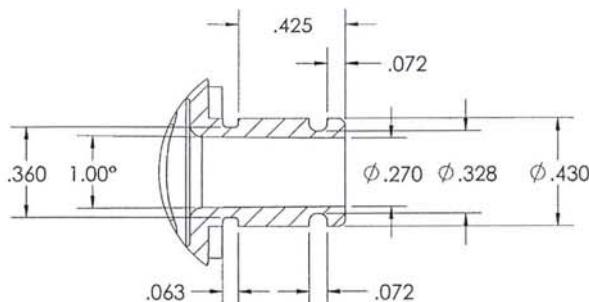


Figure #1

- 6.1.2. Using a threaded/barb connector and 22 mm port connector confirm that the intake interface achieves the desired fit.

6.2. Force to insert filter (Test B)

- 6.2.1. Filter is placed inlet down on the Instron. The filter should be supported to allow for insertion into the exhaust port. Attach the Colder fitting #LCD10006 to the Instron traveling head. Set the rate to mimic the speed of insertion into a box. Record the rate used and the force observed in Appendix 1

6.3. Flow Test (Test C)

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	MASTER DOCUMENT	
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 5 of 17

- 6.3.1. Connect the filter to a MVP. Set the box to Open - max flow and measure flow rate. Perform the same test at Open – minimum flow, Lap - max & min flow. Record flow rates on Appendix 2. Use a #2110-09 IC Med smoke pencil for the flow testing.
- 6.3.2. As a second element to the test, the filter will be exposed to a 100 lpm \pm 6 lpm flow to visually observe for any dislodgement of the filter media from the housing. Record any dislodgement observed on Appendix 2.
- 6.4. Weld Joint Seal Pressure Test (Test D)
 - 6.4.1. Create a plug for the inlet by sealing the ID of a threaded/barb fitting and attaching it to the inlet of the filter. Connect a tubing set to the exhaust port. Pressurize the filter to 7 psi. Place unit under water to check for weld joint seal leaks by observing for air bubbles around the joint. Observe for 30 seconds and note if the unit leaked (P/F) in Appendix 3. The fact that this is a positive pressure test presents a worst case effect on the filter design. Also, air leak testing is a worst case scenario, air will flow 53 times more units of volume through a hole at low pressures compared with water.
- 6.5. Shear Force Test (Test E)
 - 6.5.1. Attach the Colder fitting #LCD10006 to the secured vice on the Instron. Use the 100 lb load cell. Connect the filter to the LDC1006 fitting. Set the travel head to a rate of 1.6 in/sec. This mimics the filter being side loaded causing the filter to shear off at the exhaust port. Record the force of the shear observed in Appendix 4. Evaluate the data using a T-test.
- 6.6. Thermal Conditioning
 - 6.6.1. Follow the protocol # 1150095-10 for thermal conditioning of all product prior to testing
- 6.7. Ship Testing per ASTM D4169 (Test F)
 - 6.7.1. Tests shall be performed under typical warehouse conditions. Typical warehouse conditions are:

Temperature: 23°C \pm 5°C
Relative Humidity: 50% \pm 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.

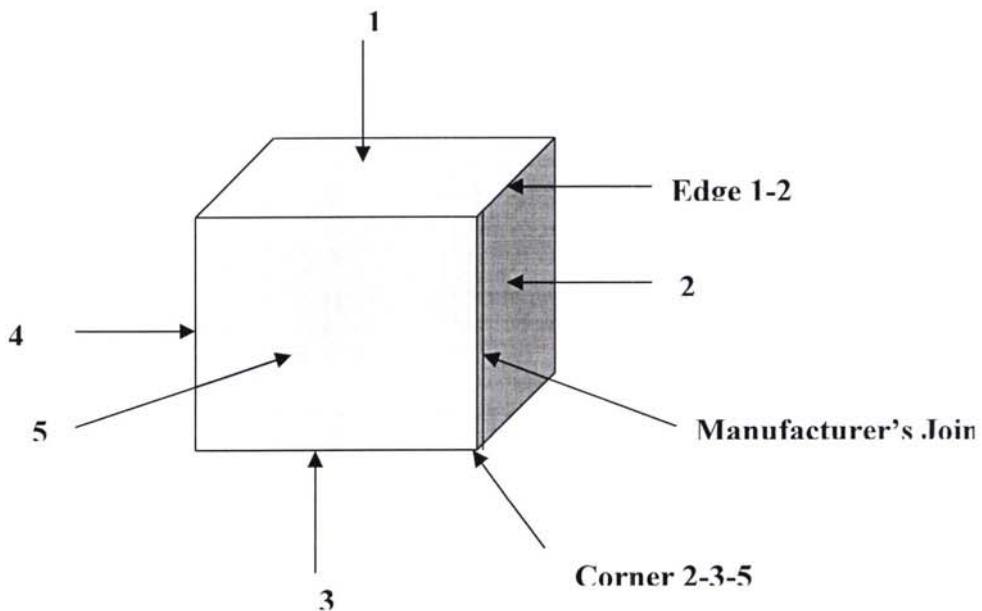
Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number
	MASTER DOCUMENT	1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 6 of 17

- 6.7.2. 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.
- 6.7.3. The test 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 product.
- 6.7.4. Shipping and Storage Cycle Preconditioning
- 6.7.4.1. Pre-Conditioning will follow the temperature and humidity schedule listed below.

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

- 6.7.4.2. SHIP Testing
- 6.7.4.2.1. Following the conditioning, using a permanent marker and identify the faces of the shipping boxes according to the following diagram.

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER MASTER DOCUMENT	Revision: A
		Effective Date: 2014 APR 07
		Page 7 of 17



- 6.7.4.2.2. Record the gross weight (Wt.) of the shipper box containing product in pounds.
- 6.7.4.2.3. Record the Catalog number of the product.
- 6.7.4.2.4. Record the Lot Number of the product.
- 6.7.4.2.5. Perform the Handling test (drop test) as follows.
 - 6.7.4.2.5.1. The required drop height from ASTM D4169 paragraph 10.2.3 using assurance level II is 15 inches for packages from 0 to 20 pounds. Package weight is approximately 2.9 pounds.
 - 6.7.4.2.5.2. Set the height on the LAB AccuDrop 160 to 15 and drop.

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

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Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
	MASTER DOCUMENT	Effective Date: 2014 APR 07
		Page 8 of 17

- 6.7.4.2.5.3. Record package drops on the data sheet in Appendix 5.
- 6.7.4.2.6. Perform the compression test. 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 boxes will be shipped from the supplier on a pallet. The pallet carries a maximum stack is 14 boxes high (5 inches per box) therefore a height of 70 inches will be used in the formula. The formula for the weight of the compression is as follows:
- $$L = M \times J \times ((H-h)/h) \times F$$
- Where the mass $M = 2.9$ lbs., $J = 1$ lbf/lb, $H=70$ inches, and $h= 5$ 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. Record information in Appendix 5.
- | Catalog Number | Carton Weight (lbs.) | Stack Height (ft.) | Compression (lbs.) |
|----------------|----------------------|--------------------|--------------------|
| 2211 | 2.9 | 14 | 113.1 |
- Note that the carton weight listed above is estimated from prototypes. If the actual carton weight varies from this value the compression weight needs to be adjusted.
- 6.7.4.2.6.1. Place *Face 3* of the shipper box on the ground.
- 6.7.4.2.6.2. 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.
- 6.7.4.2.6.3. Place the test load (determined above) on the center of the wood board.
- 6.7.4.2.6.4. Allow the weight to remain on the wood board for a minimum of 3 seconds.
- 6.7.4.2.6.5. Inspect the package for damage. Record observed shipper box damage, if applicable.
- 6.7.4.2.7. Following the compression test perform the Loose Load Vibration test, record information in Appendix 5.
- 6.7.4.2.7.1. Place the shipper box containing packaged product on the vibration table so that *Face 3* rests on the platform.
- 6.7.4.2.7.2. Start the vibration system beginning at the lowest frequency.

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Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
	MASTER DOCUMENT	Effective Date: 2014 APR 07

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

6.7.4.2.7.4. Check the frequency using the shim.

6.7.4.2.7.4.1. 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.

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

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

6.7.4.2.7.7. Check the frequency using the shim.

6.7.4.2.7.7.1. 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.

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

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

6.7.4.2.8. 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.

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Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
	MASTER DOCUMENT	Effective Date: 2014 APR 07
		Page 10 of 17

- 6.7.4.2.8.1. Following the shipping test, evaluate the product as follows:
- 6.7.4.2.8.2. Inspect the exterior of each box and note any damage
- 6.7.4.2.9. The burst test will not be performed. The product is not packaged sterile.
- 6.7.4.2.10. Product should not show any visual signs of damage from ship testing.

7. Carbon / Muffler Testing

7.1. Thermal Conditioning

- 7.1.1. Follow the protocol # 1150095-10 for thermal conditioning

7.2. Ship Test (Test A)

- 7.2.1. Follow steps outlined in section 6.7 for ship testing the Carbon/Muffler.
- 7.2.1.1. These parts are to be done at an assurance level II, and a distribution cycle 3.
- 7.2.1.2. Note: The pallet carries a maximum stack is 18 boxes high (4 inches per box) therefore a height of 72 inches will be used in the formula with a weight of 8.65 per box. This results in a compression of 441.2 lbf.
- 7.2.1.3. The burst test will not be performed. The product is not packaged sterile.

- 7.2.2. Product should not show any visual signs of damage from ship testing.

8. ULPA Filter Acceptance Criteria

8.1. Feature Measurements (Test A)

- 8.1.1. Measurement of the 2211 and 2210 should be similar and/or justification for the differences should be stated.
- 8.1.2. Intake connections should connect to filters as intended. Pass/Fail

8.2. Force to insert filter (Test B)

- 8.2.1. The force to insert the filters of both styles should be comparable or the 2211 could be lower than the 2210.

8.3. Flow Test (Test C)

- 8.3.1. The flow rate of filters of both styles should be comparable or the 2211 be better than the 2210.
- 8.3.2. The media should not visibly dislodge from the housing when exposed to a flow of 100 lpm ± 6 lpm.

8.4. Weld Joint Seal Pressure Test (Test D)

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Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	MASTER DOCUMENT	Revision: A
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Effective Date: 2014 APR 07

8.4.1. There should be no leaks / air bubbles around the ultrasonically welded seals when under pressure for 30 seconds.

8.5. Shear Force Test (Test E)

8.5.1. The shear force at the exhaust ports of both styles should be comparable or the 2211 be stronger than the 2210.

8.6. Ship Test (Test F)

8.6.1. Case box shall remain intact and not break open during the test. Indentations on edges or corners are acceptable.

8.6.2. Product should not show any visual signs of damage.

9. Carbon / Muffler ULPA Filter Acceptance Criteria

9.1. Ship Test (Test A)

9.1.1. Case box shall remain intact and not break open during the test. Indentations on edges or corners are acceptable.

9.1.2. Product should not show any visual signs of damage.

10. Revision History

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-056-01	Initial Release	2014 APR 07

Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 12 of 17

Appendix 1

Force to insert Log Sheet

Enter the force value in the box below.

Sample	Force to insert Filter (lbf)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	

Comments: _____

Inspected by: _____ Date completed _____

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	MASTER DOCUMENT	
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 13 of 17

Appendix 2

Flow Testing Log Sheet

Enter the flow value and if dislodgement occurs.

Sample	2211	Dislodgement @ 100 lpm	2210	Dislodgement @ 100 lpm
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				

Comments: _____

Inspected by: _____ Date completed _____

Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 14 of 17

Appendix 3

Bubble Leak Test @ 7psi for 30 seconds Log Sheet

Catalog #_____

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

Sample	Pass	Fail	Comment
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			
32			

Signature: _____

Date: _____

Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 15 of 17

Appendix 4

Shear Force Test Log Sheet

Enter the force value in the box below.

Sample	2211	2210
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
11		

Comments: _____

Inspected by: _____ Date completed _____

Megadyne Medical Products, Inc.	TEST PROTOCOL MASTER DOCUMENT	Document Number 1150751-10
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Revision: A
		Effective Date: 2014 APR 07
		Page 16 of 17

Appendix 5

Shipping Test Log Sheet

Preconditioning:

Start Date: _____ Chamber Number: _____

Completion Date: _____ Last Calibration: _____

Signature/Date: _____ Calibration due: _____

Drop Test:

Catalog _____ Weight _____ Drop Height: _____

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:

Catalog _____ Pounds Force _____

Comments: _____

Signature: _____ Date: _____

Megadyne Medical Products, Inc.	TEST PROTOCOL	Document Number 1150751-10
	MASTER DOCUMENT	Revision: A
	ULPA REPLACEMENT FILTER & CARBON/MUFFLER	Effective Date: 2014 APR 07
		Page 17 of 17

Appendix 5 Continued

Shipping Test Log Sheet

Vibration:

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

Completion Date: _____

Signature: _____ Date: _____

Second Drop Test:

Catalog _____ Weight _____ Drop Height: _____

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: _____