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Megadyne Medical Products, Inc.	TEST PROTOCOL	***Document Number*** **1150778-10**
	ULPA REPLACEMENT FILTER TESTING	**Revision: A**
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		Page 1 of 3

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TABLE OF CONTENTS

1. Scope

This protocol pertains to the comparison of the 9522/2221 & 9329/2221 filter media combinations against the 2210 control smoke filter in regards to filter life and flow characteristics. Filter efficiency has been measured for the 9522/2221 & 9329/2221 filter media combinations as a part of the filter manufacturing process at the vendor.

2. Purpose

The purpose of this protocol is to determine if the 9522/2221 & 9329/2221 filters are comparable to or better than the 2210 ULPA filter. The filters will be tested using the same MVP and connectors to limit any testing variability.

3. Experiment Design and Sample Size Justification

The testing will compare 3 filters from each group. The testing will be done by taking one unit from each group and running it through the series of tests defined in section 4.0. This is intended to minimize variation between the units in smoke capture per tissue used.

Filter/Media combinations for testing	
2210	99.999954% eff. Control w/Gore media (Per Jill e-mail 11/5/2013)
9522/2221	99.999% eff. ULPA / tight glass weave pre-filter
9329/2221	99.9999% eff. SULPA / tight glass weave pre-filter

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		Page 2 of 3

4. Procedure

4.1. Measure Ambient pressure

4.2. Measure flow and vacuum pressure MVP w/o filter

4.3. Measure flow and vacuum pressure MVP w/o filter

4.4. Measure flow and pressure of each filter prior to testing.

4.5. Humidity Liver Coag/Cut Testing

4.5.1. Connect a large plastic bag, simulating a Peritoneum, to the humidifier

4.5.2. Connect the bag to a lap tubing

4.5.3. Set MVP to a flow rate of 15 lpm and timer for 15 second interval activation.

4.5.4. Place a bovine liver into the bag

4.5.5. Activate using a lap electrode (electrode entry point sealed around electrode) for 15 seconds @ 60 W spray coag on the MegaPower and then 15 seconds no activation. The 2 cycles/min will continue for 15 minutes. The smoke evacuation will be constantly running. This is intended to simulate 3.75 minutes coag/hour in a two hour procedure.

4.5.6. Measure filter flow rate and resistance by locating a flow meter between the filter pump. Record flow and pressure readings at the end of 15 minutes or if the filter alarm sounds. Note if the change filter light comes on.

4.5.7. Repeat 4.3-4.4.6 testing cycle a 2nd time.

4.6. Skin Cut Testing / Muscle/Tissue coag. Testing (Pig leg)

4.6.1. Make 20 skin incisions each 5 inch long per filter (Filter settings at Open mode/max flow/max time)\

4.6.2. Use a Zip pencil and 0012 tip in 60 W pure cut mode on the MegaPower.

4.6.3. Activation of the smoke pencil will be done @ 60 W spray coag on the MegaPower with smoke capture for 15 minutes continuous or until filter alarm sounds. Note if the change filter light comes on. This is intended to simulate 7.5 minutes coag/hour in a two hour procedure.

4.6.4. Use 60 W spray coag on the MegaPower to create pockets for coag/smoke pencil capture.

4.6.5. Measure filter flow rate and resistance by locating a flow meter between the filter pump. Record flow and pressure readings at the end of 15 minutes or if the filter alarm sounds.

4.6.6. Repeat 4.5 testing cycle a 2nd time.

4.7. Acceptance Criteria

4.7.1. The 9522/2221 & 9329/2221 filter medias will be equivalent to or better than the 2210 filter in filter life and higher air flow. This testing estimates 8 hours of heavy smoke use. Criteria for acceptance is that the filter media tested continues to function (MVP filter alarms not activating and/or change filter light does not comes on) following the testing noted in section 4 or if medias perform to the same level as the 2210 filter.

5. Revision History

REVISION	DOCUMENT CHANGE ORDER NUMBER	DESCRIPTION OF CHANGE	EFFECTIVE DATE
A	14-069-01	Initial Release	2014-07-11