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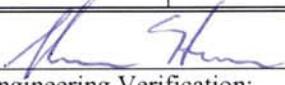
All dates and times are in Mountain Standard Time.

Quick Approval

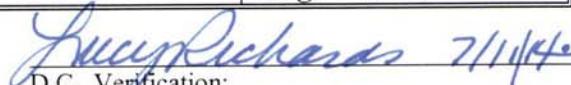
Approve Now

Name/Signature	Title	Date	Meaning/Reason
Lucy Richards (LRICHARDS)	Document Specialist	11 Jul 2014, 03:14:11 PM	Approved

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 Engineering Verification:

7/1/14

 D.C. Verification:

7/1/14

Authored By: Shawn Horner

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1. ABSTRACT

The 9522/2221 & 9329/2221 media in the 2211 filter body are equivalent to the 2210 filter in filter life and air flow. This testing estimates 8 hours of heavy smoke use: 4 hours of laparoscopic tissue cauterization & skin dissection with 4 hours of muscle cauterization. Though the filters were taken to full alarm occlusion for information collection, the data identified below represents the pressures and estimated flows at the time the change filter light was activated.

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

Product tested:

2210 Lot # 5260 – 3 Control units

2211 Drawing rev ____ with 9522/2221 Media – 3 test units

2211 Drawing rev ____ with 9329/2221 Media – 3 test units

2. APPENDIX

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Appendix A – 1st Round of testing (1 of each filter type)

Appendix B – 2nd Round of testing (1 of each filter type)

Appendix C – 3rd Round of testing (1 of each filter type)

Appendix D – E-mail and documents supporting 2210 information

3.0 FILTER TESTING EQUIPMENT

3.1 Equipment:

- 3.3.1. MegaVac serial # I3427 /w 2210 Carbon Filter Lot# 5241 (Used to Measure Flow)
- 3.3.2. MegaVac Plus serial # I4211 /w 2210 Carbon Filter Lot# 4352 (Used to draw smoke for testing in Lap and Open modes)
- 3.3.3. Flow Meter tag # 01272, Calibrated April 2013, Due April 2014

4.0 RISK ASSESSMENT

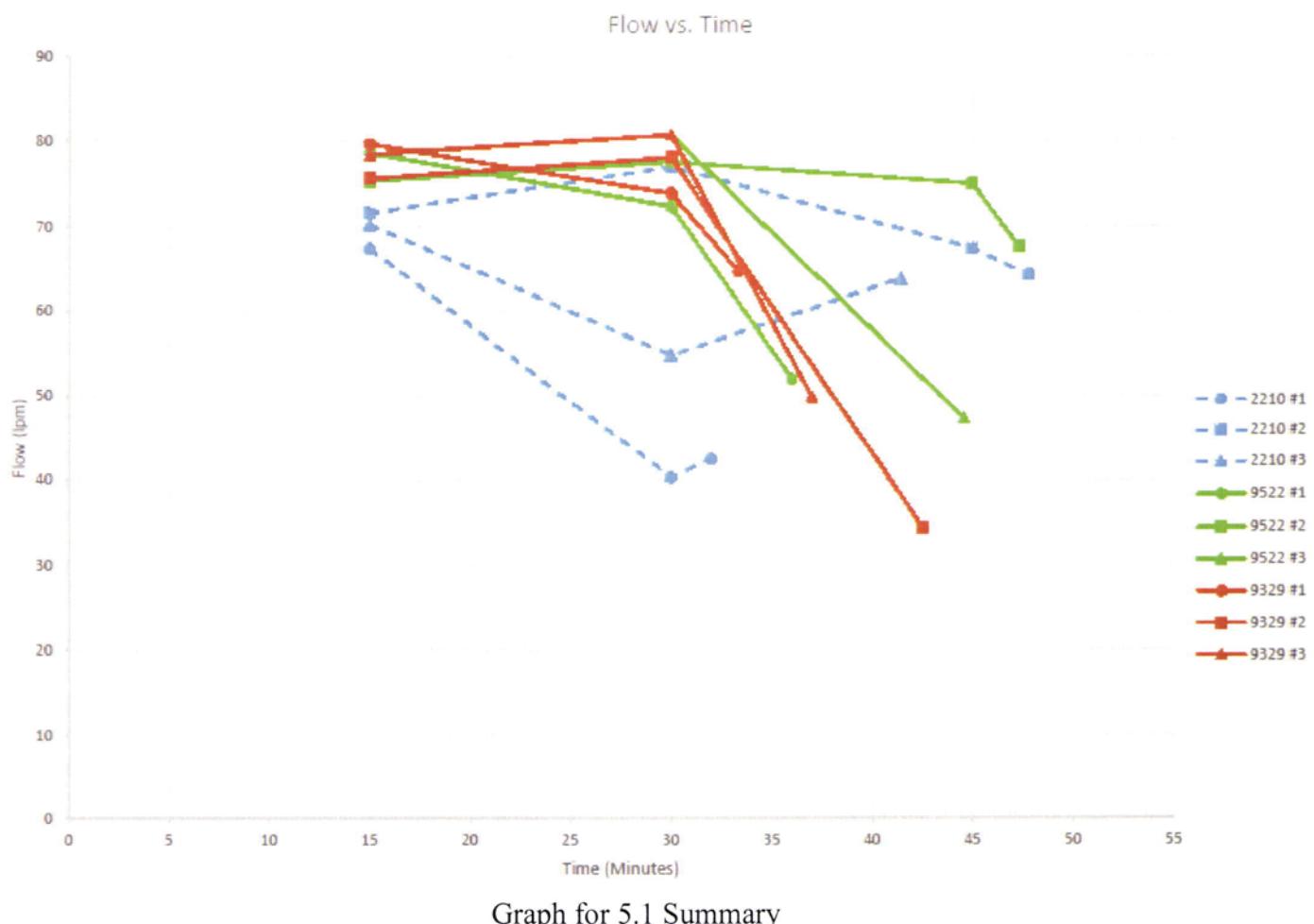
A risk assessment is addressed in FMEA 1300041-01. This report was intended for direct comparison of devices. The risks do not change as the predict device function is no different than the test unit. No additional risk has been identified.

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5. TESTING RESULTS

Graph Key:

- Control Group – Blue Dash line
- 9522/2221 Test Group – Green Solid line
- 9329/2221 Test Group – Brown Solid line
- 1st Round Testing – Circle nodes
- 2nd Round Testing – Square nodes
- 3rd Round Testing – Triangular nodes



5.1. Summary

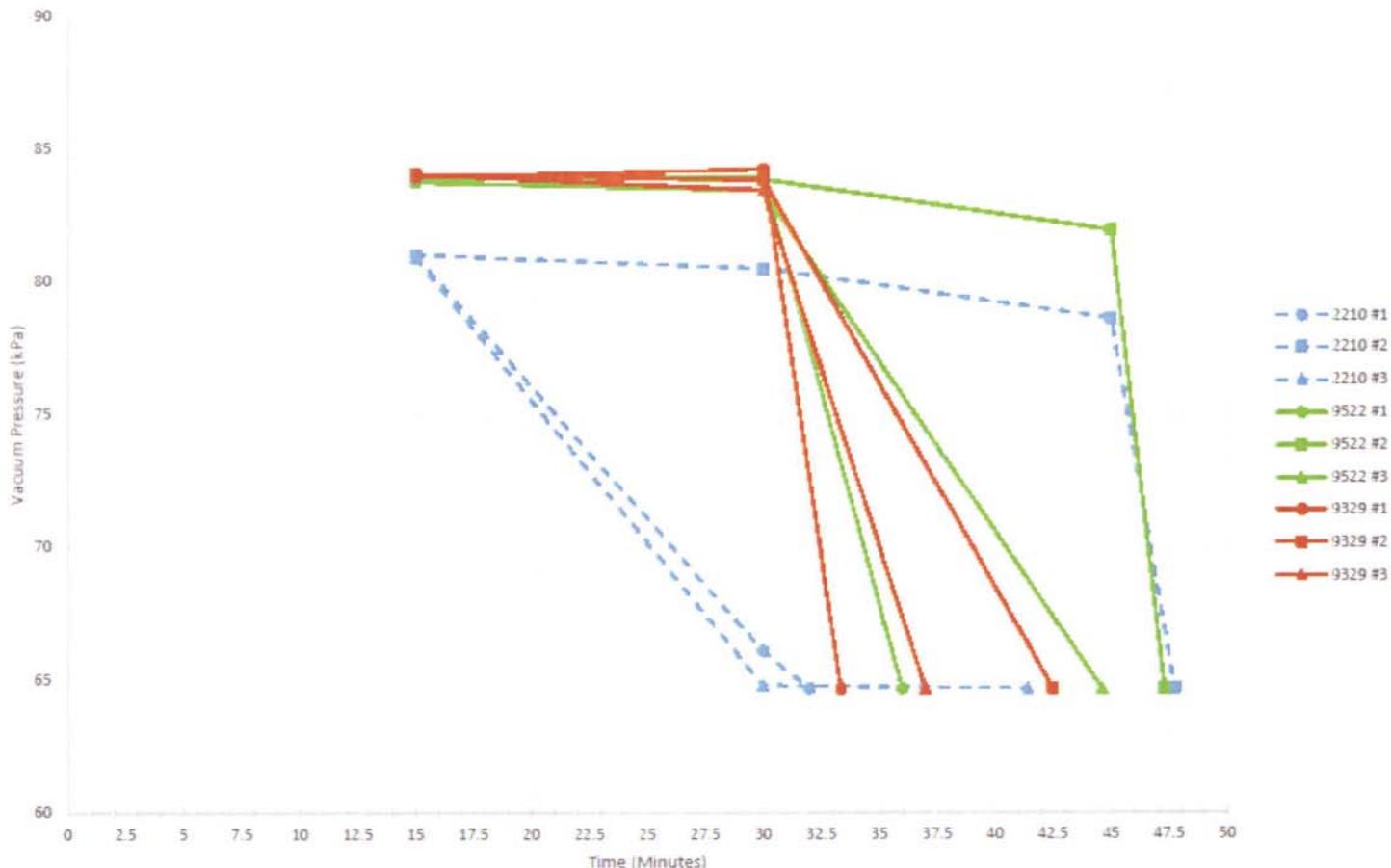
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- 5.1.1. The Humidity Liver Coag/Cut Testing, exposed all the filters to an aggressive amount of humid smoke. The 9522/2221 (Brown) & 9329/2221(Green) filters are equivalent to or better than the 2210 control filters (Blue). After 30 minutes of this simulated laparoscopic testing, the flow values of the test groups are better than or equivalent to the control. The 2211 filters with 9522/2221 (Brown) & 9329/2221(Green) filter media meet the requirements of the protocol.
- 5.1.2. All but one of the test group filters had the “Change Filter” light activate during the 1st cycle of the Skin/Muscle tissue testing (simulating a drier smoke in an open case). The 2nd Round 2210 & 9522 filters extended into the 2nd cycle of Skin/Muscle tissue testing. Flow was not measured when the filter light activated. Flow was measured at the end of the cycle of testing (15 minutes). The flow data measured at the end of 2nd Laparoscopic cycle and 1st Skin/Muscle tissue cycle were analyzed and the flow values was interpolated at the time the “Change Filter” light activated.

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Filter Pressure vs Simulated Life Test



Graph for 5.2 Summary

5.2. Summary

- 5.2.1. The pressure differential seen across the filter is measured. This pressure difference is what activated the “Change Filter” light. Thus, defining the useful life of a filter. The “Change Filter” light vacuum pressure sensor is set approximately to 175 mmHg (23.33 kPa) off ambient pressure. The ambient pressure was 88.0 kPa on the day of testing which resulted in a vacuum sensor activation at 64.67 kPa.
- 5.2.2. The Humidity Liver Coag/Cut Testing, exposed all the filters to an aggressive amount of humid smoke. The 9522/2221 (Brown) & 9329/2221(Green) filters maintain less pressure resistance across the filter than the 2210 control filters (Blue) over the 30 minutes of simulated laparoscopic testing.

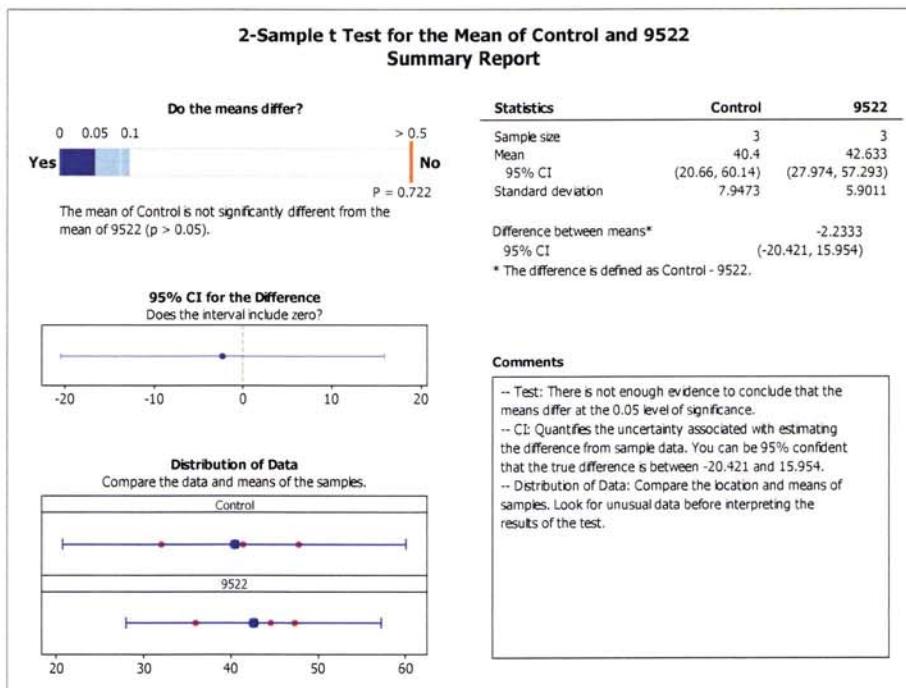
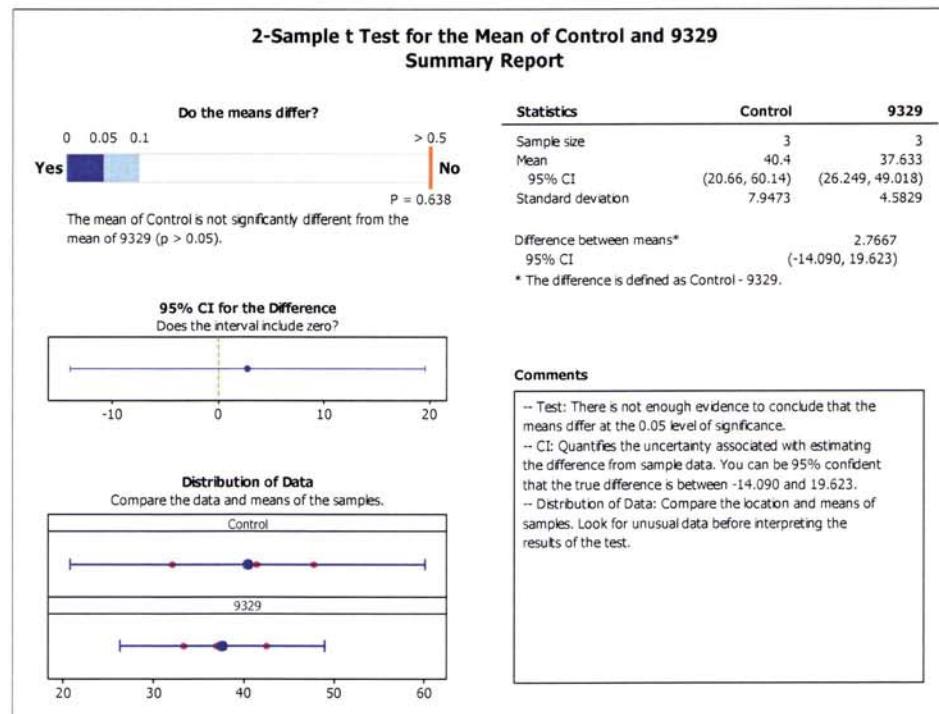
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- 3.4.5. All but one of the test group filters activated the “Change Filter” light during the 1st round of the Skin/Muscle tissue dissection (simulating a drier smoke in an open case). The 2nd Round 2210 & 9522 filters extended into the 2nd cycle of Skin/Muscle tissue testing.
- 3.4.6. The average time for the filters to activate the “Change Filter” light per test group resulted in the 2211 filter w/ 9522/2221 media having a life span average of 42.6 minutes. The 2210 controls had an average life span of 40.4 minutes. The 2211 filter w/ 9329/2221 media had an average life span of 37.6 minutes. The minor differences in average time are negligible. The three design comparisons within a 5 minute average. The 2 sample Test identifies no difference from the control to the 9329/2211 or 9522/2221. See the Sampling reports below.

**AVERAGE TIME TO ACTIVATE "CHANGE FILTER"
LIGHT**

	2210 Control	9522	9329
Round 1	32	36	33.4
Round 2	47.8	47.3	42.5
Round 3	41.4	44.6	37
Average Time (minutes)	40.4	42.6	37.6

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6. RAW DATA

6.1. 1st Round test

6.1.1. Summary

Pressures and flow of the system and filters were measured. See Appendix A for pretest measurements.

All devices completed 2 cycles of the simulated lap testing as outlined in Section 4.4 of 1150778-10. The greatest change in pressure/resistance and flow was seen by the 2210 control. The two test group filter media styles measured very little change in pressure/resistance and flow over the first 30 minutes of testing.

The “Change Filter” light activated for all units early in the 1st cycle of simulated Skin/Muscle tissue testing as outlined in Section 4.5 of 1150778-10. During the 2nd cycle of Skin/Muscle tissue testing, all the devices activated the “Occlusion” alarm testing early in the testing.

See Figure(s) 1, 2 and 3.



Figure #1



Figure #2

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Figure #3

6.2. 2nd Round test

6.2.1. Summary

Pressures and flow of the system and filters were measured. See Appendix B for pretest measurements.

All devices completed 2 cycles of the simulated laparoscopic testing as outlined in Section 4.4 of 1150778-10. The control and two test group filter media styles measured very little change in pressure/resistance and flow during the 30 minutes of laparoscopic cycles.

The “Change Filter” light activated for the 9329 filter near the end of the 1st cycle of Skin/Muscle tissue testing as outlined in Section 4.5 of 1150778-10. Early in the 2nd cycle of Skin/Muscle tissue testing the other two filters activated the “Change Filter” light. The 9329 activated the “Occlusion” alarm 1:30 minutes into 2nd cycle of Skin/Muscle tissue testing. The 2210 and 9522 saw extremely diminished smoke removal between 11-12 minutes into the 2nd cycle of Skin/Muscle tissue testing but did not activate the “Occlusion” alarm. See Figure(s) 4, 5 and 6.

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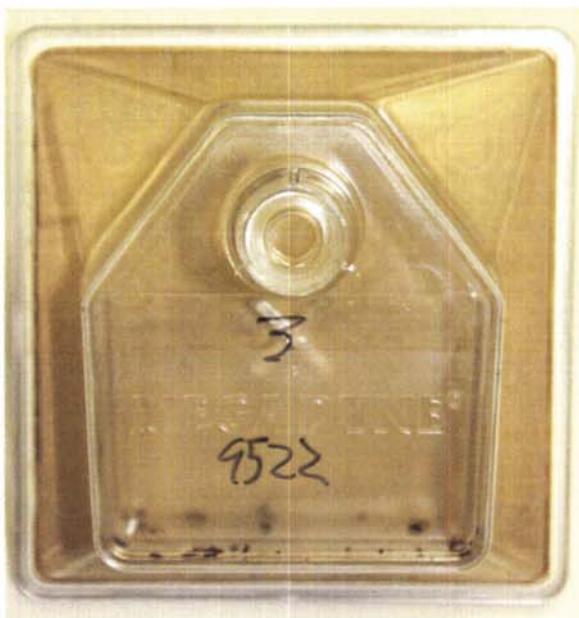


Figure #4



Figure #5



Figure #6

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6.3. 3rd Round test

6.3.1. Summary

Pressures and flow of the system and filters were measured. See Appendix C for pretest measurements.

All devices completed 2 cycles of the simulated laparoscopic testing as outlined in Section 4.4 of 1150778-10. The greatest change in pressure/resistance and flow was seen by the 2210 control. The two test filter media styles measured very little change in pressure/resistance and flow.

The “Change Filter” light activated for the 2210 at 11:25 minutes into the 1st cycle of Skin/Muscle tissue testing. The 9522 filter activated the “Change Filter” light at 14:36 minutes into the 1st cycle of Skin/Muscle tissue testing. The 9329 filter had the “Change Filter” light signal at 7:00 minutes into the 1st cycle of Skin/Muscle tissue testing with the “Occlusion” alarm activating at 14:40 minutes. 4 minutes into the 2nd cycle the 2210 filter saw extremely diminished smoke removal but did not activate the “Occlusion” alarm. The 9522 also had extremely diminished smoke removal from 2:30 minutes into the 2nd Cycle but did not activate the “Occlusion” alarm. See Figure(s) 7, 8 and 9.



Figure #7



Figure #8

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Figure #9

7. CONCLUSION

The 9522/2221 & 9329/2221 Filter media's perform equivalent to or better than the 2210 filter is shown by the tests in filter life and air flow up to the "Change Filter" light activation indicated the end of the useful filter life.

8. REVISION HISTORY

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

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APPENDIX A

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1st Round Testing

	Ambient Pressure	Flow/pressure w/o Filter		Pre Smoke		Post Smoke		Observations 1st Group
		Flow	Pressure kPa	Flow	Pressure kPa	Diff. Press kPa	Time	
1st Lap	2210	Control w/gore media Lot # 5260	67.4	81	-7	55.7	71.4	-16.6 15:00
1st Lap	9522/2221	99.999% eff ULPA with a tight glass weave prefilter	78.6	83.9	-4.1	74.1	84.1	-3.9 15:00
2nd Lap	2210	Control w/gore media	79.6	83.9	-4.1	74.1	84.2	-3.8 15:00
2nd Lap	9522/2221	99.999% eff ULPA with a tight glass weave prefilter	75.3	84.3	-3.7	72.4	83.9	-4.1 15:00
2nd Lap	9329/2221	99.999% eff SULPA with a tight glass weave prefilter	75.2	84.3	-3.7	73.9	84.2	-3.8 15:00
2nd Open	2210	Control w/gore media	52.2	68.6	-19.4	56.5	72.4	-15.6 15:00 Change filter light @ 2min.
1st Open	9522/2221	99.999% eff ULPA with a tight glass weave prefilter	75	83.7	-4.3	22.9	51.1	-36.9 15:00 Change Filter light @ 6 min.
1st Open	9329/2221	99.999% eff SULPA with a tight glass weave prefilter	Measurement not taken	Measurement not taken	Measurement not taken	32.5	56.2	-31.8 15:00 Change Filter light @ 3:35 min.
2nd Open	2210	Control w/gore media	60.1	75	-13	18.9	48.2	-39.8 2:25 Alarmed
2nd Open	9522/2221	99.999% eff ULPA with a tight glass weave prefilter	19.2	53.2	-34.8	18.4	53.5	-34.5 1:00 Alarmed
2nd Open	9329/2221	99.999% eff SULPA with a tight glass weave prefilter	26.6	59.2	-28.8	15.1	55.4	-32.6 1:43 Alarmed

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APPENDIX B

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APPENDIX C

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3rd Round Testing

3rd Round Testing		Ambient Pressure		Flow/pressure w/o Filter		Flow		Pressure kPa		Observations 3rd	
						80.4	87.2				
				Pre Smoke				Post Smoke			
				Flow	Pressure kPa	Diff Press kPa	Flow	Pressure kPa	Diff Press kPa	Time	Time
		1st Lap									
	2210	Control w/gore media Lot # 5260		70.2	80.9	80.9	58.8	73.5	73.5	15:00	15:00
	9522/2221	99.999% eff ULPA with a tight glass weave prefilter		78.5	83.7	83.7	78.8	83.4	83.4	15:00	15:00
	9329/2221	99.9999% eff SULPA with a tight glass weave prefilter		78.4	84	84	77	84.1	84.1	15:00	15:00
	2210	Control w/gore media		66.5	77	77	54.9	64.8	64.8	15:00	15:00
	9522/2221	99.999% eff ULPA with a tight glass weave prefilter		80.3	83.4	83.4	80.2	83.1	83.1	15:00	15:00
	9329/2221	99.9999% eff SULPA with a tight glass weave prefilter		80	83.8	83.8	80.7	83.4	83.4	15:00	15:00
	2210	Control w/gore media		59	68.5	68.5	66.6	73.7	73.7	15:00	15:00
	9522/2221	99.999% eff ULPA with a tight glass weave prefilter		78.4	83.3	83.3	45.89	40.3	40.3	15:00	Change Filter light @ 11:25 minutes observed fluid ingress through seal area
	9329/2221	99.9999% eff SULPA with a tight glass weave prefilter		80.46	83.5	83.5	14.6	43.6	43.6	14:40	Change Filter light @ 14:36 minutes
	2210	Control w/gore media		67.3	74.5	74.5	56.7	66.3	66.3	15:00	Alarm @ 14:40 min.
	9522/2221	99.999% eff ULPA with a tight glass weave prefilter		23.6	42.5	42.5	23.1	44.8	44.8	15:00	Very limited smoke removal from 4 minutes on observed fluid ingress through seal area
	9329/2221	99.9999% eff SULPA with a tight glass weave prefilter		N/A	N/A	N/A	N/A	N/A	N/A	N/A	Very limited smoke removal from 2:30 minutes on

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APPENDIX D

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Shawn Horner

From: Jill Trasamar
Sent: Tuesday, November 05, 2013 3:28 PM
To: Paul Borgmeier; Mike Hintze
Cc: Mark Glassett; Shawn Horner; Ryan Lewis; Wayne Chappell
Subject: RE: ZIP - FW: Winston - ULPA Replacement Filter RFQ
Attachments: smoke_evacuation_units.pdf; one micron report Ulpa Filter, Nelson Labs.pdf; three micron report Nelson Labs.pdf; wl gore letter Ulpa Filter.pdf

Hi Paul,

I hate to muddy the waters, but can you tell us what the quote would be for filtration that more closely matches our competitors as shown in the table below?

I've attached a section from the Lina brochure (below) and 99.999 vs. 99.9999 makes a big difference. As we know, smoke (as well as our other products) will be very prone to spec-man ship, especially internationally.

That said, the Nelson reports attached provided by IC Medical many years ago imply that their Ulpa filter filtration rate is more along 99.999% than the number quoted in their IFU.

I don't want to over spec and/or over pay for more filtration than we need, but I would like to match the competitive specs. Each of our competitors list the filtration on their marketing materials, so if we fall short, it may well be a competitive disadvantage.

What are our options regarding the quote?

Ulpa Filter Brand	Efficiency	Micron
IC Medical	99.999954%	0.1000
AerDefenese ConMed	99.9995%	0.1000
ViroVac Buffalo	99.9990%	.1 -.2
ERBE	99.999900%	0.01 µm
Lina	99.999900%	.1µm
RapidVac Covidien	99.999500%	0.0120



W. L. GORE & ASSOCIATES, INC.

P.O. BOX 1550 • ELKTON, MARYLAND 21922-1550
PHONE 410/392-4440 • FAX: 410/506-8749
MEDICAL MEMBRANE TECHNOLOGIES

May 28, 2002

2014 JUL 11

Mr. Craig Harshman
I.C. Medical, Inc.
2002 W Quail Avenue
Phoenix, AZ 85027

MASTER DOCUMENT

Dear Mr. Harshman:

I would like to address your concerns regarding the filter media you purchase as Gore Part No. D30251. The material we supply is a multi layer laminate, which includes a microfiberglass prefilter and an expanded PTFE membrane filter. We do not attribute the microfiberglass prefilter with a reference pore size. However, we have characterized the filtration efficiency of the multi layer laminate. Below is a table with results of TSI filtration efficiency testing for both versions of this laminate you have received.

D30255 Rev 2(Blue) Air Filtration Efficiency Test (DOP)

Challenge Particle Size (μ)	Face Velocity (cm ² /sec)	Efficiency %
0.1	5.33	99.99994
0.3	5.33	99.99993

D30255 Rev 3 (White) Air Filtration Efficiency Test (DOP)

Challenge Particle Size (μ)	Face Velocity (cm ² /sec)	Efficiency %
0.1	5.33	99.99999
0.3	5.33	99.999

Sincerely,

Carrie Ortiz
Carrie Ortiz
Associate

CO/rI

ASIA • AUSTRALIA • EUROPE • NORTH AMERICA
GORE-TEX and ZINTEX are trademarks of W. L. Gore & Associates, Inc.



Certificate No. FM 26038



MASTER DOCUMENT

2014 JUL 11

FINAL REPORT

LATEX PARTICLE CHALLENGE TEST
AT INCREASE CHALLENGE

PROTOCOL NO. 200231213-02

LABORATORY NO. 222768

PREPARED FOR:

CRAIG HARSHMAN
I.C. MEDICAL
2002 WEST QUAIL AVENUE
PHOENIX, AZ 85027

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 SOUTH REDWOOD ROAD
SALT LAKE CITY, UT 84123-6600
801-963-2600





LATEX PARTICLE CHALLENGE TEST AT INCREASE CHALLENGE

LABORATORY NUMBER:	222768
PROTOCOL NUMBER:	200231213-02
SAMPLE SOURCE:	I.C. Medical
SAMPLE IDENTIFICATION:	ICM-000-0014 ULPA filter and water trap using gore filter media part number D30255 Rev 3 Lot #2010
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
PARTICLE SIZE:	0.1 μ m (0.102 ± 0.003 μ m)
SAMPLE AREA TESTED:	Entire filter
PROTOCOL APPROVAL DATE:	15 Nov 2002
SAMPLE RECEIVED DATE:	14 Nov 2002
LAB PHASE START DATE:	15 Nov 2002
LAB PHASE COMPLETION DATE:	26 Nov 2002
REPORT ISSUE DATE:	27 Nov 2002
TOTAL NUMBER OF PAGES:	7

REFERENCES:

ASTM F1215. 1989. American Society for Testing and Materials. Standard Test Method for Determining the Initial Efficiency of a Flatsheet Filter Medium in an Airflow Using Latex Spheres. American Society for Testing and Materials, 1916 Race St. Philadelphia, PA. (This document has been discontinued but is referenced in ASTM F2100-01).

ASTM F2100-01. 2001. American Society for Testing and Materials. Standard Specifications for Performance of Materials Used in Medical Face Masks. American Society for Testing and Materials, 1916 Race St. Philadelphia, PA.

Australian Standard 4381-1996. Appendix A. Method for Determining Particle Filtration Efficiency. Standards Australia, 1 The Crescent, Homebush, New South Wales.

INTRODUCTION:

This report details the results of a non-viable, particle filtration efficiency study. The procedure involved the generation of a mono-dispersed aerosol of latex (polystyrene) microspheres using a Particle Measurement Systems (PMS) Model PG-100 particle generator. The aerosol particles are dried and passed through the test filter. The effluent air was assayed for the presence of 0.1 μ m particles using a PMS Model micro-LASAIR 110 laser particle counter.



I.C. Medical
Lab Number 222768

Latex Particle Challenge
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The procedure employed the basic test method described in ASTM F1215, but incorporates a non-neutralized challenge and a test challenge concentration of $\geq 10^8$ particles/test article. In real use, particles carry a charge, thus a neutralized challenge does not represent a natural state. The use of a non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. The high test challenge was added to provide filtration efficiency measurements of 99.999%.

ACCEPTANCE CRITERIA:

The filtration efficiency of the reference material must be within ± 3 standard deviations of the mean established in the control chart for latex testing. Ambient background particles detected through the sample holder must be below 1% of the challenge total (< 100 particles).

PROCEDURE:

Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2 μm rated air filter. Extraneous particulate "background noise" through the sample holder produced <1 particles at one cubic foot per minute (CFM) with the nebulizer output clamped off. The flow rate through the test system was maintained at 1 CFM \pm 5%.

The latex microspheres, traceable to the National Institute of Standards and Technology, were obtained from Duke Scientific, Palo Alto, CA. An aliquot of the latex spheres was transferred to particle free USP water for irrigation and then atomized using a Particle Measuring System (PMS) Model PG-100 nebulizer. The latex aerosol was mixed with additional filtered, dried air and passed through the test system. The particles delivered were collected and enumerated using a PMS laser based particle counter.

A specimen was placed into the system, the system allowed to stabilize, then a 5 minute particle reading determined. A 5 minute control reading was taken prior to and after each sample. Particle concentration was maintained at $>1 \times 10^8$ particles/5 minutes.

A reference material was included at the beginning and at the end of testing to assure the test system was operating properly. The particle concentration for the reference material was maintained at 10,000 - 15,000 particles/CFM, to allow for comparison against historical data.



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The percent filtration efficiency value was determined using the following equation:

$$\% \text{ EFF} = \frac{\text{SUM } C - \text{SUM } T}{\text{SUM } C} \times 100$$

Where C = Average of the 5 minute control count reading (before and after sample run)
T = 5 minute particle reading with a test sample in the airstream

RESULTS:

The particle filtration efficiencies and total average counts for the test samples and controls are detailed in Table 1.

STATEMENT OF UNCERTAINTY:

Due to the large number of data points available for the standard reference material used in the latex particle challenge test, the Type B uncertainty factors have been determined to be incorporated into the Type A uncertainty.

Statistical analysis of the latex particle challenge test data resulted in the following:

Latex Particle Filtration Efficiency (FE) Mean = 99.6%
Standard Deviation = 0.12%

The combined uncertainty for the latex particle challenge test is 0.015% Filtration Efficiency and the expanded uncertainty with a 95% confidence level is 0.03% Filtration Efficiency.

It should be noted that the statistical analysis was conducted on data from Nelson Laboratories' standard reference material with a mean of 99.6%. It is expected that test materials submitted for latex particle challenge testing which have a FE greater than 99.6% would have a combined uncertainty and an expanded uncertainty less than the uncertainty values reported here. Conversely, test materials with latex particle FE values lower than 99.6% would be expected to yield a combined uncertainty and an expanded uncertainty greater than the uncertainty values reported here.

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Test samples were not collected by the laboratory and therefore the representative nature of the samples is not included in the uncertainty statement.

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Quality Assurance Reviewer

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Karl Perkes, B.S. RM(NRM)
Study Director

02 Dec 2002

Study Completion Date

KLP/bdk

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TABLE 1. Results of Particle Filtration Test

Sample ID: ICM-000-0014 ULPA filter and water trap using gore filter media
Part Number D30255 Rev 3, Lot #2010

SAMPLE NUMBER	AVERAGE CONTROL COUNTS	SAMPLE COUNTS	PERCENT FILTRATION EFFICIENCY
Filler #1	1.3×10^6	7	99.9994%
Filler #2	1.1×10^6	16	99.999%
Filler #3	1.2×10^6	17	99.999%

PARTICLE SIZE: $0.1 \mu\text{m}$ ($0.105 \pm 0.003 \mu\text{m}$)

AVERAGE FILTRATION EFFICIENCY: 99.999%

STANDARD DEVIATION: 0.0005



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FINAL REPORT

SODIUM CHLORIDE (NaCl) AEROSOL TEST

PROCEDURE NO. SOP/ARO/022B.1

LABORATORY NO. 221507

PREPARED FOR:

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SODIUM CHLORIDE (NaCl) AEROSOL TEST

LABORATORY NUMBER:	221507
PROCEDURE NUMBER:	SOP/ARO/022B.1
SAMPLE SOURCE:	I.C. Medical
SAMPLE IDENTIFICATION:	ICM-000-0014 ULPA Filter Media, Gore Part #D30255 Rev. 3 Lot #2010 P.O. #3194
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
SAMPLE AREA TESTED:	81 cm ²
SAMPLE RECEIVED DATE:	28 Oct 2002
LAB PHASE START DATE:	30 Oct 2002
LAB PHASE COMPLETION DATE:	11 Nov 2002
REPORT ISSUE DATE:	11 Nov 2002
TOTAL NUMBER OF PAGES:	8

REFERENCES:

TSI® CERTITEST® Model 8130 Automated Filter Tester Instruction Manual, P/N 1980207/Revision C/July 2000. TSI Incorporated, 500 Cardigan Road, St. Paul, MN 55164.

Public Health Service. Department of Health and Human Services. 2000. 42 CFR Part 84. Approval of Respiratory Protective Devices. The Office of the Federal Register, National Archives and Records Administration, Washington, D.C.

Occupational Safety and Health Administration. Department of Labor. 29 CFR Part 1910.134. Subpart 1-Personal Protective Equipment. The Office of the Federal Register, National Archives and Records Administration, Washington, D.C.

Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health care facilities, 1994. MMWR Vol. 43, No. RR-13.

ACCEPTANCE CRITERIA:

The filter tester must pass the "TESTER SET UP" procedure program provided by the manufacturer. The filtration efficiency for the reference material must be within ± 3 standard deviations of established control mean.

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Sodium Chloride (NaCl) Aerosol Test
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INTRODUCTION:

This report details the results of a particle retention and air flow resistance study. A neutralized, polydispersed aerosol of sodium chloride (NaCl) was generated and passed through test samples. The filtration efficiency and pressure differential of the test samples were calculated.

TEST SET-UP PROCEDURE:

The filter tester used in this procedure was a TSI® CERTITEST® Model 8130 Automated Filter Tester. The tester is capable of efficiency measurements of up to 99.999%. It produces a particle size distribution with a count median diameter of $0.075 \pm 0.020 \mu\text{m}$ and a standard geometric deviation not exceeding $1.86 \mu\text{m}$ as determined with a scanning mobility particle sizer (SMPS). The geometric mean diameter is approximately $0.3 \mu\text{m}$, which is found to be the most penetrating aerosol size.

The filter tester was filled with a 2% NaCl solution. The power was turned on to the filter tester, heater, and neutralizer and allowed a minimum warm-up time of 30 minutes. The main regulator pressure was set to 75 ± 5 pounds per square inch (psi). The filter holder regulator pressure, which controls the amount of clamping force that is applied to the test sample, was set to approximately 25 psi. The NaCl aerosol generator pressure was set to approximately 40 psi and the make-up air flow rate was set to approximately 70 L/min.

With the filter holder empty the transducer and photometer zeros, the aerosol concentration level, and the photometer correlation factor (CF) were checked and determined to be acceptable. The CF is used to correlate upstream photometer measurements with those made downstream.

FILTER TEST PROCEDURE:

A flatsheet sample was placed into the 81 cm^2 sample holder and the NaCl aerosol was passed through the specimen at a flow rate of $85.0 \pm 2 \text{ L/min}$ (3.0 cubic feet per minute). The percent filtration efficiency value for each sample and the pressure differential across the sample was determined.

A reference material was tested before and after every test set to verify the test system was within acceptable control limits.

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RESULTS:

The results for the aerosol test are summarized in Tables 1-3. The percent filtration efficiency value and the pressure differential values are provided.

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Quality Assurance Reviewer

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Karl Perkes, B.S. RM(NRM)
Study Director

11 Nov 2002

Study Completion Date

spw

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Sodium Chloride (NaCl) Aerosol Test
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TABLE 1. Results of Sodium Chloride Aerosol Test
ICM-000-0014 ULPA Filter Media, Gore Part #D30255 Rev. 3

SAMPLE IDENTIFICATION	FLOW RATE (Lpm)	AIRFLOW RESISTANCE (mm H ₂ O)	FILTRATION EFFICIENCY (%)
1	85.0	>151.1*	99.999

* The resistance value is reported as an estimate, since the sample exceeds the detection limit of the filter tester.

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Sodium Chloride (NaCl) Aerosol Test
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TABLE 2. Results of Sodium Chloride Aerosol Test
ICM-000-0014 ULPA Filter Media, Gore Part #D30255 Rev. 3

SAMPLE IDENTIFICATION	FLOW RATE (Lpm)	AIRFLOW RESISTANCE (mm H ₂ O)	FILTRATION EFFICIENCY (%)
2	85.2	>151.1*	99.999

* The resistance value is reported as an estimate, since the sample exceeds the detection limit of the filter tester.

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TABLE 3. Results of Sodium Chloride Aerosol Test
ICM-000-0014 ULPA Filter Media, Gore Part #D30255 Rev. 3

SAMPLE IDENTIFICATION	FLOW RATE (Lpm)	AIRFLOW RESISTANCE (mm H ₂ O)	FILTRATION EFFICIENCY (%)
3	85.0	>150.9*	>99.999

* The resistance value is reported as an estimate, since the sample exceeds the detection limit of the filter tester.



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