ViriMASK™

ViriMASK, Ltd. Document Control

06 April 2020

Document:

Release of ViriMASK, Ltd. Final Testing Report for testing to ASTM F 2100 standards.

Terms:

- ASTM, ASTM International (formerly the American Society for Testing and Materials, is an international standards organization that develops and publishes voluntary consensus technical standards.
- ASTM F 2100 Standard Specification for Performance of Materials Used in Medical Face Masks. https://www.astm.org/Standards/F2100.htm

Summary:

The ASTM F 2100 Standard Specifications are recognized by the US Food and Drug Administration (FDA) and other international bodies for evaluation of protective face masks.

Results:

Physical tests were performed to assess the main criteria for filters and masks. The penetration test and the Differential Pressure test have both shown results that are equivalent or better than the highest standard protective devices available, using tests conforming to the NIOSH and EN standards.

Flammability test and synthetic blood test were performed in a modified method and should only be used as indication, pending formal tests results from Nelson Laboratory.

We did not perform NaCl penetration tests, nor did we conduct bio-compatibility and bio-burden tests which are being performed by external laboratories.

We have not performed tests of the eye protection capabilities of ViriMASK. And Fit-tests are planned with a focus group of healthcare providers of both genders.

For more information, contact info@virimask.com

ViriMASK™

April 15, 2020

Tirat Carmel Research and Quality Control Laboratory
4 Etgar Street, Tirat Carmel
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Summary: Tests performed on ViriMASK HEPA H14 filters 11-14 April 2020.

Objectives: Perform standard tests on production line ViriMASK Filters according to standard procedures and regulations.

Outline:

1. Executive Summary
2. Filter components and construction
3. Laboratory equipment and tools
4. Differential pressure test
5. Particles Penetration test
6. Liquid penetration test
7. Flammability test
8. Effects of water immersion on filter
9. Comparison with other masks and filters
10. Summary and Conclusions

Acknowledgements: Tests were performed by Prof. Noam Gavriely (Pulmonary Physiology and Biomedical Engineering).

Disclosure: Gavriely is the Founder and stakeholder in ViriMASK Ltd.

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1, Executive Summary

The ViriMASK™ is a unique protective oculo-respirator device that is designed to prevent small particles such as viruses from penetrating into the patient's mucus membranes and the respiratory tract. It is also designed to prevent particles emitted by the wearer from being spread to the environment since its filter operates in both inhalation and exhalation direction. The ViriMASK™ uses pleated H14 HEPA filter material which is for limited time use, while the mask itself is durable. The mask is fitting snugly around the mouth/nose area and (separately) around the eyes using 5 adjustable straps. Each filter is supplied with a special cover that facilitates an efficient fit-test of the mask with no leak around its perimeter.

The tests described here were conducted in our Tirat Carmel Research and QC laboratory to test the main physical characteristics of the ViriMASK™ filter. External independent tests are being carried out, in parallel, at Nelson Laboratories in Salt Lake City, USA, and will be reported by Nelson Labs separately.

Our tests are summarized as follows.

The results indicate low differential pressure of 70 Pascal per L/s flow (0.7 cmH2O/L/s) and no particles penetration in the range of 0.3 – 10.0 Micron at a flow of 6 L/s. Flammability test indicate Class II or better. Liquid penetration test (i.e. "synthetic blood") shows no penetration of liquid through the filter over time. The water-immersion test (not a formal standard test) indicated that the filter changed its physical properties by immersing it in water (lower flow resistance, lighter weight by 10%) and as such washing / rinsing the filter in water is contra-indicated.

Test Performed	ViriMASK Results
Differential pressure test	70 Pascal per L/s flow (0.7 cmH2O/L/s)
Particles Penetration test	no particles penetration in the range of 0.3 – 10.0 Micron at a flow of 6 L/s.
Liquid penetration test	no penetration of liquid through the filter over time.
Flammability test	test indicates Class II or better
Effects of water immersion on filter (not a formal standard test)	filter physical properties changed by immersion in water (lower flow resistance, lighter weight by 10%). Unlike the ViriMASK frame & visor, washing the filter is contra-indicated.

Please contact Noam Gavriely MD, DSc, at Info@virimask.com for clarifications.

2. Filter components and construction

The VM filter consists of a pleated HEPA H14 "cake" and polypropylene housing. The cake snuggly fits into the housing and is sealed inside as shown in the figures below.

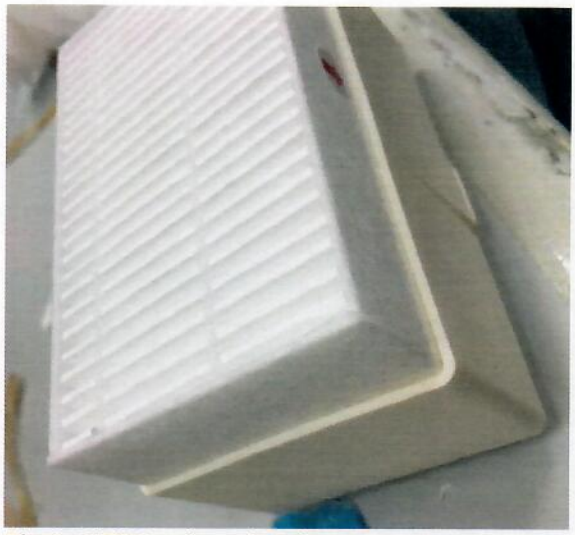
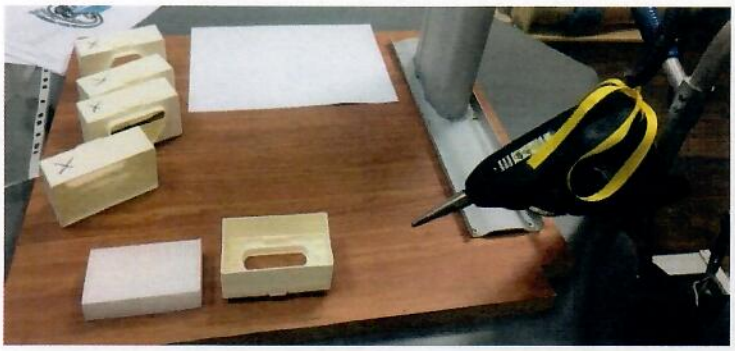
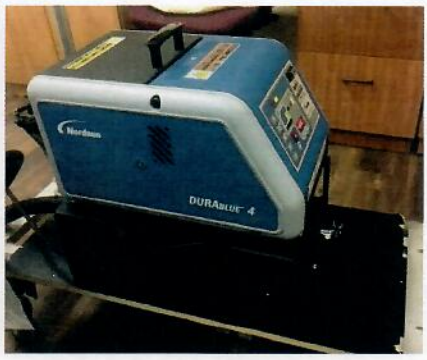


Fig 1. HEPA cake, showing snug fit.

Fig 2. Sealing material to receive cake.

The sealing is accomplished with a powered injector shown in the figures below. The factory will use multiple injectors to reach its required capacity.



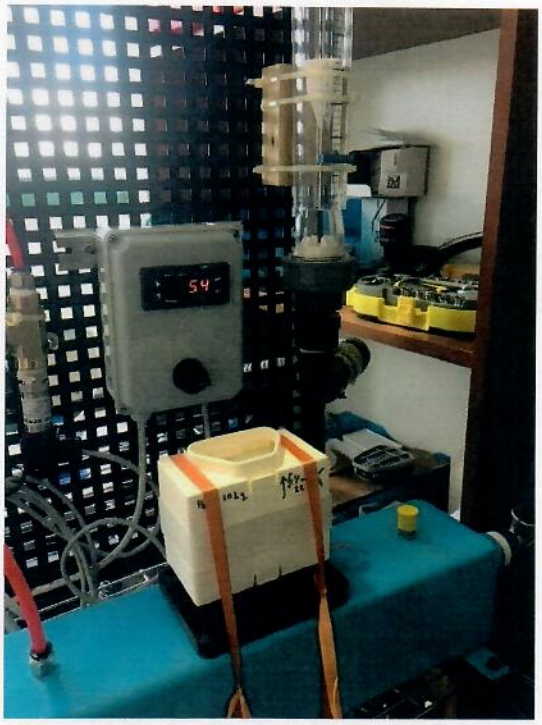


The sealing of the HEPA inside the filter housing is critical to ensure ultimate filtration of the inhaled and exhaled air, so that no air passes between cake and housing. As such, our standard of operation requires 100% seal QC testing of all filters.

This document describes the tests required by the regulatory authorities (EN (Eu; CE), FDA and NIOSH) and how they were performed. The in-process QC test is a subset of the regulatory validation tests.

3, Laboratory equipment and tools

The Tirat Carmel Testing Laboratory was designed to meet Scientific standards as used in Physiological and Biomedical research. The tests do not deem to be official or accredited, and should be viewed as such. Tests by an outside independent laboratory (Nelson Labs) are being conducted in their facility in Salt Lake City, USA.

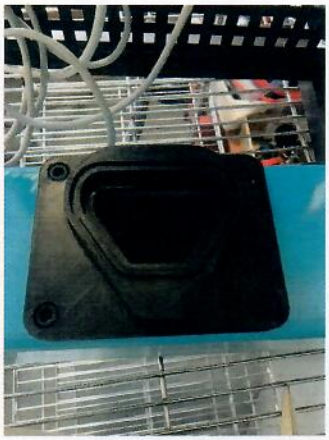


Lab equipment

- Bench-top filter-mounting jig
- Variable Flow airflow pump
- Calibrated Flow meter
- Pressure sensor
- Filter mounting jig
- Particles counter

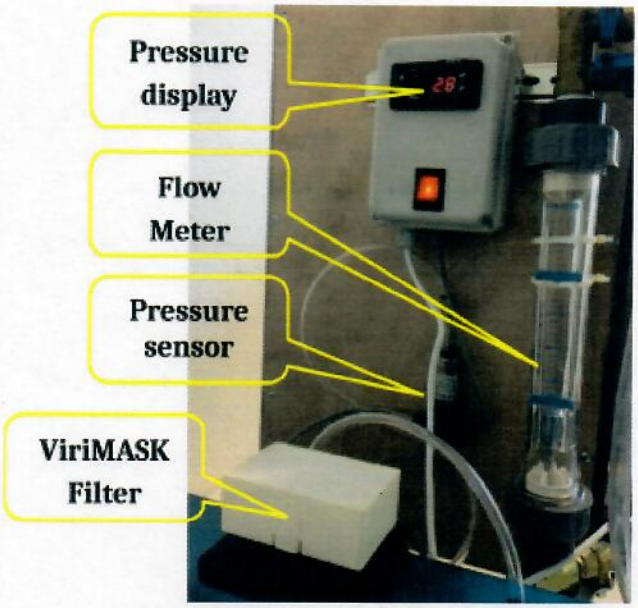
Filter mounting Jig

The filter-mounting jig (right) is a 3D printed receptacle of the size and shape of the filter female receptacle in the VM Mask (picture, bottom). The filter's semi-trapezial protrusion fits snuggly into the receptacle, and when pressed down it forms an air-tight connection with it (filter shown between jig & receptacle in picture at right).



4, Differential pressure test - System overview and calculation of resistance

The pressure-flow measuring system measures the resistance to airflow R of the filter cake by measuring the pressure drop ΔP for any given flow F, where ΔP is equal to the measured pressure inside the table-top chamber with the filter P_{filt} minus the baseline pressure measured in the absence of the filter P_0 so that:



$$\Delta P = P_{filt} - P_0$$

And

$$\mathbf{R = \Delta P / F = (P_{filt} - P_0) / F}$$

For example, at flow

$F = 22\ m^3/h$

$F = 22{,}000 / 3600 = 6.1\ L/s$

The measured pressure without the filter P_0 is 1.3 mBar (or cmH2O) and with the filter the pressure P_{filt} is 5.4 mBar and the resistance R is equal to

$R = (5.4 - 1.3) / 6.1 = 4.1 / 6.1 =$ **0.67 mBar / L / s**

Airflow pump
We use an Ametek® Windjammer Pro blower that generates steady flow from 0.5 to 6.5 L/sec. Air temperature may be up to 4^0C above ambient temperature during continuous operation.

Flow meter
Flow is measured using a float air-flow meter (at right) using a stainless steel float calibrated at 6-60 M^3/h and a Teflon float calibrated at 3-30 M^3/h ATPD.

Pressure measurements

We measured the pressure with a linear BD Sensor, Model 18-601 G 0-100 mBar with a digital readout display (lower right). We verified the pressure readings using a water manometer (U-tube) as well as a mechanical Gauge (Cugell Labs). The pressure resolution is validated to 0.1 mBar.

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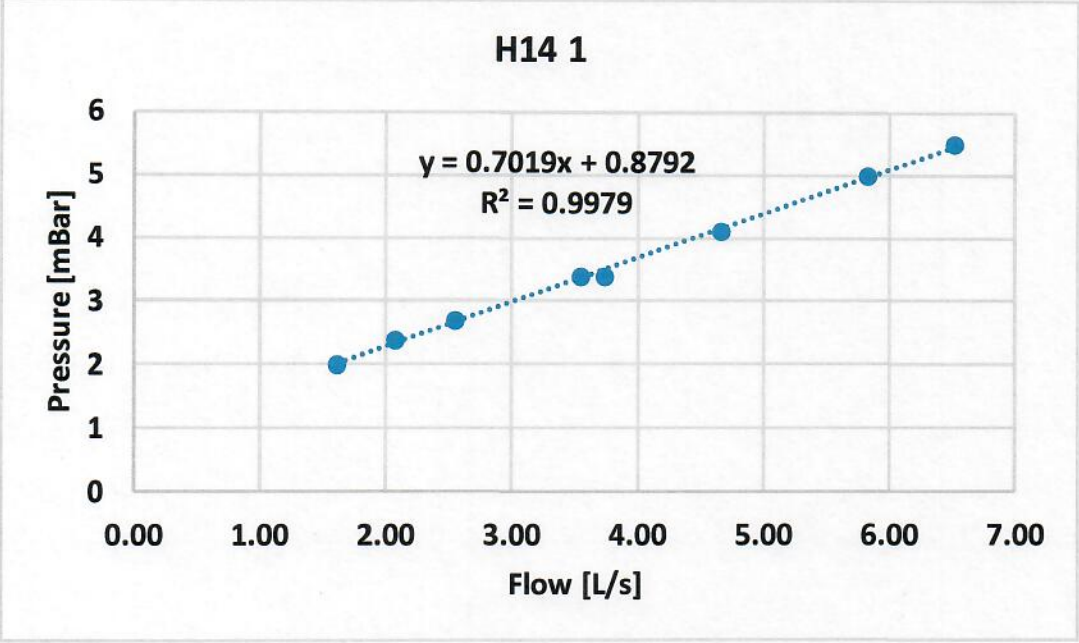
- **Differential pressure test**

HEPA H14 filter pressure test, Sample #1.

Graph shows the measured pressure at a range of flows. The data are plotted as Pfilt (i.e. before removing P_0)

Note:

1. Linear relationships with $R^2 = 0.998$ (i.e. flow is laminar)
2. Slope is 0.70 mBar (cm H2O) per L/s
3. Intercept at 0.88 cmH2O which is the pressure with no filter (P_0)



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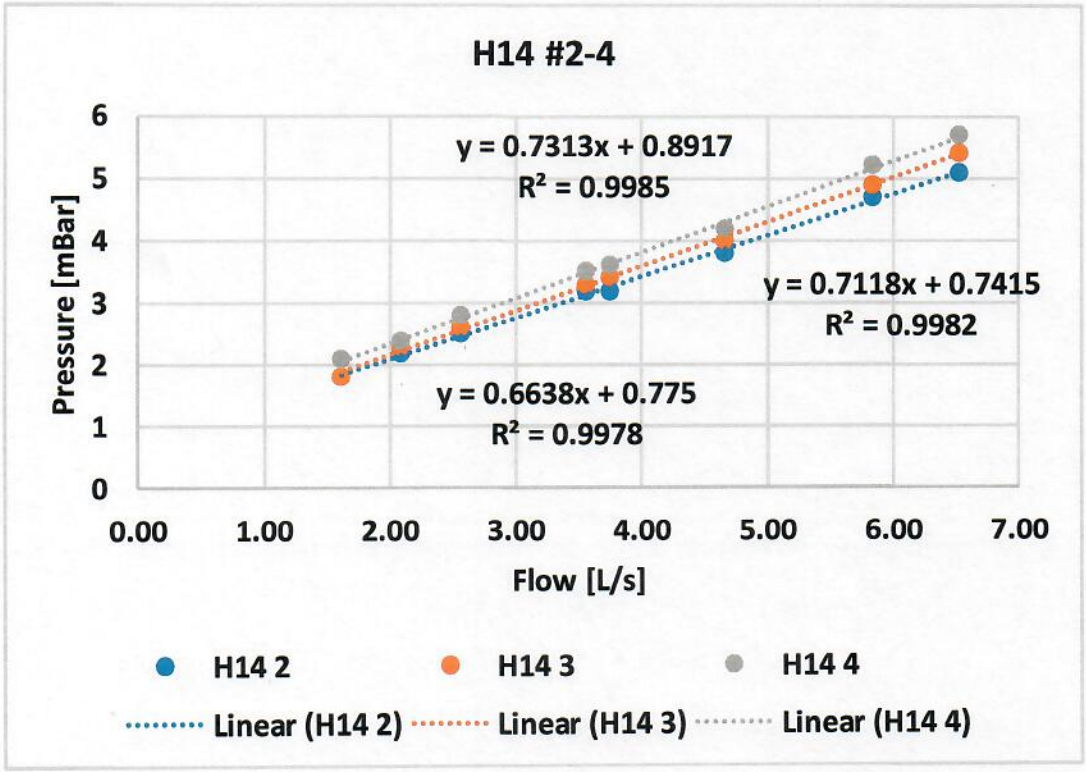
HEPA H14 additional filters (#2 to #4) pressure tests.

Graph shows the pressure measured at a range of flows.

Note:

1. Linear relationships; all R^2 values are ~0.998 (i.e. laminar flow)
2. Average Slope is 0.702 mBar (cm H2O) per L/s
3. Average Intercept at 0.814 cmH2O which is the pressure with no filter
4. We measured Pfilt of 100 filters. The average was 5.3 mBar at 6.1 L/s with SD of 0.2. **we consider any filter with Pfilt < 5.3 – 2*SD = 4.9 mBar as potentially defective and it is discarded**.



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5, Particles Penetration Test

We use a Nord-Ex NE-PC2020 Clean Room particle counter (https://www.exdron.co.il/images/Products/files/Nord-Ex-Cleanroom-Particle-Counter-PC2020-datasheet.pdf). The device contains an internal sampling pump at 2.8 l/min and has 6 particles size channels from 0.3 to 10 µm.

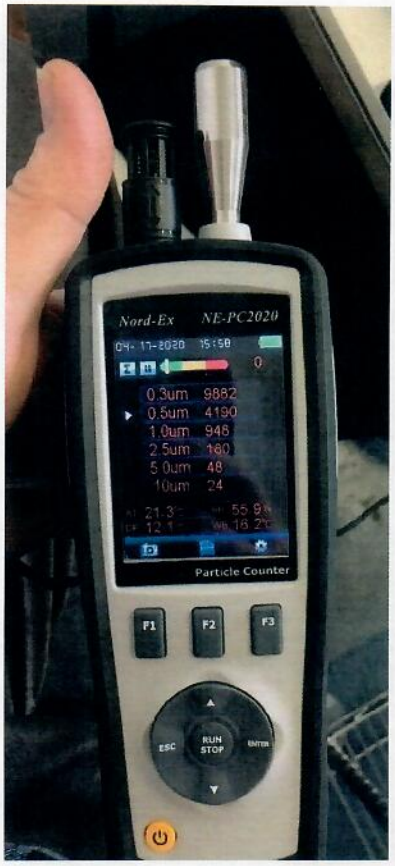
Particle Counter	**NE-PC2020**
Channel	0.3, 0.5, 1.0, 2.5, 5.0, 10µm
Flow Rate	0.1ft3(2.83L/min) controlled by internal pump
Count Modes	Totalize, Concentration, Audio
Coincidence Loss	5%, 2000000 particles per ft3

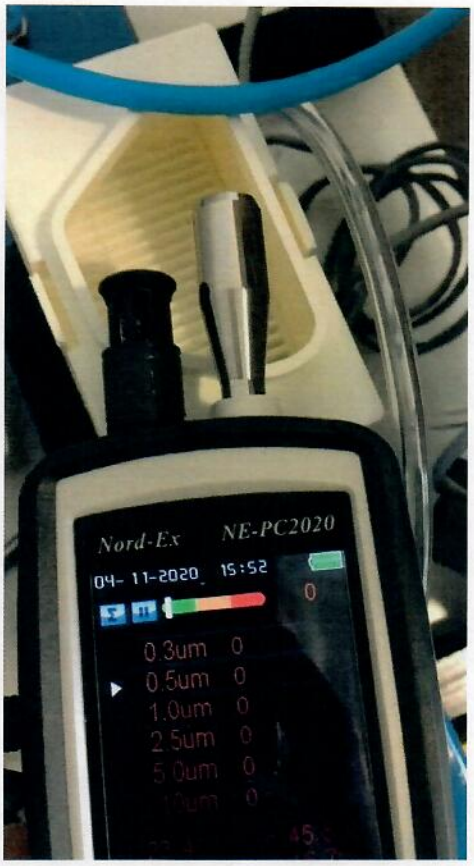
Typical ambient levels (left picture) counts during 20 seconds sampling are:

~10,000 0.3µm particles; ~4,000 0.5µm particles; ~1,000 1.0µm particles; and 200, 50, 25 particles at 2.5, 5 and 10 microns, respectively.

The device also measures temperature (ºC), relative humidity (RH%) and dew point (DP ºC).

The number of particles found after filtration with Pleated HEPA H14 filter were essentially zero (right picture).





5, continued, Tests Results for Particles Penetration Test

In order to stress the system to maximum We used high flow of 20-22 M^3/h (~6 L/s). This flow rate is significantly higher than in standard tests (NIOSH standard is 85 L/min =~1.5 L/s). The flow was partially filtered at the pump level with a particles load about 4-5 times less than in ambient air (see table below. Four HEPA H14 filters were tested, 2 times each. The results are shown below.

		particles size [micron]							
time	Status	0.3	0.5	1	2.5	5	10	Temp C	RH %
15:16	ambient air	13484	4537	676	166	44	29	22	65.3
15:18	ambient air	14010	4570	702	118	38	13	22	65.3
15:21	22m^3/h no HEPA	2372	416	43	11	3	3	22	65.3
15:24	22m^3/h no HEPA	2566	710	129	11	5	6	22	65.3
15:26	20m^3/h HEPA H14 samp #1	0	0	0	0	0	0	22	65.3
15:28	20m^3/h HEPA H14 samp #2	0	0	0	0	0	0	22	65.3
15:30	20m^3/h HEPA H14 samp #3	0	0	0	0	0	0	22	65.3
15:51	20m^3/h HEPA H14 samp #4	0	0	0	0	0	0	22	65.3
15:26	20m^3/h HEPA H14 samp #1	0	0	0	0	0	0	22	65.3
15:28	20m^3/h HEPA H14 samp #2	0	0	0	0	0	0	22	65.3
15:30	20m^3/h HEPA H14 samp #3	0	0	0	0	0	0	22	65.3
15:51	20m^3/h HEPA H14 samp #4	0	0	0	0	0	0	22	65.3

Conclusion: no particles penetrated through the filters.

Critique: The particles load may not have been high enough to identify a very small statistical penetration rate, and so it appears that the filter is 100% blocking. Also, the smallest particles identified by our measuring device are 0.3 Micron. We are not able to separately measure smaller particles in our TC laboratory.

6, Liquid penetration test

This is a modified "synthetic blood" splash test where normally 2 cc of blood-like fluid are squirted on the filter at a velocity corresponding to a 160 mmHg of blood pressure (= 1.36 X 160 = 218 cmH2O). Our test was performed from only 50 cm height, so it is not a real substitute to the official accredited lab test. However, we allowed the liquid to sit on the filter. The photographs below show that after 20 minutes of sitting on the filter (top pictures), the bottom side of the filter was not wet (bottom left picture).

7, Flammability test

Four VM Filters (Polypropylene housing + Pleated HEPA H14) were incinerated over intense open fire (bottom photographs).
In all tests, filters did not catch fire for at least 30 sec (top photograph).

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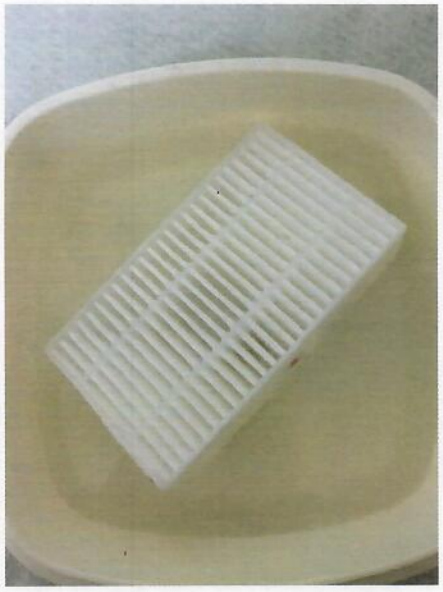
Rinsed HEPA pressure test

HEPA filter was immersed in tap water for 120 sec. Dried in room air overnight.

No visible changes.

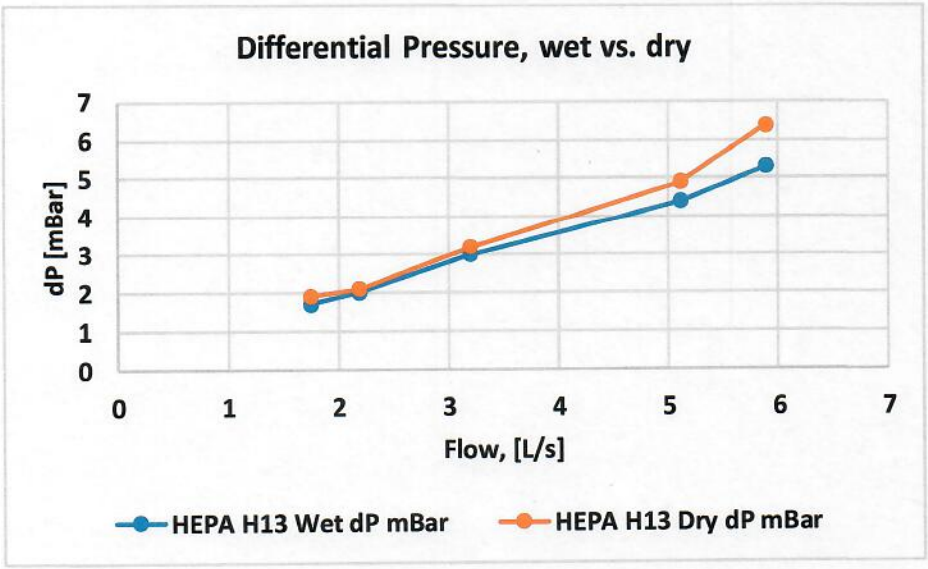
Weight before wetting 22g, weight after drying 20g.

See pressure drop (dP) before and after wetting below.



Conclusion: filter should not be washed in water

- Note, wetted HEPA dP is lower than in dry control.
- This means lower resistance. A substance was apparently washed away by rinsing.



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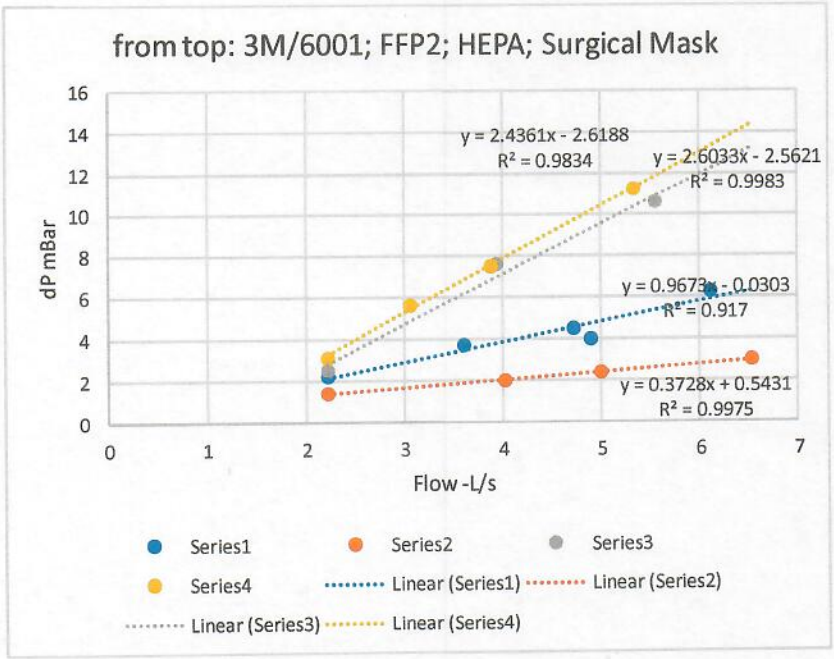
Pressure tests, other filters

The following filters/ masks were tested:

Yellow: 3M 6001; Gray: FFP2; Blue: Pleated HEPA H14 (different manufacturer); Orange: Surgical Facemask.

- HEPA H14 (different manufacturer) in VM Filter housing: 0.97 mBar/L/sec
- Surgical mask: 0.37 mBar/L/sec
- 3M 6001: 2.44 mBar/L/sec

  (if 2 are used in parallel, then 1.22 mBar/L/sec
- FFP2 (N95): 2.60 mBar/L/sec



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