Technical Report

Filtration Efficiency of the Pall Ultipor® 50 for SARS-CoV-2

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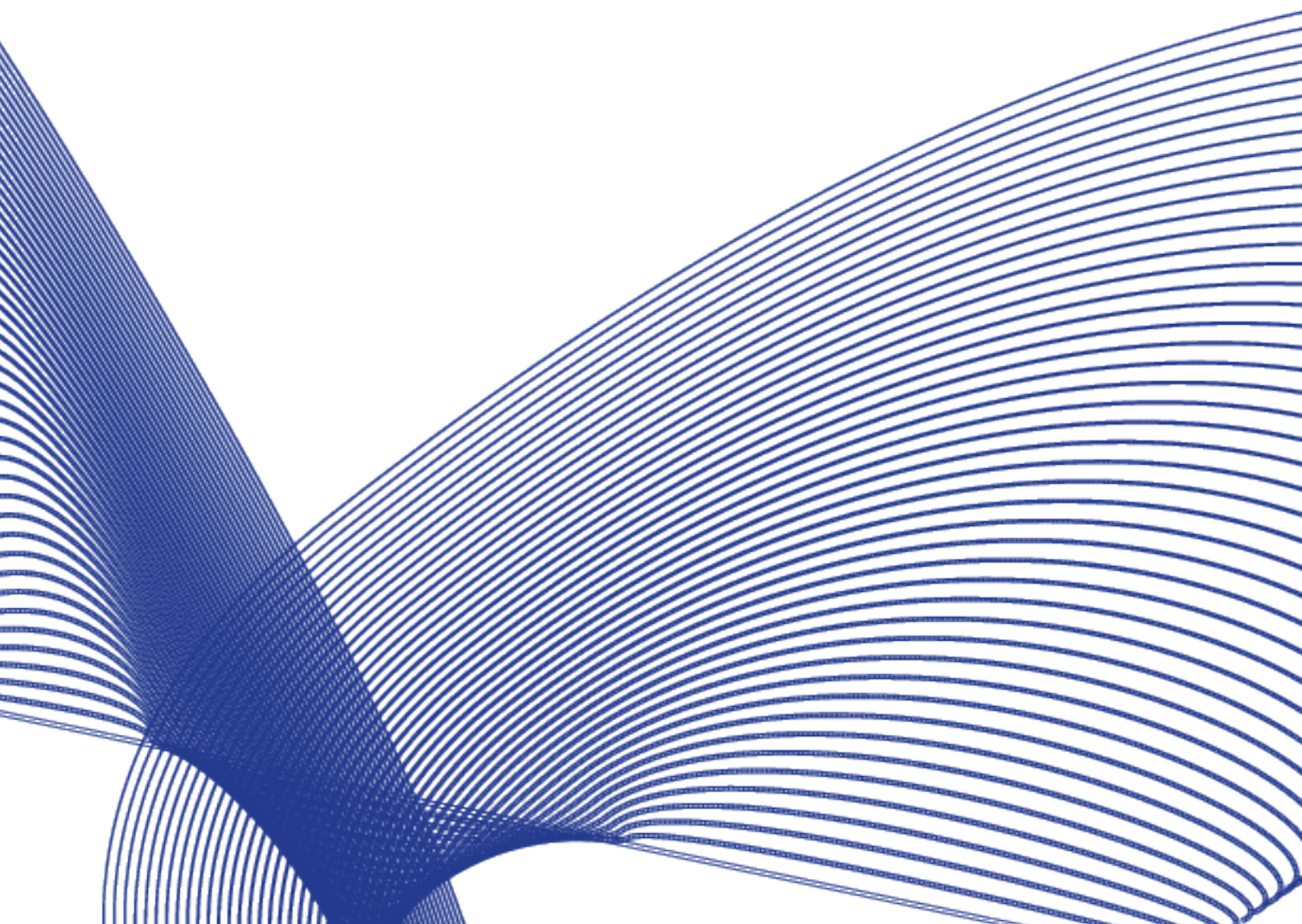

1 Introduction

In early December 2019, the first pneumonia cases of unknown origin were identified in Wuhan, the capital city of Hubei province[1]. The pathogen was identified as a novel enveloped RNA beta-coronavirus which currently is named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Patients with the infection were documented both in hospitals and in family settings.

The World Health Organization (WHO) subsequently declared coronavirus disease 2019 (COVID-19) a public health emergency of international concern, i.e. the state of pandemic.

The SARS-CoV-2 pandemic has been and still is a big challenge for modern medicine. Today more than 160 million cases and 3 million deaths have been registered by the WHO, about 5 % of patients have been hospitalized in Intensive care with 2.3 % requiring mechanical ventilation.

Transmission of the SARS-CoV-2 virus is primarily respiratory in nature. The virion is around 120 nanometers in diameter (60–140 nm), and is transmitted in aerosols, which are generated during breathing, coughing, sneezing, speaking and in the medical setting also during aerosol generating procedures associated to mechanical ventilation and respective care of ventilated patients[2]. Virus containing droplets have been shown to be as big as 20 µm in diameter, but the virus may also be transmitted via aerosols, which are less than 5-10 µm size[3].

There is hardly any information about the number of virus particles exhaled by spontaneously breathing or ventilated patients. Numbers can be expected to vary with breathing manoeuvres and ventilation modes and patterns. One study investigated seasonal coronavirus infected patients exhaled and found that up to 200,000 virus particles were coughed-out per hour[4] (approximately 3.3 x10^3 per minute).

The Pall Ultipor 50 has been tested for filtration efficiency in accordance with ISO 23328-1:2003 Breathing System Filters for anaesthetic and respiratory use Part 1: salt test method to assess filtration performance which is the only international standard for breathing circuit filter performance testing and uses Sodium Chloride particles of the most penetrating size, 0.1 µm to 0.3 µm as the test agent with an efficiency of approx. 99.98 % when dry and approx. 99.99 % when conditioned for 24 hours. Additionally, Ultipor 50 has been subjected to testing with monodispersed bacterial (*Brevundimonas diminuta*) and viral (MS-2 coliphage) organisms that represent gold standards for airborne filtration efficiency testing and shown to have > 99.999 % and > 99.995 % efficiency respectively.

Coronavirus species have a single stranded RNA and their size ranges from 120 nm to 160 nm which is considerably larger than the 27 nm MS2 Coliphage. Based on the size of the SARS-CoV-2 there would be no reason to expect that Pall Breathing Circuit Filters would not be effective with regard to the passage of SARS-CoV-2, however, this study tested the filtration efficiency of Pall Ultipor 50 using Sars-CoV-2 Heat inactivated 2019 Novel Coronavirus in droplets of approximately 3 µm using the principles of ASTM F2101[5] and EN 14683:2019[6].

2 Materials and Methods

Pall Ultipor 50 were analyzed for their ability to retain aerosolized heat inactivated 2019 Novel Coronavirus (SARS-CoV-2) Isolate USA-WA1/2020.

The test apparatus (Figure 1) consisted of an aerosol nebulizer which produced 3 µm aerosol droplets, as required by EN 14683:2019 (Medical Face Masks) connected to the patient side of the Ultipor 50 and an Andersen cascade impactor downstream of the Ultipor 50. A vacuum pump was used to pull the viral aerosol through an Andersen Cascade Impactor at 28 L/min.

The presence of the viral challenge on the Andersen impactor (with or without the Pall Ultipor 50 between the nebulizer and the Andersen impactor) was determined by swabbing the Andersen cascade impactor, extraction and RT-PCR.

Efficiency of the test apparatus and loss of the viral challenge to the system was evaluated by running the apparatus without the Pall Ultipor 50 between the nebulizer and the Andersen impactor.

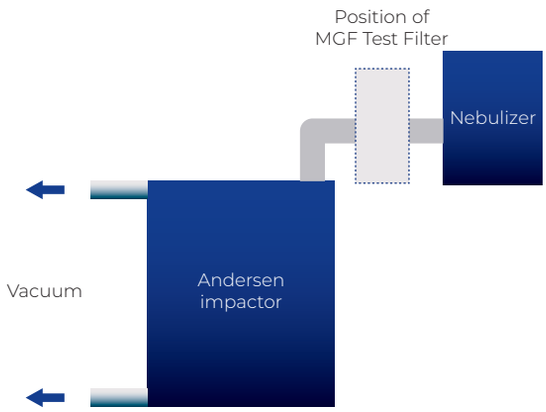

Figure 1: Diagrammatic representation of the test apparatus

3 Results

SARS-CoV-2 test apparatus detection efficiency

Table 1 shows the total viral challenge nebulized through the test apparatus without a filter in place and the viral load detectable on the downstream Andersen impactor and log_{10} loss to the apparatus. This data shows that without a Pall Ultipor 50 in place the viral challenge is detectable on the Andersen impactor with a loss to the apparatus of approx. 1.11 Log_{10}.

Table 1: Total SARS-CoV-2 challenge from the nebulizer and viral load detected on the Andersen Impactor

Challenge viral load (Log_{10} genomic copies)	Impactor recovery (Log_{10} genomic copies)	Log_{10} loss to rig
1.15×10^{10} (10.06)	1.02×10^{9} (9.01)	1.05
3.82×10^{10} (10.58)	4.80×10^{9} (9.68)	0.9
5.16×10^{10} (10.71)	4.00×10^{9} (9.60)	1.11

SARS-CoV-2 nebulization challenge of the Pall Ultipor 50

Table 2 shows the actual viral challenge (nebulized viral challenge - 1.11 Log_{10} loss to the apparatus) and the SARS-CoV-2 viral load detected on the Andersen impactor downstream of the Pall Ultipor 50. The Pall Ultipor 50 filter efficiency for removal of the SARS-CoV-2 aerosol challenge is shown as percentage reduction and Log_{10} reduction.

Table 2: Pall Ultipor 50 SARS-CoV-2 Challenge results

Filter	Corrected Viral challenge (Log_{10} genomic copies	Viral recovery downstream of Ultipor 50 (Log_{10} genomic copies)	Virus Filtration Efficiency %	Log_{10} reduction
1	3.47×10^9 (9.54)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 6.24
2	3.50×10^9 (9.51)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 6.21
3	2.69×10^9 (9.43)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 6.13
4	2.75×10^9 (9.44)	$< 2 \times 10^3$ (< 3.30)	> 99.999	>6.14
5	1.10×10^9 (9.04)	2.44×10^3 (3.39)	> 99.999	5.14
6	2.04×10^9 (9.31)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 6.01
7	8.32×10^8 (8.92)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.62
8	7.76×10^8 (8.89)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.59
9	1.07×10^9 (9.03)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.73
10	8.71×10^8 (8.94)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.64
11	1.00×10^9 (9.00)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.70
12	4.47×10^8 (8.65)	2.02×10^3 (3.31)	> 99.999	5.34
13	6.17×10^8 (8.79)	2.06×10^3 (3.31)	> 99.999	5.48
14	5.62×10^8 (8.75)	$< 2 \times 10^3$ (<3.30)	> 99.999	> 5.45
15	2.45×10^9 ()	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.58
16	6.31×10^9 ()	2.16×10^3 (3.33)	> 99.999	5.47
17	8.91×10^8 (8.95)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.65
18	1.45×10^9 (9.16)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.86
19	2.09×10^9 (9.32)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 6.02
20	1.86×10^9 (9.27)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.97
21	7.24×10^9 (8.86)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.56
22	9.77×10^8 (8.99)	$< 2 \times 10^3$ (< 3.30)	> 99.999	> 5.69

If no RT-PCR signal was detected, $< 2 \times 10^3$ (<3.3 Log_{10}) was reported.

4 Conclusions

Pall Ultipor 50 were tested for their ability to retain a challenge of aerosolized heat inactivated SARS-CoV-2. The data presented here showed that the Pall Ultipor 50 is able to retain > 99.999 % of SARS-CoV-2 when challenged with > 10^8 genomic copies, equivalent to a more than 5 Log_{10} reduction.

5 References

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5. ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
6. EN 14683 :2019 Medical Face Masks – Requirements and test methods

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