Technical Report

Testing of the Pall Ultipor® 55 for the retention of aerosolized bacteria and viruses and the penetration of NaCl particles to ISO 23328-1:2003

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1 Summary

The Pall Ultipor 55 (reorder code U55) is a highly efficient, single-use bacterial/viral filter for use at patient end or machine end applications in breathing systems for the protection of patient, staff, equipment and the environment. It is also a heat and moisture exchanger when used in patient end applications.

The purpose of this study was to test the Pall Ultipor 55* for the retention of aerosolized bacteria and viruses and 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”. The ISO 23328-1 standard is the only international standard for breathing system filter performance testing. It uses sodium chloride particles of the most penetrating size (0.1 µm to 0.3 µm) as the test agent.

The 5 Pall Ultipor 55 tested showed filtration efficiencies of > 99.96 % unconditioned and > 99.99 % following conditioning on a ventilated artificial patient for 24 hours when tested as per ISO 23328-1 for retention of NaCl.

In addition to the ISO 23328-1:2003 performance evaluation the Pall Ultipor 55 were tested for retention of monodispersed, aerosolized bacterial and viral challenges. The organisms used (*Brevundimonas diminuta* and MS-2 bacteriophage) represent gold standards for airborne filtration efficiency testing. The testing was carried out using an apparatus designed to produce a monodispersed bacterial/viral challenge, i.e. a “dry” bacterial and viral aerosol in which the organisms are no longer presented in a droplet allowing test of a filter with bacterial and viral particles of known size.

Challenge of 5 unconditioned Pall Ultipor 55 with monodispersed *B. diminuta* or MS-2 bacteriophage showed retention of > 99.999 % and > 99.995 % respectively.

2 Materials and Methods

Pall Ultipor 55 Breathing System Filters were analyzed for filtration performance as per ISO 23328-1 and for their ability to retain monodispersed aerosolized *B. diminuta* and MS-2 bacteriophage.

For testing as per ISO 23328-1 the conditioning system consisted of a patient model (humidity generator connected to a ventilator), which was maintained at 37 ± 1 °C. The breathing parameters were set at a tidal volume of 500 mL per filter, breathing frequency of 15 breaths/min and equal inspiratory and expiratory times (1:1 ratio).

The filter was positioned in accordance with ISO 23328-1 at position “A” (Figure 1), with an inspiratory limb humidity generator attached. The salt aerosol challenge was carried out on a TSI® CERTITEST® Model 8130 Automated Filter Tester within five minutes of the filters’ removal from the conditioning rig.

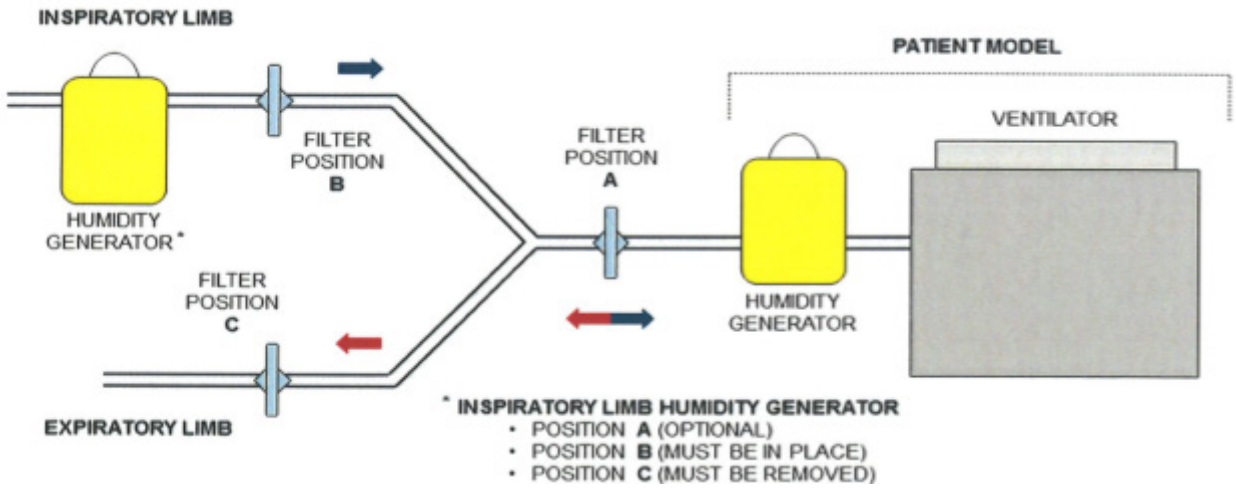


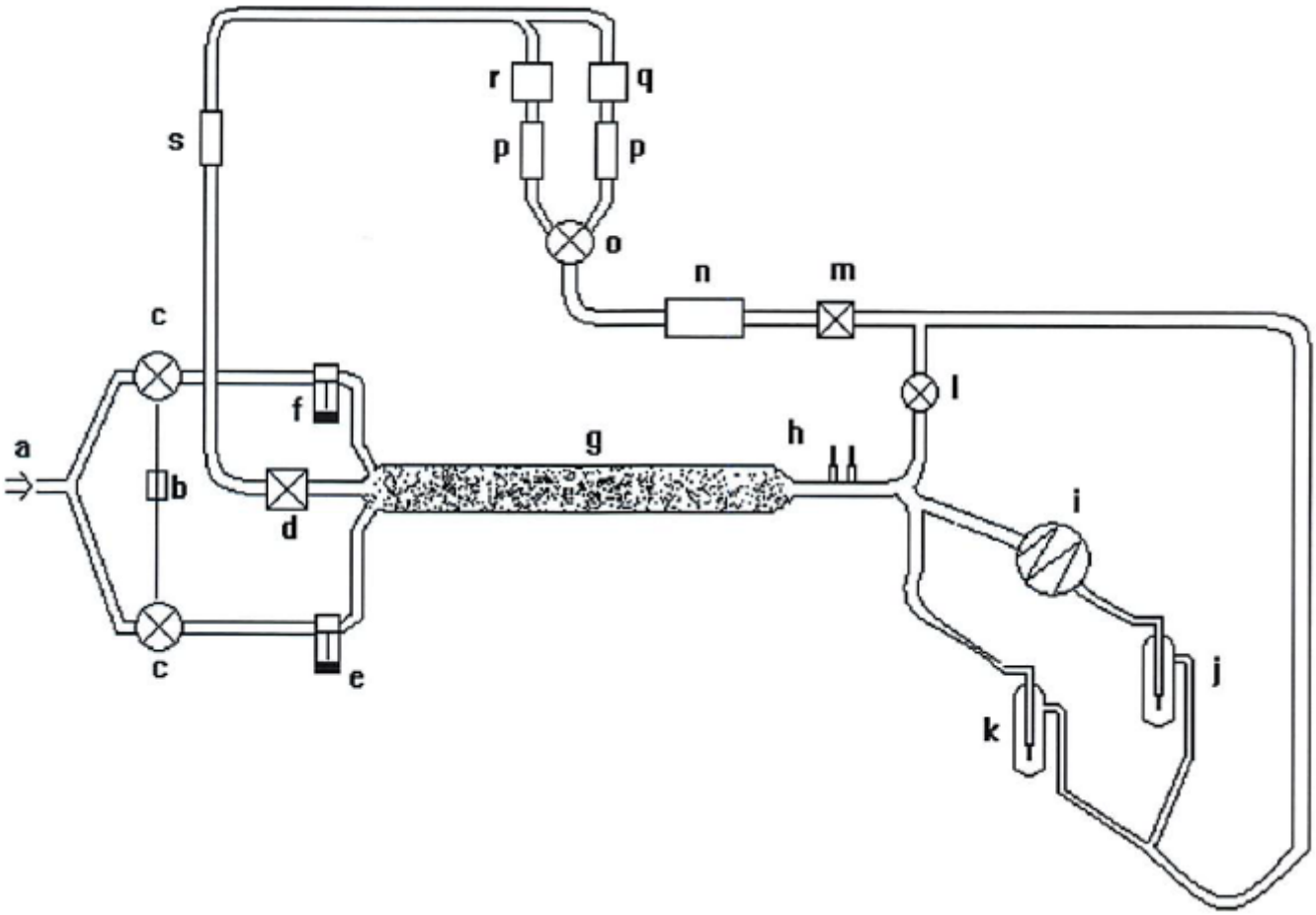
Figure 1. ISO 23328-1 Conditioning Parameters

* Testing was carried out with the European variant of the U55, which is identical in shape, filter media and other materials of construction.

Pall Ultipor 55 were also analyzed for their ability to retain monodispersed, aerosolized *B. diminuta* and MS-2 bacteriophage on an apparatus based on that originally developed by Henderson and Druett. During microbial testing, the test filter was placed into the apparatus shown in Figure 2.

The monodispersed *B. diminuta* (NCIMB 11091, ATCC 19146) or MS-2 bacteriophage (NCIMB 10108) aerosol challenge was generated using a Collison spray (Figure 2, e) which was injected into an air stream flowing into a stainless steel tube (Figure 2 ,g) which generated the monodispersed microbial challenge. The humidity was maintained at approximately 94 % at a flow rate of 28 L/ minute. Two 28 L/min all glass impingers were placed upstream and downstream of the filter to give the challenge sample and filtered sample respectively (Figure 2, k and j respectively).

The efficiencies of the filters were calculated by determining the airborne concentration of viable micro-organisms in the challenge sample without the filter and the downstream filtered sample. *B. diminuta* was assayed on Tryptone Soya Agar (TSA) plates and MS-2 bacteriophage was assayed using a plaque assay on Tryptone soya broth agar using *Escherichia coli* (NCIMB 9481) as the host.



Key:

a	Compressed air	g	Spray Tube	o	Valve
b	3-Was Switch	h	Wet and Dry Thermometers	p	Flowmeters
c	Solenoid Valves	i	Filter to be Tested	q	Humidifier
d	Filter	j	Downstream Impinger	r	Drier
e	Collison Spray Containing Challenge Mircor-organisms	k	Upstream Impinger	s	Flowmeter
		l	Valve		
f	Collison Spray Containing Distilled Water	m	Filter		
		n	Compressor-Vacuum Pump		

Figure 2. Diagrammatic representation of the Microbial Filtration Test Apparatus (With kind permission of Public Health England)

3 Results

Testing to ISO 23328-1:2003 "Breathing System Filters for anesthetic and respiratory use Part 1: salt test method to assess filtration performance"

Tables 1 and 2 show the results for ISO 23328-1 testing (% particle penetration and resulting % efficiency) on unconditioned filters and 24-hour conditioned filters respectively.

Table 1. Results for unconditioned Pall Ultipor 55 tested to ISO 23328-1

Filter Number	Particle Penetration %	Filtration Efficiency %
1	0.032	99.968
2	0.021	99.979
3	0.022	99.978
4	0.024	99.976
5	0.035	99.965

Table 2. Results for 24-hour conditioned Pall Ultipor 55 tested to ISO 23328-1 in position A with inline humidifier

Filter Number	Particle Penetration %	Filtration Efficiency %
6	0.005	99.995
7	0.007	99.993
8	0.007	99.993
9	0.009	99.991
10	0.009	99.991

Challenge with aerosolized *B. diminuta* and MS-2 bacteriophage

Table 3 and Table 4 show the results from Pall Ultipor 55 with approximatley 3.6×10^8 cfu *B. diminuta* and approx. 3×10^9 pfu of MS-2 bacteriophage respectively on unconditioned filters at a flow rate of 28 L/min, titer reduction and % efficiency are shown for each.

Table 3. Titre reduction and filtration efficiency results from challenging Pall Ultipor 55 with approx. 3.6×10^8 cfu *B. diminuta*

Filter Number	Titre Reduction	Filtration Efficiency %
1	5.45×10^5	99.9998
2	2.98×10^5	99.9997
3	3.66×10^5	99.9997
4	5.45×10^5	99.9997
5	9.63×10^4	99.9990

Table 4. Titre reduction and filtration efficiency results from challenging Pall Ultipor 55 with approx. 3 x 10^9 pfu of MS-2 bacteriophage

Filter Number	Titre Reduction	Filtration Efficiency %
6	3.02 x 10^4	99.997
7	3.67 x 10^4	99.997
8	2.94 x 10^4	99.997
9	2.62 x 10^4	99.996
10	3.35 x 10^4	99.997

4 Conclusions

The Pall Ultipor 55 showed filtration efficiencies of > 99.96 % unconditioned and >99.99 % following conditioning on a ventilated artificial patient for 24 hours when tested as per ISO 23328-1 for retention of NaCl particles. Challenge of unconditioned Pall Ultipor 55 with monodispersed *B. diminuta* and MS-2 bacteriophage showed retention of > 99.999 % and > 99.995 % respectively.

The test results in this report show that the Pall Ultipor 55 pleated hydrophobic filtration media is highly retentive of bacterial, viral and particulate contamination and is unaffected by humidity, which may be present in ventilation applications.

5 References

ISO 23328-1:2003 Breathing system filters for anaesthetic and respiratory use -- Part 1: Salt test method to assess filtration performance

Henderson, D.W., 1952; An apparatus for the study of airborne infections. J. Hyg. Camb. 50:53-67

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