



Pall Kleenpak™ Water Filters (KA2IN4)

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Introduction

Pall Kleenpak Water Filters (KA2IN4) have been designed as 0.2 µm-rated liquid sterilising filters for use at high water temperatures (≤ 85 °C) and with a wide range of chemical compatibility. The filter is comprised of two layers of polyethersulphone membrane. The coarser asymmetric upstream membrane layer provides built in pre-filtration for the finer downstream sterilising grade membrane.

This product is supplied non sterile and has been validated by:

Liquid microbial challenge tests using *Brevundimonas diminuta* (ATCC 19146) using an industry standard test method for 0.2 µm sterilising grade filters

Maximum operating temperature and pressure rating testing

Typical flow rate measurements at various inlet water pressures

Product Summary

Table 1

Materials of Construction

Membrane	Hydrophilic 0.2 µm Polyethersulphone Membrane
Membrane support/drainage	Polypropylene
Capsule	Polypropylene
Endcap	Polypropylene
Cage	Polypropylene
Core	Polypropylene
Effective Filtration Area (EFA)	780 cm ²
Nominal Dimensions	Overall filter length: 190 mm
	Filter width (excluding vent port): 61 mm
	Filter width (including vent port): 94 mm



Note: Pall Kleenpak Water Filters (KA2IN4) must not be autoclaved dry.

Do not autoclave if heat labile chemical contaminants are present on the filter.

Whilst autoclaving it is important that the product is not subjected to undue weight/ load bearing on the product which can cause deformation at elevated temperatures.

Chemical Compatibility

- Continuous chlorine dioxide disinfection (up to 1 ppm ClO₂)
- Chlorine shock treatment (up to 100 ppm free chlorine for up to 1 hour at ambient temperature)
- Continuous free chlorine disinfection (up to 3 ppm at ambient temperature)
- pH 12.8 (up to 1 hour at ambient temperature)
- Commonly used surface disinfectants (iso-propyl alcohol, quaternary ammonium compounds, benzyl ammonium chlorides, iodides and non-ionic surfactants)
- Peracetic acid (up to 1000 ppm at 60 °C for up to 2 hours)

Methods

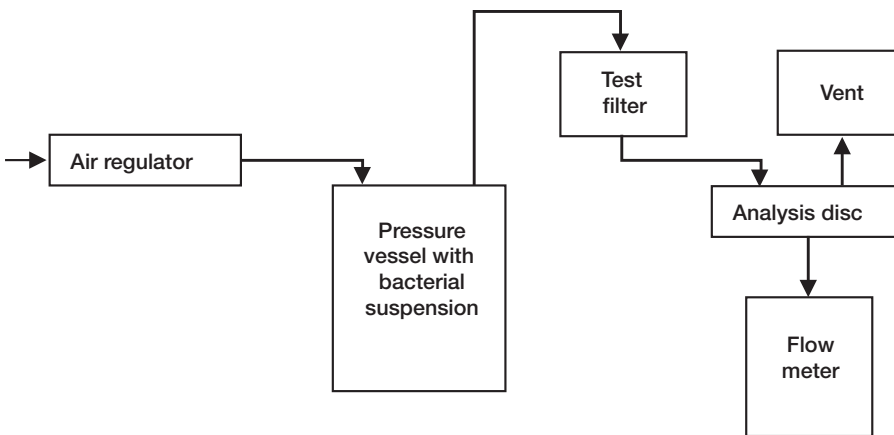
Microbial Challenge Testing for Verification of 0.2 µm Sterilising Grade Filter Performance

This method follows the principles of ASTM F838-05¹ for validating 0.2 µm sterilising grade filters. The apparatus was assembled as shown in Figure 1.

Ten filters (KA2IN4) were each subjected to a liquid microbial challenge test. The sterile pressure vessel was filled with 10 L of 0.2 µm filtered sterile deionised water. A single bolus inoculum of *Brevundimonas diminuta* (ATCC 19146) was added to the vessel and mixed thoroughly to give a challenge level of greater than or equal to 1 x 10⁷ colony forming units (CFU)/cm² of effective filtration area. This was sampled aseptically to confirm the challenge level. The complete challenge solution was passed through the test filters at 500 mL/minute and the filtrate passed through 0.2 µm analysis membrane filter discs placed in a holder downstream of the filter. The analysis membranes were incubated on Tryptone Soya Agar at 30 °C for at least 48 hours and examined for microbial growth.

Figure 1

Microbial Challenge Test Rig for Verification of Sterilising Grade Filter Performance

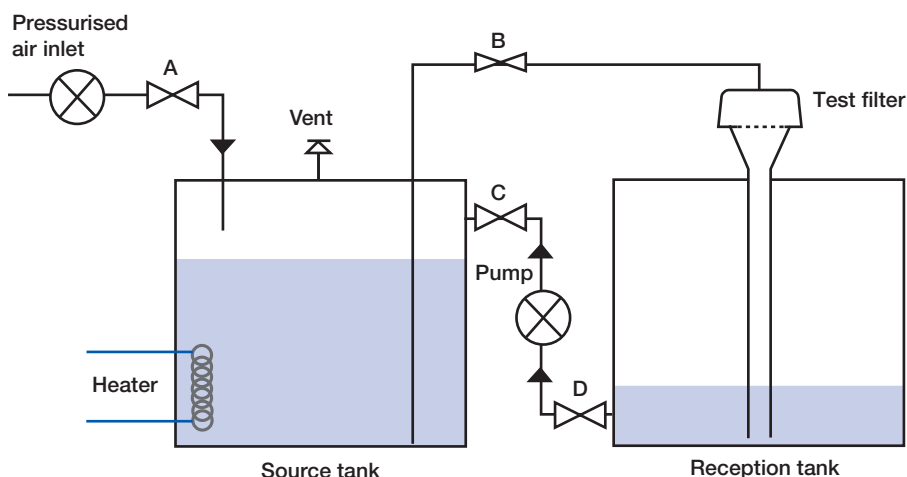


Maximum Operating Temperature and Pressure Rating

Two Pall Kleenpak Water Filters (KA2IN4) were integrity tested using the Diffusive Forward Flow non-destructive integrity test method* at an applied air pressure of 2760 mbar (40 psi) water wet and then placed into a purpose built rig designed to re-circulate hot water under high pressure in defined cycles (see Figure 2). The filters were subjected to 50 x 4 minute cycles of hot water at 85 °C and at an inlet pressure of 5 bar. Each filter was integrity tested again after the cycling was complete.

* This test is directly correlated with bacteria removal efficiency.

Figure 2
Hot Water Test Rig



Typical Flow Rates at Various Inlet Water Pressures

Three Pall Kleenpak KA2IN4 filters were subjected to water flow pressure drop as follows:

The test rig consisted of a recirculation loop containing pre-filtered de-ionised water. After a short period of recirculation to allow the system to stabilise, readings were taken of flow rate at different pressure levels (1 bar increments). Water temperature was approximately 20 °C.

Results

Microbial Challenge Testing for Verification of 0.2 µm Sterilising Grade Filter Performance

A summary of results is shown in Table 2. All analysis membranes were found to be free of the test organism.

Table 2

Liquid Bacterial Microbial Challenge Test Results (Brevundimonas diminuta)

Part Number	Serial Number	Total Challenge	Recovery	Titre Reduction	CFU/cm ² EFA
KA2IN4	PB2265/0003	4.62 x 10 ¹⁰	0	> 4.62 x 10 ¹⁰	4.62 x 10 ⁷
KA2IN4	PB2265/0008	3.04 x 10 ¹⁰	0	> 3.04 x 10 ¹⁰	3.04 x 10 ⁷
KA2IN4	PB2265/0011	3.84 x 10 ¹⁰	0	> 3.84 x 10 ¹⁰	3.84 x 10 ⁷
KA2IN4	PB2265/0017	5.00 x 10 ¹⁰	0	> 5.00 x 10 ¹⁰	5.00 x 10 ⁷
KA2IN4	PB2265/0048	4.59 x 10 ¹⁰	0	> 4.59 x 10 ¹⁰	4.59 x 10 ⁷
KA2IN4	PB2265/0070	4.74 x 10 ¹⁰	0	> 4.74 x 10 ¹⁰	4.74 x 10 ⁷
KA2IN4	PB2265/0078	5.29 x 10 ¹⁰	0	> 5.29 x 10 ¹⁰	5.29 x 10 ⁷
KA2IN4	PB2265/0083	4.92 x 10 ¹⁰	0	> 4.92 x 10 ¹⁰	4.92 x 10 ⁷
KA2IN4	PB2265/0087	2.40 x 10 ¹⁰	0	> 2.40 x 10 ¹⁰	2.40 x 10 ⁷
KA2IN4	PB2265/0091	5.74 x 10 ¹⁰	0	> 5.74 x 10 ¹⁰	5.74 x 10 ⁷

Maximum Operating Temperature and Pressure Rating

A summary of results is shown in Table 3. Filters retained their integrity after multiple cycle hot water testing (85 °C) at 5 bar inlet pressure.

Table 3

Forward Flow Integrity Test Results

Part Number	Serial Number	Forward Flow Integrity Test Result Pre-exposure	Forward Flow Integrity Test Result Post-exposure (85 °C)
KA2IN4	IN34580094	PASS	PASS
KA2IN4	IN34580059	PASS	PASS

Typical Flow Rates at Various Inlet Water Pressures

A summary of results is shown in Table 4 and represented graphically in Figure 3.

Table 4

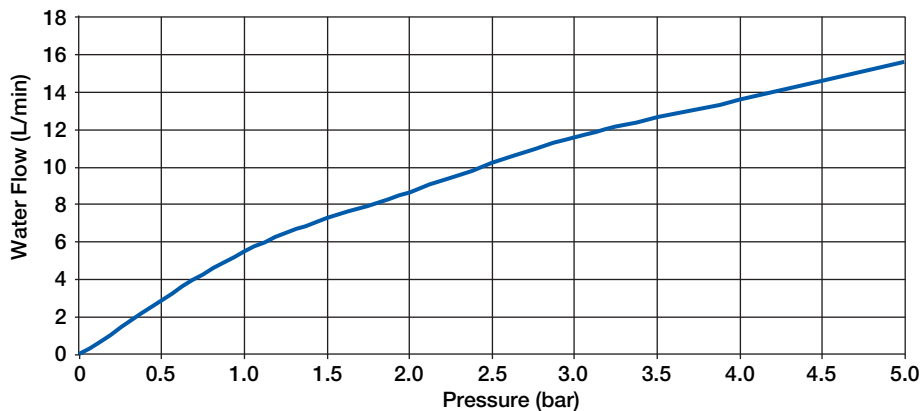
Typical Clean Water Flow Rates** at Various Inlet Water Pressures, Water Temperature 20 °C

		Water Flow** (L/min) at Pressures of (bar)					
		0	1	2	3	4	5
KA2IN4	PB2265 0028	0.0	5.5	8.6	11.5	13.6	15.6
KA2IN4	PB2265 0041	0.0	5.5	8.7	11.6	13.6	15.6
KA2IN4	PB2265 0059	0.0	5.5	8.7	11.6	13.5	15.6
Average:		0.0	5.5	8.7	11.6	13.6	15.6

** Walther adapters were connected to the inlet of the KA2IN4

Figure 3

Graph of Flow Rate** Against Inlet Water Pressure



Conclusion

Pall Kleenpak Water Filters (KA2IN4) are capable of retaining *Brevundimonas diminuta* in laboratory liquid challenge tests defining 0.2 µm sterilising grade filters at a level of $\geq 10^7$ CFU/cm² of effective filtration area.

Pall Kleenpak Water Filters (KA2IN4) have been demonstrated to operate at a continuous water pressure of 5 bar (approx 75 psi) at 85 °C and maintain their integrity over their simulated service life.

At 1 – 6 bar (15 – 75 psi) water pressure, Pall Kleenpak Water Filters (KA2IN4) typically deliver 5.5 – 15.6 L/min.

References

1. American Standard Test Method (ASTM) F838-05 “Determining Bacterial Retention of Membrane Filters Utilised for Liquid Filtration”.



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