Acro® 50 Vent Filter with Emflon® II Membrane

Description
The Acro 50 vent filter with Emflon II membrane is made with a proprietary, low pressure drop, hydrophobic polyvinylidene fluoride (PVDF) membrane for use in air, gas and vent applications. Emflon II membrane filters have a removal rating of 0.2 μm in liquid service and < 0.02 μm particulate for air/gas applications. The Emflon II filter can be integrity tested. These filters are stable to gamma irradiation up to 5 mRads, and are provided non-sterile. An autoclave cycle can also be used to render the filter sterile if needed.

Acro 50 vent filters are designed to connect easily to hoses of various sizes “in-line” or as a final filter. This lightweight device (< 27 grams) prevents crimping of tubing. It’s hydrophobic PVDF membrane will not pass water unless its water breakthrough pressure is exceeded (refer to Integrity Test section). Surfactants and solvents (i.e. alcohol) can be used to “wet-out” the membrane to enable filtration of aqueous solutions or to verify integrity of the device.

Ordering Information

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Pkg</th>
</tr>
</thead>
<tbody>
<tr>
<td>A50/V0G2P2</td>
<td>Hose barb with vent, 0.2 μm</td>
<td>3/pkg</td>
</tr>
<tr>
<td>A50/V0G2P2NV</td>
<td>Hose barb, no vent, 0.2 μm 100% integrity tested during manufacturing</td>
<td>100/pkg</td>
</tr>
<tr>
<td>A50/V0G2NV300</td>
<td>Hose barb, no vent, 0.2 μm 100% integrity tested during manufacturing</td>
<td>300/pkg</td>
</tr>
<tr>
<td>4252</td>
<td>Integrity Test Kit (includes pressure gauge, 3-way stopcock, and 10 mL syringe)</td>
<td>1/pkg</td>
</tr>
</tbody>
</table>

All filters have membrane, pore size and lot number pad printed on each Acro 50 vent filter housing.

Specifications

Materials of Construction
Filter Media: Hydrophobic polyvinylidene fluoride (PVDF)
Housing: Polypropylene
Filter Diameter
50 mm
Effective Filtration Area
19.6 cm²
Typical Air Flow Rate
27 Lpm at 1 bar (100 kPa, 15 psi)

Maximum Operating Temperature
60 °C (140 °F)
Maximum Operating Pressure
4.1 bar (410 kPa, 60 psi) at ambient temperature (20 °C or 68 °F)
Inlet/Outlet Connections
Stepped hose barbs, 6.4-12.7 mm (1/4-1/2 in.) diameter with slip luer ID in the hose barb.
Endotoxin Level
< 0.25 EU/mL using Limulus Amebocyte Lysate (LAL) test

Biological Safety
Passes United States Pharmacopeia (USP) Biological Reactivity Test, In Vivo <88>

Bacterial Retention
Lot samples retain 10^7 cfu/cm² of Brevundimonas diminuta per modified ASTM F838, current revision

Minimum Bubble Point
1.1 bar (10 kPa, 16 psi) using 60/40 Isopropanol/Water

Maximum Autoclave Stability
3 cycles at 131 °C (268 °F) for 30 minutes

Sterilization

Autoclaving
Wrap the Acro 50 vent filter in autoclave paper and autoclave at 121 °C (250 °F) for 20 minutes.

Note: It may be necessary to remove residual condensation from the product before using. (Check installation integrity section.) Reuse requires individual integrity testing and consideration for other problems including cross-contamination.

Gamma Irradiation
Specific cycles for sterilization and associated studies should be validated by the user. Pall recommends a maximum of 5 mRads (50 kilograys) gamma irradiation dosage. Higher levels can adversely affect filter performance.

Integrity Testing

Bubble Point Method
(An Integrity Test Kit is available to aid in this test. See Ordering Information section).

1. Fill a 10 mL or larger syringe with a fresh solution of 60/40 Isopropanol/Water.
2. Insert the syringe male luer into the Acro 50 vent filter, and orient the outlet in an upward direction.
3. Gradually (with low pressure) wet the Acro 50 vent filter membrane, allowing the Isopropanol/Water mixture to displace the air within the housing.
4. Flush the wetted filter with an additional 10-30 mL of 60/40 Isopropanol/Water at higher syringe pressure to assure thorough wetting (using less than a 10 mL flush may result in incomplete wetting).
5. Attach a syringe pressure gauge to an air-filled syringe or pressure vessel. Attach the Acro 50 vent filter and orient the filter in an upward direction.
6. By applying increasing pressure, gradually push the air into the filter while constantly watching for bubbles at the outlet of the Acro 50 vent filter.
7. Read pressure gauge at the moment rapid continuous bubbling appears to determine bubble point (see Specifications).

Installation Integrity

Due to the unacceptable nature of alcohol in many applications, and the need for an easy, routine procedure for integrity testing, we recommend the Water Breakthrough Test (WBT). This test is also referred to as water intrusion pressure or water entry pressure.

Note: A WBT cannot be performed on units following an alcohol bubble point test due to the residual alcohol “wetting out” the membrane.

This relatively simple and reproducible test has been adopted by membrane manufacturers and reported in their literature and specifications for hydrophobic membranes. If water penetration is not evident at significant pressures, the basic integrity of the filter assembly is confirmed. Any physical destruction or rupture of the membrane is easily detected. The WBT takes only a minute to run and is very reproducible. A test kit is available from Pall Laboratory (see Ordering Information section).

<table>
<thead>
<tr>
<th>Pore Size (μm)</th>
<th>60/40 Isopropanol/Water Bubble Point psi</th>
<th>Water Breakthrough Point psi</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.2</td>
<td>16</td>
<td>15</td>
</tr>
</tbody>
</table>

1 Lot samples of filters retain 10^7 cfu/cm² of Brevundimonas diminuta liquid challenge per modified ASTM F838, current revision and FDA guidelines.
2 By CNC particle analysis.

Note: This device is intended for use with aqueous solutions or to verify integrity of the device.
Integrity Testing (continued)

Water Breakthrough Test

1. Fill a 10 mL syringe* (male luer) with water.
2. By using a 3-way connector, attach the calibrated syringe pressure gauge (must measure up to 30 psi, 2.1 bar, 210 kPa), syringe, and the external connector of the Acro 50 vent filter.
3. Gently fill the housing and connectors with water.
4. Apply appropriate pressure, 15 psi (1.0 bar, 100 kPa) with syringe plunger and hold this pressure for 15 seconds.
5. Integrity of housing and membrane is proven by retention of water in the syringe, and by the pressure remaining steady.
6. If failure occurs, check connectors for leaks and repeat above steps. If failure reoccurs, discard filter unit.
7. After completing test procedure, expel water from the syringe and fill with air. Remove the luer vent plug, orient the vent down and force air from the syringe into the Acro 50 vent filter housing. Water in the housing will be forced out the vent port clearing all passages for easy air flow. Alternatively, aspirate the water back into the syringe by pulling back on the syringe plunger.

*Over a period of time, the syringe and stopcock can begin to wear and may affect water breakthrough test results. Any standard 10 mL (or greater) syringe with luer slip fittings may be substituted.