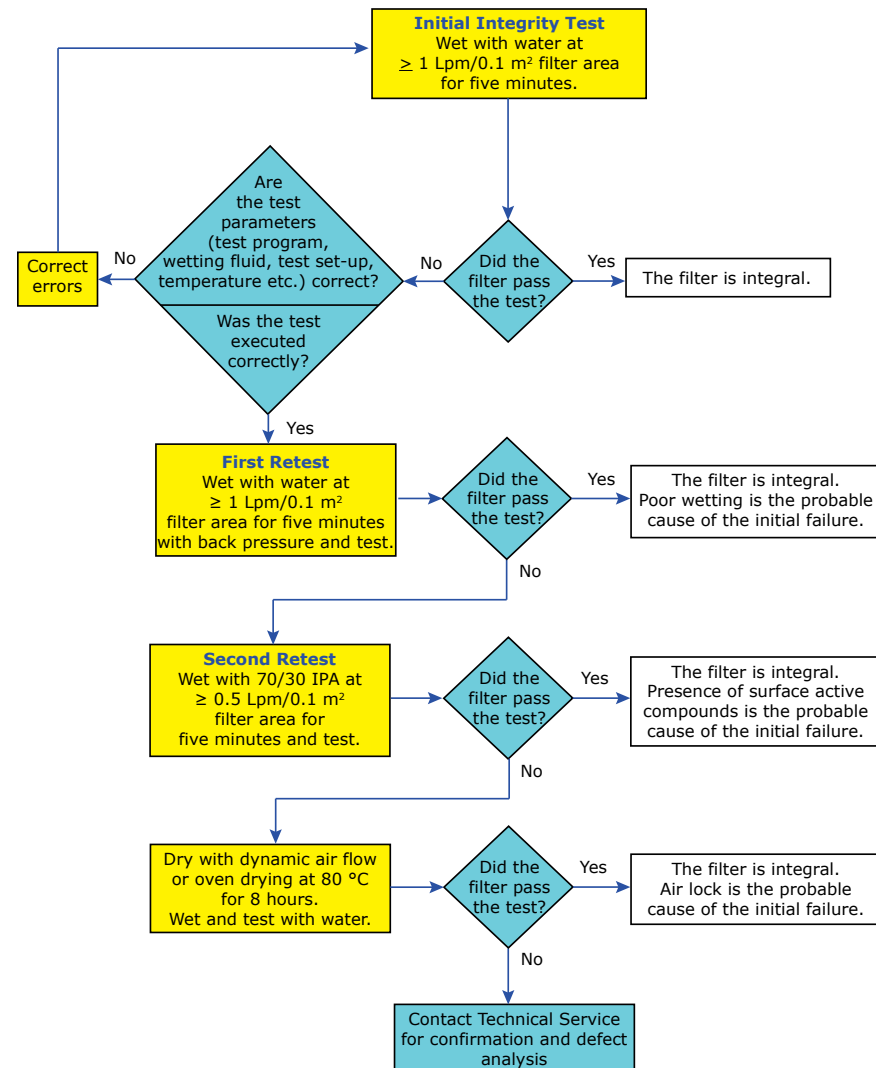


Troubleshooting

Integrity Testing Decision Tree



Wetting

An integrity test value out of specification may be caused by:

- Improperly or incompletely wet filter
- Contaminant or residue on the filter
- Improper O-ring seal
- Temperature not within manufacturer's specification
- System hardware leak (automatic integrity tester)

Integrity Testing

If a problem is encountered:

- Do not remove the filter from its housing (for a post-use test).
- Check connections for leaks (automatic integrity tester).
- Ensure that appropriate integrity test specifications are used for the filter and housing.
- Ensure the environmental and/or test fluid temperature is within the manufacturer's specification.
- Ensure an appropriate test fluid is used.

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For additional information and documentation please contact:
 Merck KGaA, Darmstadt, Germany
 Corporation with General Partners
 Frankfurter Str. 250
 64293 Darmstadt, Germany
 Phone: + 49 6151-72 0

For requests from USA and Canada please contact:
 MilliporeSigma
 A subsidiary of Merck KGaA, Darmstadt, Germany
 400 Summit Drive
 Burlington, MA 01803 USA
 Phone: 1-800-645-5476

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Millipore
 Preparation, Separation,
 Filtration & Testing Products

Wetting Instructions

for Filter Units with Durapore® Membrane

To achieve optimal results, use this wetting procedure prior to conducting an integrity test. Refer to the appropriate Emprove® Dossier, Validation Guide or Certificate of Quality for specifications for the filter to be tested.

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Water Wetting Instructions

NOTE The filter should be completely dry to ensure complete and adequate wetting of the membrane.

Use purified ambient temperature water.

CARTRIDGE FILTERS ONLY: Moisten the filter O-ring with fluid to be filtered to allow ease of insertion into the filter housing.

1. Set up installation as shown here and close V1, V2 and V3.

2. Open V2, then slowly open V1 to fill the filter. When fluid flows through V2 and all air has been released, close V2.

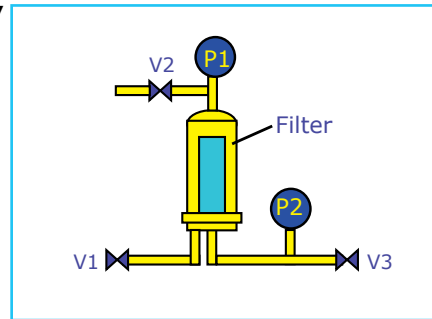
3. Gradually increase the upstream pressure to 2.8 bar (40 psig). Do not exceed the maximum differential pressure rating (see Certificate of Quality) for the filter. Maintain this pressure for a minimum of one minute to dissolve any residual gas within the filter and to ensure membrane wetting.

4. After one minute, gradually open V3 and begin to flow fluid through the filter at the minimum flow rate shown in the *Minimum Recommended Flow Rates* table.

5. Flow for five minutes.

6. Close V1 to stop the fluid flow and allow the upstream pressure (P1) to drop to zero.

7. Perform an integrity test.



Typical installation

70/30 IPA Wetting Instructions

70/30 IPA (70% isopropanol, 30% purified water) wetting may be used to integrity test hydrophilic filters and to troubleshoot post use integrity test failures of hydrophilic filters.

NOTE The polysulfone component of Millidisk® and Millipak® Final Fill filters is not compatible with alcohol at the high temperatures necessary for autoclaving or steam sterilization. IPA used in integrity testing these filters must be completely removed by either air blow down for a specified time or flushing with water at a specified flow rate prior to sterilization.

Ensure that the unit is properly grounded. Use a nitrogen pressure source to minimize flammability.

CARTRIDGE FILTERS ONLY: Moisten the filter O-ring with 70/30 IPA to allow ease of insertion into the filter housing.

1. Set up installation as shown here and close V1, V2 and V3.

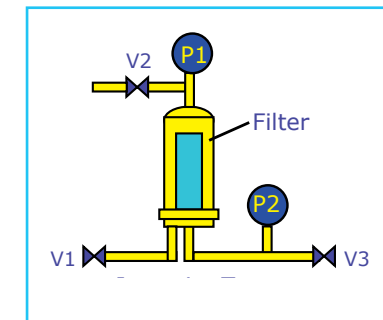
2. Open V2, then slowly open V1 to fill the filter. When fluid flows through V2 and all air has been released, close V2.

3. Gradually increase the upstream pressure to 1 bar (15 psig). Do not exceed the maximum differential pressure rating (see Certificate of Quality) for the filter. Maintain this pressure for a minimum of one minute to dissolve any residual gas within the filter and to ensure membrane wetting.

4. After one minute, gradually open V3 and begin to flow fluid through the filter at the minimum flow rate shown in the *Minimum Recommended Flow Rates* table.

5. Flow for five minutes.

6. Close V1 to stop the fluid flow and allow the upstream pressure (P1) to drop to zero and perform an integrity test.



Typical installation

Minimum Recommended Flow Rates

Filter Unit	Flow Rate (Lpm)	
	Water	70/30 IPA
Millidisk® Filters		
10	0.5	0.25
20	1	0.5
30	1.5	0.75
40	2	1
Millipak® and Millipak® Final Fill Filters		
20/40/60/100	0.5	0.25
200	1	0.5
Optiseal® Filters		
All	2	1
Durapore® Cartridges		
12.5 cm (5 in.)	4	2
25 cm (10 in.)	7.5	4
50 cm (20 in.)	15	7.5
100 cm (30 in.)	22	11
Multimedia Durapore® Cartridges		
25 cm (10 in.)	7.5	4
50 cm (20 in.)	15	7.5
100 cm (30 in.)	22	11
Multilayer Durapore® Cartridges		
25 cm (10 in.)	6	3
50 cm (20 in.)	12	6
100 cm (30 in.)	18	9