Millipore®

Wetting Instructions, Integrity Testing, Sterilizing and Drying Guidelines

Filters with Milligard® PES Membrane

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Wetting **Instructions**

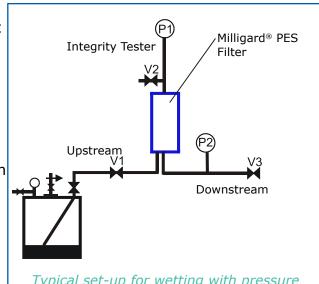
- To achieve optimal results, use this wetting procedure prior to conducting an integrity test. Refer to the appropriate Certificate of Quality for specifications of the filter to be tested.
- The filter should be completely dry to ensure complete and adequate membrane wetting.
- Use purified ambient temperature water or the product to be filtered.
- CARTRIDGE FILTERS ONLY: Moisten the cartridge filter O-ring with water to allow ease of insertion into the filter housing.

Wetting with Pressure

- Set up the filtration system as shown here and close V1, V2 and V3.
- Set the inlet pressure to the filter to at least 3.3 bar (48 psig).
- Gradually open the upstream valve V1. The flow rate should be < 2 LPM.
- Gradually open V2 to vent the filter housing from the highest point until all upstream air has been released.
- Allow fluid to flow through V2 for 20 seconds.

- Partially close V2 and continue to maintain 2.8 bar (40 psig) for at least one minute to dissolve and evacuate any residual gas within the filter and ensure complete membrane wetting.
- Close V2 almost completely and gradually open V3.
- Throttle V1 and V3 until the pressure reading on P2 and the flow rate shown in the Water Wetting Parameters table are achieved. The wetting time and the differential pressure (P1-P2) should be as specified in the table.

V2 must be kept slightly open Note: during the wetting procedure to allow continuous venting and ensure the filter remains fully wetted.



Typical set-up for wetting with pressure

- Close V1 to stop the fluid flow and allow the upstream pressure (P1) to drop to zero.
- 10. Fully open V2 and V3 to drain the wetting fluid from the housing and vent the filter.
- 11. Depressurize the pressure tank and open V1 to drain the wetting fluid from the upstream side into the tank.
- 12. Close V1 and disconnect pressure vessel from system.

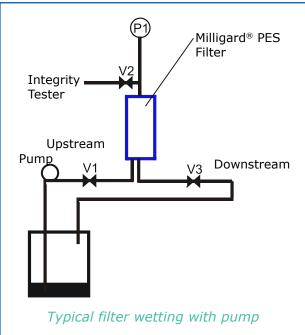
Water Wetting Parameters

Filter length cm (inch)	Differential Pressure bar (psi)	Back Pressure bar (psi)	Flow Rate (LPM)	Flow Time (min.)
25 (10)	≤0.2 (≤3)	3.1 (45)	6	10
50 (20)	≤0.2 (≤3)	3.1 (45)	12	10
75 (30)	≤0.2 (≤3)	3.1 (45)	18	10

Wetting with a Pump

Using a pump can allow for recirculating purified ambient temperature water through the filtration system and can reduce the volume of water required for wetting. Do not exceed the maximum pressure rating for the pump tubing.

- Set up the filtration system as shown here to meet the maximum pressure rating for the tubing and close all V1, V2 and V3.
- 2. Set the pump at the correct setting and start the system.
- Gradually open the upstream valve (V1) and vent the filter housing from the highest point (V2) until all upstream air has been released.
- 4. Allow fluid to flow through V2 for 20 seconds.
- Partially close V2 and maintain the pressure for at least one minute to dissolve and evacuate any residual gas within the filter and to ensure complete membrane wetting.



NOTE The vent valve (V2) must be kept partially open to allow continuous venting and ensure the filter remains fully wetted.

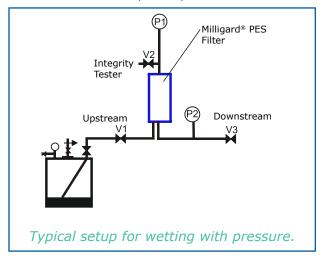
- 6. After one minute, gradually open the downstream valve (V3).
- 7. Throttle V1 and V3 to the back pressure, differential pressure and flow rate listed in the <u>Water Wetting Parameters</u> table. Flow until the pressure or flow rate is stable for 10 minutes.

Integrity Testing Guidelines

Optional integrity testing may be performed either before or after use.

The recommended integrity test is the air/water bubble point test performed with the cartridge filter in a housing, or a capsule filter, isolated from the rest of the system, with the outlet open to the atmospheric pressure.

Refer to the Certificate Of Quality for the minimum bubble point pressure.



- 1. Completely wet the filter following the <u>Wetting Instructions</u>.
- 2. Connect an integrity tester to V2.
- 3. Ensure the downstream line is vented at atmospheric pressure.
- 4. Perform an air/water diffusion integrity test.

Sterilizing Guidelines

NOTES Pre-test treatment conditions described are not a substitute for filter sterilization validation.

Validate the steam-in-place cycle or the autoclave cycle using thermocouples and biological indicators. Contact Technical Service for more information.

Wet filters before sterilizing by autoclave or steam.

Capsule filters must be gamma irradiated dry.

Maximum Autoclave Specifications

Temp (°C)	Time (min)	No. Cycles
Milligard® PES Membrane Cartridge Filters		
128	60	25
Milligard® PES Membrane Capsule Filters		
123	60	3

Maximum Steam Specifications

Temp (°C)	Time (min)	No. Cycles
Milligard® PES Membrane Cartridge Filters		
135	30	10 forward/ 5 reverse

Gamma Irradiation Specifications

Gamma Dose (kGy)		No Cycles	
Min	Max	No. Cycles	
Milligard® PES Membrane Capsule Filters			
25	40	1	

Drying Guidelines

Oven Drying Procedure for Milligard® PES Cartridge Filter

A cartridge may be dried in a ventilatedoven for \geq 36 hour at 65 °C (149°F).

Verify cartridge drying by weighing a dry, unused cartridge and comparing it to the cartridge weight measured after oven drying.

Capsule filters should not be dried.

Filter Storage Conditions

Store filters in their original packaging, away from direct sunlight, and at room temperature. Do not remove the filter from its bag until ready to use.

Troubleshooting

Replace the filter

and return it to

the manufacturer

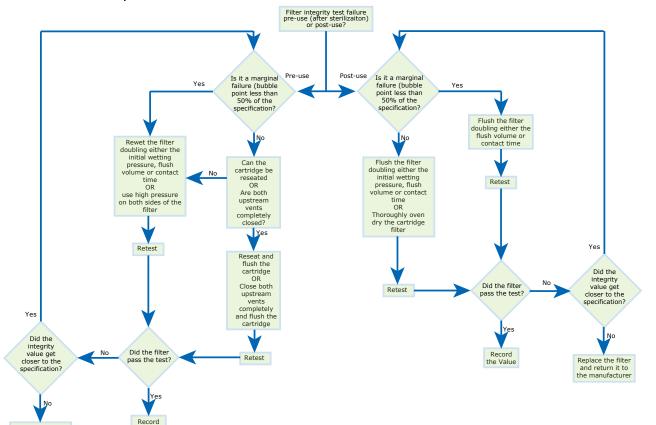
the Value

NOTE Drying and rewetting the filter prior to retesting can minimize integrity test failure.

Do not remove the cartridge from the housing (for a post-use test).

Ensure that appropriate integrity test specifications are used for the filter and housing.

Check the flow diagram or table below for causes and remedies for integrity test values that are out of specification.



Possible Cause	Remedy	
Improperly or incompletely wet filter	Rewet filter	
Contaminant or product residue on the filter	Ensure an appropriate test fluid is used	
Improperly seated cartridge filter		
Improper O-ring seal on cartridge filter	Check filter installation	
Improper upstream vent seal		
Temperature outside manufacturer's recommended temperature	Ensure the environmental and/or test fluid temperature is within the manufacturer's recommended specification	
System hardware leak (automatic integrity tester)	Check connections for leaks	

Warranty

The applicable warranty for the products listed in this publication may be found at www.millipore.com/terms (within the "Terms and Conditions of Sale" applicable to your purchase transaction).

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For technical assistance please visit: www.emdmillipore.com/techservice. Worldwide contact information is available at www.emdmillipore.com/offices

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

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