

Wetting Instructions, Integrity Testing, Sterilizing and Drying Guidelines

Filters with Millipore Express® Membrane

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

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Wetting Instructions

- The filter should be completely dry to ensure complete and adequate wetting of the membrane.
- Use purified ambient temperature water or the product to be filtered.
- CARTRIDGES ONLY: Moisten the cartridge O-ring with water to allow ease of insertion into the filter housing.

Wetting with Pressure

(most efficient and preferred method)

1. Set up the filtration system as shown in [Figure 1](#) and close all valves (V1, V2 and V3).
2. Set the inlet pressure at 2.8 bar (40 psig).
3. Gradually open the upstream valve V1.
4. Gradually open valve V2 to vent the filter housing from the highest point until all upstream air has been released.
5. Allow some water to flow through the highest point (V2).
6. Partially close the vent valve (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.
7. After one minute, gradually open the downstream valve (V3) and set the differential pressure (P1 - P2) to the flow rate listed in [Table 1](#). Continue to flow water through the filter at the appropriate ΔP /flow rate for at least 5 minutes.
For Opticap® XL 150, 300 and 600 capsules: After 1 minute, gradually open the downstream valve (V3) and continue to flow the wetting fluid through the filter for another two minutes at 5 psid.
8. Close V1 to stop the fluid flow and allow the upstream pressure (P1) to drop to zero.
9. Fully open V2 and V3 to drain the wetting fluid from the housing and vent the filter.
10. Depressurize pressure tank and open V1 to drain the wetting fluid from the upstream side into the tank.
11. Close V1 and disconnect pressure vessel from system.
12. Connect an integrity tester to V2, ensure the downstream line is vented at atmospheric pressure and, when required, perform an air/water diffusion integrity test.

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

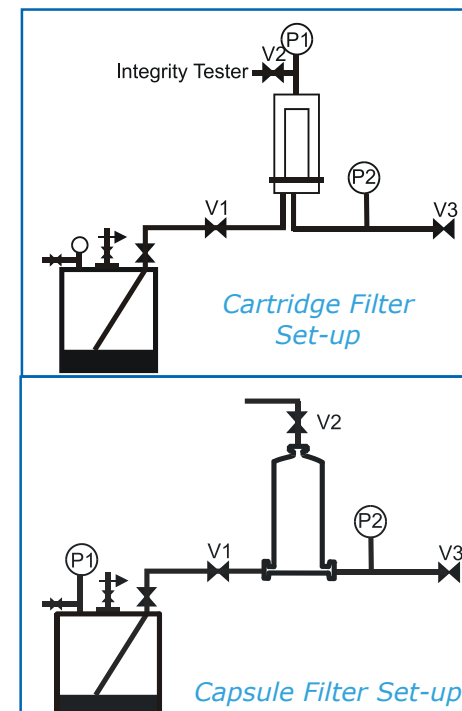


Figure 1. Typical setup for wetting with pressure.

Table 1. Minimum Recommended Flow Rates for Water Wetting

Membrane	Filter Size	Differential Pressure mbar (psi)	Minimum Flow Rate (LPM)	Total Flush Volume Required* (L)
Millipore Express® SHF, Millipore Express® PHF	≤3 inch	45 (<1)	1.5	7.5
	5 inch	45 (<1)	3	15
	10 inch	55 (<1)	6	30
	20 inch	50 (<1)	12	60
	30 inch	50 (<1)	18	90
Millipore Express® SHC	≤3 inch	60 (<1)	1.5	7.5
	5 inch	60 (<1)	2.5	12.5
	10 inch	80 (1)	6	30
	20 inch	70 (1)	11.5	57.5
	30 inch	70 (1)	17	85
Millipore Express® SHR	≤3 inch	90 (<2)	2	10
	5 inch	105 (<2)	3.5	17.5
	10 inch	55 (<1)	7.5	37.5
	20 inch	55 (<1)	15	75
	30 inch	55 (<1)	22.5	112.5
Millipore Express® SHR with Prefilter	≤3 inch	90 (<2)	1.5	7.5
	5 inch	105 (<2)	2.5	12.5
	10 inch	95 (<2)	6	30
	20 inch	95 (<2)	12	60
	30 inch	95 (<2)	18	90

*System void volumes (housing, piping, hoses, etc.) should be additive to these minimum recommended flush volumes shown on the Certificate of Quality.

Wetting with a Peristaltic Pump

Using a peristaltic pump allows recirculating pure water through the filtration system and reduces the volume of water required to ensure proper wetting. Do not exceed the maximum pressure rating for the pump tubing.

1. Set up the filtration system to meet the maximum pressure rating for the tubing as shown in [Figure 2](#) and close all valves (V1, V2 and V3).
 2. Set the peristaltic pump with the flow rate listed in [Table 1](#) and start the system.
 3. 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 the highest point (V2) for 20 seconds.
 5. Partially close the vent valve (V2) and continue to 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. Regulate the peristaltic pump to set the differential pressure at the appropriate flow rate and continue to flow water through the filter for at least 5 minutes.
8. Close V1 to stop the fluid flow and allow the upstream pressure (P1) to drop to zero.
9. Fully open V2 and V3 to drain the wetting fluid from the housing and vent the filter.
10. Close V2.
11. Disconnect pump and ensure V2 is fully closed.
12. Connect integrity tester to V2 and open the valve.
13. Ensure the downstream line is vented at atmospheric pressure.
14. When required, perform an air/water diffusion integrity test.

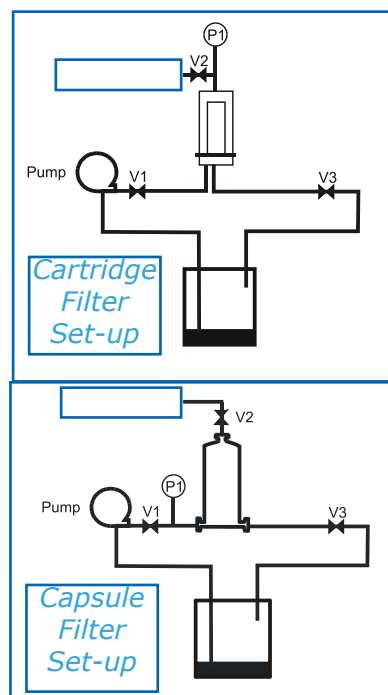


Figure 2. Typical set-up for wetting with a peristaltic pump.

Table 2. Minimum Recirculation Volumes for Water Wetting Using a Peristaltic Pump

Filter Size	Required Recirculation Volume (Liters)
≤3 inch	3
5 inch	6
10 inch	10
20 inch	20
30 inch	30

Integrity Testing Guidelines

Integrity Testing Parameters

- The recommended integrity test for hydrophilic filters is the air/water diffusion performed with the cartridge in a housing, or a capsule filter, isolated from the rest of the system, with the outlet open to atmospheric pressure.
- Refer to the enclosed Certificate of Quality for the maximum diffusion rate.

Post Use 70/30 IPA Alcohol Reference Test

Millipore Express® membranes are not for use with alcohol. Alcohol based integrity tests should only be performed post use.

To minimize the volume of alcohol required, a peristaltic pump is recommended for wetting the filter (see [Wetting with a Peristaltic Pump](#)).

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

- The filter should be completely dry to ensure complete and adequate wetting of the membrane prior to the procedure.
 - Use 70/30 IPA (70% isopropanol 30% purified water).
 - **It is recommended that an IPA/ Water integrity test be performed one time post-use, prior to filter disposal.**
 - CARTRIDGES ONLY: Moisten the cartridge O-ring with water to allow ease of insertion into the filter housing.
1. Set up installation as shown in Figure 2 and close all valves (V1, V2 and V3).
 2. Open V1 and V2. Flow 70/30 IPA through the filter housing until 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 for the filter unit. 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 the downstream valve (V3) and continue to flow 70/30 IPA through the filter at the minimum recommended flow rate and differential pressure shown in [Table 1](#) for five minutes.

For Opticap® XL 150, 300 and 600 capsules: After one minute, gradually open the downstream valve (V3) and continue to flow the wetting fluid for another two minutes at 5 psid.

5. Stop the fluid flow and allow the upstream pressure (P1) to drop to zero.
6. Drain the wetting fluid from the housing.
7. Disconnect pump and ensure V2 is fully closed.
8. Connect integrity tester to V2 and open the valve.
9. Ensure the downstream line is vented at atmospheric pressure
10. When required, perform an integrity test.

Sterilizing Guidelines

Autoclaving Parameters for Sterilizing Wet or Dry Filters

- Pre-test treatment conditions described are not a substitute for filter sterilization validation.
- Validate the autoclave cycle using thermocouples and biological indicators. Contact Technical Service for more information.
- Refer to the Certificate of Quality for autoclave specifications.

Steam in Place Parameters for Sterilizing Dry Cartridges

- DO NOT STEAM-IN-PLACE CAPSULE FILTERS.
- TO AVOID EXCESSIVE DIFFERENTIAL PRESSURE, ENSURE THAT FILTER IS THOROUGHLY DRY PRIOR TO STEAM STERILIZATION.
- Refer to the Certificate of Quality for steam-in-place and maximum differential pressure specifications.

- Perform steam sterilization on a dry cartridge to ensure that process sterility is not compromised during steaming.
- IF A PRE-USE INTEGRITY TEST IS REQUIRED, IT MUST BE PERFORMED AFTER FILTER STERILIZATION.
- The recommended integrity test for hydrophilic filters is an air/water diffusion test performed with the cartridge in a housing, or with a capsule filter, isolated from the rest of the system, with the outlet open to atmospheric pressure.

Drying Guidelines

Cartridge Blow Down Drying Procedure for Millipore Express® SHF or SHC Filters

NOTE DO NOT BLOW DOWN Millipore Express® SHR CARTRIDGES OR SHR WITH PREFILTER CARTRIDGES.

1. With the outlet open to atmospheric pressure, set compressed gas pressure to 340 mbar (5 psig). Start compressed gas flow into the filter. Slowly increase pressure to 6.9 bar (100 psig).
2. As the filter dries, the air flow rate will increase and the differential pressure will decrease.
3. Allow air flow through the cartridge until either the inlet pressure decreases to < 340 mbar (5 psig) or, apply 6.9 bar (100 psig) pressure to the cartridge until bulk air (physically detectable air flow through the filter) is detected at the outlet. Continue to flow air through the cartridge for an additional 30 minutes.

Oven Drying Procedure for Millipore Express® SHF, SHC, SHR or SHR with Prefilter Cartridges

A standard area cartridge may be dried in a ventilated oven for 4.5 hours at 80 °C (176 °F) or > 9 hours at 60 °C (140 °F).

A high area cartridge may be dried in a ventilated oven for 10.5 hours at 80 °C (176 °F).

Cartridge drying can be verified by weighing a dry unused cartridge and comparing it to the cartridge weight measured after oven drying.

Filter Storage Conditions

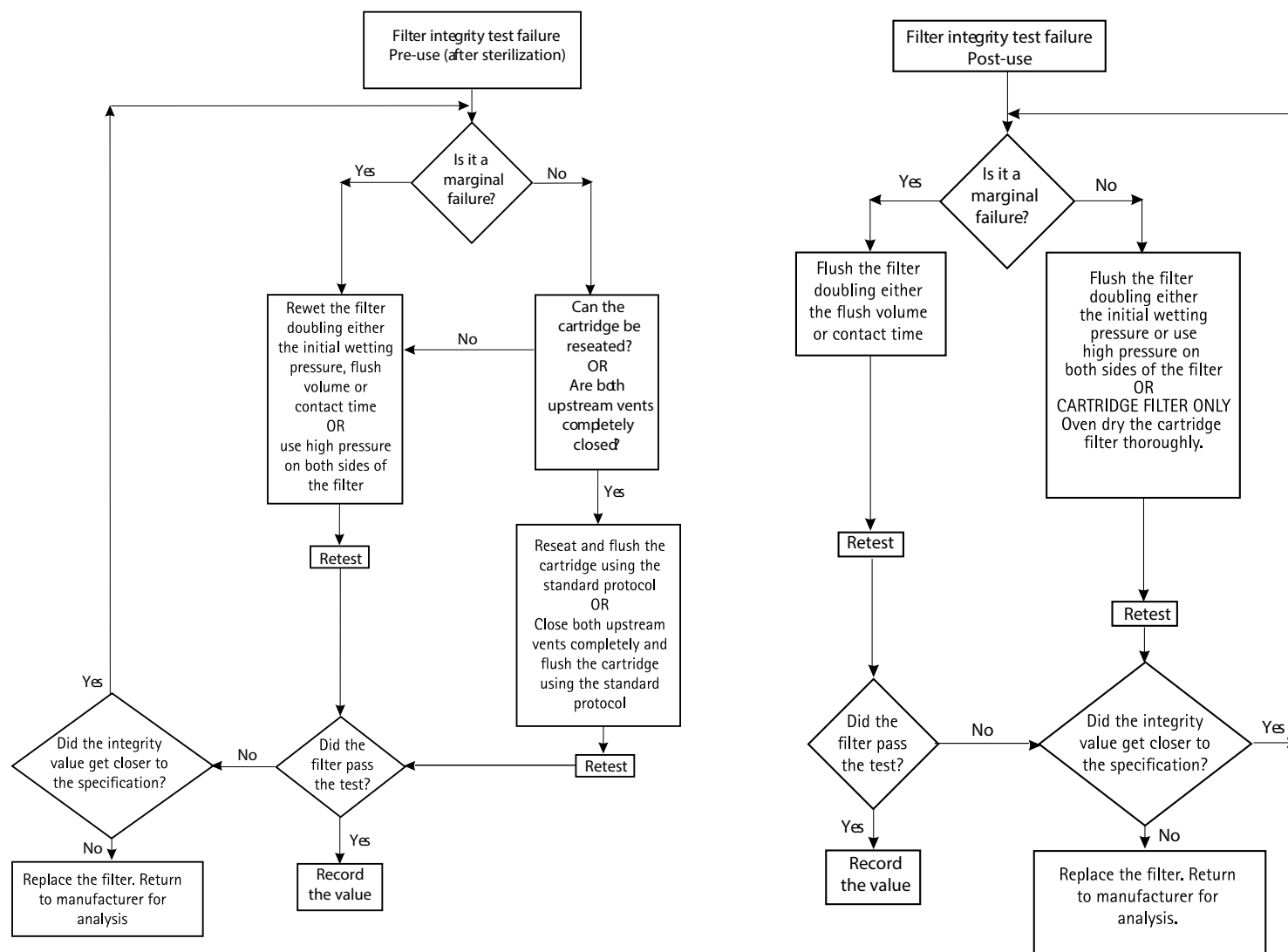
Store filters in their original packaging, away from direct sunlight, and at room temperature. Do not remove the filter from its bag until ready to use.

Troubleshooting

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

Integrity test values that are out of specification may be caused by:

- Improperly or incompletely wetted filter
- Contaminant or product residue on the filter
- Improper O-ring seal on cartridge
- Improper upstream vent seal
- Temperature outside manufacturer's recommended temperature
- System hardware leak (if automatic integrity tester is used)
- If a problem is encountered:
 - Do not remove the cartridge from the housing (for a post-use test).
 - Check connections for leaks (if automatic integrity tester is used).
 - 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 recommended specification.
 - Ensure an appropriate test fluid is used.



A marginal failure is defined as a diffusional flow rate less than approximately 150% of the specification.

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