

CAPSULES

Directions For Use

Installation

1. Inspect the capsule for any damage. Do not use any damaged capsules.
2. Locate the “flow direction” label on the capsule. (The o-ring side of the cartridge is the outlet.)
3. Connect the inlet of the capsule to the fluid supply line. Ensure the connection is securely attached to prevent leaks during operation.
4. Connect the outlet to the outlet line. Ensure the connection is securely attached to prevent leaks during operation.
5. Position the capsule vent valves so that they are at the high point of the capsule.

Filter Flushing & Wetting

1. Open the capsule vent valves to allow air inside the vessel to escape freely.
2. Slowly open the upstream valve to fill the capsule, while keeping the downstream valve closed. Fill slowly to prevent turbulence (air entrapment).
3. When the fluid flows out of the capsule vent valves, without bubbles, the capsule is full.
4. Close the capsule vent valves and open the downstream valve. Re-vent after 1 minute to allow any accumulated air to escape.
5. Continue to flow fluid through the capsule at the minimum recommended flow rate. Maintain flow for 20 minutes to ensure complete wetting.

CONFIGURATION	FLOW RATE [L/min]	TIME [min]
BCP: Size A & B	1-4	20
MC: Size 5"	4-8	20
MC: Size 10"*	15	20

*For filters larger than 10", increase the flow rate as the process system allows & multiply the wetting time by the number of 10" units in the capsule

Bubble Point Testing

1. Wet cartridge following the Filter Flushing & Wetting procedure.
2. Connect regulated compressed air and a calibrated gauge to the inlet.
3. Open the outlet valve and using 3-4 psi/0.25 bar clean, oil- and moisture-free, compressed air, apply pressure to the capsule in the direction of filtration flow for one minute. This will allow residual wetting fluid to drain.
4. Connect the housing outlet to a tube extending into an open-top container partially filled with water, ensuring the tube end is held below the surface of the water.
5. Slowly increase the inlet pressure while watching for air bubbles in the open-top container.
6. The bubble point is the pressure at which a steady stream of bubbles, that break the surface, escapes from the tube into the open-top container.
7. The minimum bubble point values are listed in Table 1.

*In the event you are unable to reach the minimum bubble point as indicated in Table 1, repeat filter wetting procedure and bubble point test, as most bubble point failures are due to incomplete wetting of the filters.



TABLE 1

FILTER CARTRIDGE	MINIMUM BUBBLE POINT in DIW [psi/bar]
PRMXE0.2-SG	54/ 3.72
PRMXE0.2	49/3.37
PRMXE0.45-SG	39.9 / 2.75
PRMXE0.45	38/2.62
PRMXE0.45/0.2-SG	54/ 3.72
PRMXE0.45/0.2	49 / 3.37
PRMXE0.65-SG	21.5/1.44
PRMXE0.65	37/2.55
VM	23.5 / 1.62 (IPA)

Integrity Testing

We recommend an integrity test before each process run to ensure the integrity and function of the filter cartridges.

Capsules must be at ambient temperature to perform the integrity test.

Pressure Hold Testing

INTEGRITY TEST

1. Wet cartridges following the Filter Flushing & Wetting procedure.
2. Open the outlet valve and using 3-4 psi/0.25 bar clean, oil- and moisture-free, compressed air, apply pressure to the capsule housing in the direction of filtration flow for one minute. This will allow residual wetting fluid to drain.
3. Slowly increase pressure to the capsule up to the appropriate test pressure according to Table 2.

TABLE 2

FILTER CARTRIDGE	TEST PRESSURE [psi/bar]
PRMXE0.2-SG	40 / 2.75
PRMXE0.2	39.2 / 2.70
PRMXE0.45-SG	28 / 1.93
PRMXE0.45	30 / 2.06
PRMXE0.45/0.2-SG	40 / 2.75
PRMXE0.45/0.2	39.2/2.70
PRMXE0.65-SG	20 / 1.37
PRMXE0.65	21/1.44
VM	14/ 0.96 (IPA)

4. Upon reaching test pressure wait one minute for system to stabilize, ensuring pressure is maintained.
5. Close air inlet, isolating the system.

6. Record pressure decay, if any, over the 1-minute test period. Allowable pressure decay can be calculated by:

Pressure Drop Calculation

$$\Delta P = \frac{D \times n \times T \times P_A}{V}$$

Where:

- ΔP = Pressure drop across the system (psi)
- D = Maximum allowable air diffusion rate for the filter being tested (see Table 3)
- n = Number of equivalent 10-inch filter cartridges
- T = Test duration (minutes)
- P_A = Atmospheric pressure (14.7 psi)
- V = Inlet volume of the test system (mL)

Note: Accurate measurement of the inlet volume (V) is critical for manual integrity testing. This value is unique to each test vessel and should be determined for the specific system being used.

If during the test the pressure drops more than the allowed amount, verify all system connections are leak-free. Repeat the Filter Flushing & Wetting and Integrity Test procedures.

Diffusive Flow Testing

INTEGRITY TEST

1. Wet cartridges following the Filter Flushing & Wetting procedure.
2. Open the outlet valve and using 3-4 psi/0.25 bar clean, oil- and moisture-free, compressed air, apply pressure to the capsule in the direction of filtration flow for one minute. This will allow residual water to drain.
3. Connect appropriate air flow measuring device to the capsule outlet.
4. Slowly increase pressure to the capsule up to the appropriate test pressure according to Table 2.
5. Upon reaching test pressure wait one minute for system to stabilize, ensuring pressure is maintained.
6. After one minute, verify air diffusion flow rate (mL/min) for the system is below acceptable limits per 10-inch equivalent as

TABLE 3: In the event the air diffusion flow does not drop below the acceptable limit, repeat Filter Flushing & Wetting and Diffusive Flow Test procedures.

For 20", 30" & 40" lengths, multiply the 10" by the number of 10" sections (i.e. PRMXE0.2-SG 30" length = 1.6 x 3 = 48 mL/min)

TABLE 3

FILTER CARTRIDGE	MAX AIR DIFFUSION RATE [mL/min]			
	10"	5"	B	A
PRMXE0.2-SG	16	7.15	5	2.8
PRMXE0.2	100	45	28	15
PRMXE0.45-SG	16	7.15	5	2.8
PRMXE0.45	100	45	28	15
PRMXE0.45/0.2-SG	26	11.6	7	4
PRMXE0.45/0.2	100	45	28	15
PRMXE0.65-SG	16	7.15	5	2.8
PRMXE0.65	100	45	28	15
VM	25	10	8	4.4

QUALITY COMPLIANCE

All materials are listed in Title 21 of the US Code of Federal Regulations 175.300, 177.1520 and 177.1550 Component materials meet the biosafety criteria of the USP Reactivity Test for Class VI Plastics Component materials meet non-fiber releasing as defined in 21 CFR 210.3 (b)(6)

Capsules & cartridges are manufactured in a facility whose Quality Management System is approved by an accredited registering body to the ISO 9001:2015 standard Capsules & cartridges are produced and inspected in conformance with the applicable specifications in a GMP codex Alimentarius commission, Recommended internal code of practices, General principles of food and hygiene, CAC/RCP 1-1969, Rev 4 (2003) certified clean room.

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