

1. Attach a plastic luer-lock valve (V2) to the bottom of the feed reservoir. DO NOT OVERTIGHTEN the valve as this will force the plastic into the Luer-lock channel and obstruct it.
2. Close V2 and add 200 mL of 0.22 µm prefiltered process buffer or WHI to the reservoir. Connect the air source and pressure gauge assembly and vent valve (V3) to the top of the reservoir. Without applying pressure, partially open V2 and allow fluid to flow through the valve until approximately 5 mL has been collected in the reservoir. Close V2. This ensures that the flow path is filled with fluid.
4. Gently attach the OptiScale-25 capsule onto the bottom of V2 and (optional) attach a valve (V1) to the bottom of the OptiScale-25 capsule. Open V1. Close V2. Adjust the air/nitrogen source regulator to the desired operating pressure, 2.1 to 3.5 bar (30-50 psi), and open the gas supply line to the feed reservoir.
6. Position a filtrate collection vessel under the OptiScale-25 device. A weigh scale or a graduated cylinder can be used to record filtrate weights/volumes. Open V2 to allow flow through the Opti-

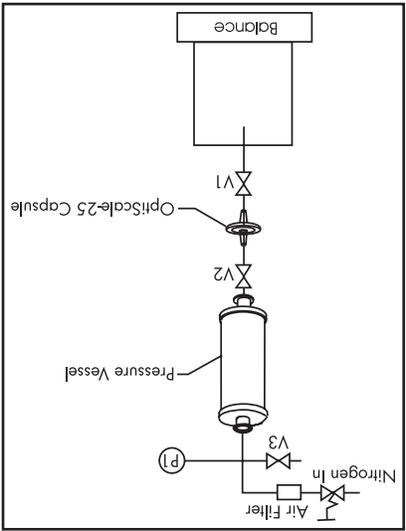


Figure 1 - Typical Installation

Installation and Operation

OptiScale-25 filters with Viresolve NFP or NFR membrane are typically used for process optimization, viral clearance validation and filtration of small batch volumes of protein. Milli-Q® water, WHI or equivalent is required to wet and flush the filters. Testing should be conducted at constant pressure between 1.4 and 3.5 bar (20 and 50 psi). A low volume constant pressure holder (Millipore catalog number VIRUSVMAX or equivalent) is recommended for constant pressure testing of Viresolve membrane.

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OptiScale®-25 Capsule Filters with Viresolve® NFP or NFR Membrane

User Guide

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Scale-25 capsule. Record the elapsed time and the weight or volume of filtrate collected for at least 10 minutes. Record the fluid temperature. At the end of 10 minutes, measure the flow rate of the fluid for one to two minutes.

7. Calculate the Normalized Water Permeability (NWP).

NWP Range at 25 °C
for OptiScale-25 Capsule Filters

Membrane	NWP Range
Viresolve NFP	116 - 261 LMH/bar (8 -18 LMH/psi)
Viresolve NFR	392 - 682 LMH/bar (27 - 47 LMH/psi)

Calculate the NWP using the following equation:

$$NWP = Q_p * F * 171.4 / P$$

Where:

Q_p is the filtrate flow rate in mL/min (assume a density of 1 g/cc for water to convert weight into volume)

F is the Temperature Correction Factor from Table 1 below

P is the test pressure in psi or bar.

Table 1. NWP Temperature Correction Factor (F)*

T (°F)	T (°C)	F	T (°F)	T (°C)	F	T (°F)	T (°C)	F
125.6	52	0.595	96.8	36	0.793	68.0	20	1.125
123.8	51	0.605	95.0	35	0.808	66.2	19	1.152
122.0	50	0.615	93.2	34	0.825	64.4	18	1.181
120.2	49	0.625	91.4	33	0.842	62.6	17	1.212
118.4	48	0.636	89.6	32	0.859	60.8	16	1.243
116.6	47	0.647	87.8	31	0.877	59.0	15	1.276
114.8	46	0.658	86.0	30	0.896	57.2	14	1.310
113.0	45	0.670	84.2	29	0.915	55.4	13	1.346
111.2	44	0.682	82.4	28	0.935	53.6	12	1.383
109.4	43	0.694	80.6	27	0.956	51.8	11	1.422
107.6	42	0.707	78.8	26	0.978	50.0	10	1.463
105.8	41	0.720	77.0	25	1.000	48.2	9	1.506
104.0	40	0.734	75.2	24	1.023	46.4	8	1.551
102.2	39	0.748	73.4	23	1.047	44.6	7	1.598
100.4	38	0.762	71.6	22	1.072	42.8	6	1.648
98.6	37	0.777	69.8	21	1.098	41.0	5	1.699

*Based on Water Fluidity Relative to 25 °C (77 °F) Fluidity Value $F = (\mu_{T_{°C}} / \mu_{25°C})$ or $(\mu_{T_{°F}} / \mu_{77°F})$

This yields NWP in LMH/psi [liters/m² hour psi] or LMH/bar [liters/m² hour bar]. If the device does not meet the specifications listed above, check the water temperature and pressure and repeat the NWP measurement. If the NWP falls outside the recommended range stated above, replace the device and start over.

8. Once wetting and NWP measurement are completed, close the gas supply valve to the reservoir and vent the reservoir. Close V2. This is necessary to ensure that a liquid column is maintained between V2 and the OptiScale-25 device. Remove excess fluid from the reservoir by tipping the tank. Do not shake the reservoir to remove excess fluid.

9. If buffer preconditioning is required prior to protein processing, add approximately 50 mL of buffer to the reservoir, pressurize the vessel to the desired operating pressure and open V2. Filter 20-25 mL through the filter. Relieve air pressure by closing the gas supply valve and opening the vent on the reservoir.

Close V2 and drain excess buffer by tipping the tank. Do not shake the reservoir to remove excess buffer.

10. Add the desired volume of protein solution to the reservoir. Pressurize the vessel to the desired operating pressure and open V2. Collect time and filtrate weight and volume measurements. Run the process for at least 60 minutes or until the flow rate has dropped to 25% of the initial flow rate (defined as weight/volume collected between t = 1 minute and t = 2 minutes), whichever occurs earlier. At the conclusion of the filtration step, relieve air pressure by closing the gas supply valve and opening the vent on the reservoir. Close V2 and disconnect the OptiScale-25 capsule from the Luer-Lok valve. Drain excess product by opening V2.

Millipore recommends no process interruptions and no depressurization during viral clearance processing.

Integrity Testing

Integrity testing of OptiScale-25 capsules is done by measuring the diffusional flow rate of air through a water wetted membrane. The diffusion flow rate specifications for OptiScale-25 Capsules with Viresolve NFP or NFR membrane are listed below.

OptiScale-25 Capsule Diffusion Specifications

Membrane	Diffusion at 50 psi test pressure
Viresolve NFP	≤ 0.0073 cc/min
Viresolve NFR	≤ 0.10 cc/min

OptiScale-25 devices have an effective membrane area of 3.5 cm². Since such low flow rates are difficult to measure accurately, Millipore recommends a gross pass/fail test as an Integrity test for OptiScale-25 devices with Viresolve membrane.

1. Close V2. Reconnect the OptiScale-25 capsule to V2 and open V1. Pressurize the feed vessel to 3.5 bar (50 ±1 psi) using air. Open V2 and wait approximately five minutes or until all liquid is drained through the device. Immerse the pressurized OptiScale-25 capsule or the filtrate tube from the device in a beaker of water. Look for any bubbles coming from the filtrate side of the capsule for approximately 1 minute. No bubbles should be seen exiting an integral device. Release the pressure in the feed vessel and discard the OptiScale-25 capsule. If the device is non-integral, store the device in a beaker of water at 2-8° C and notify your Millipore representative.