Viresolve® Pro
Modus and Magnus Devices

User Guide

Catalogue Numbers:
Modus Device VPMD101NB1, VPMD102NB1, and VPMD103NB1
Magnus Device VPMG201NB1 and VPMG202NB1

Notice

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Introduction

Viresolve Pro Modus Devices are typically used for filtration of pilot to mid-scale batch volumes of proteins.

Viresolve Pro Magnus Devices are typically used for filtration of mid to large scale batch volumes of proteins.

Operating Requirements

- Milli-Q® water, water for injection (WFI) or equivalent is required to wet and flush the filters.
- Filtration may be conducted at constant pressure between 0.7 and 4.1 bar(d) (10 and 60 psid) or using a constant flow pumping system.
- Operating temperature range: 4 to 30 °C.
- Maximum forward operating pressure: 4.1 bar(g) (60 psig).
- Viresolve Pro devices are not qualified for autoclaving or steaming. Refer to section on pre-use sanitization.
- The Viresolve Pro Magnus device must be installed in the Viresolve Pro Magnus Holder.
- Minimize process interruptions or depressurization during virus filtration processing.
- Store at room temperature.

Unpacking

1. Remove the device from the shipping box by grasping both the device and the bag. Grasping the bags only may cause the bags to tear.
2. Retain packaging materials until devices are discarded. If the bags appear opened, or the device appears damaged, return the device to Millipore in the original packaging.
3. Remove device from packaging and record the catalogue number, lot number and serial number. A peel-off label with this information is provided on the bag.

Installation

Viresolve Pro Modus Device

1. Stand the device on its support legs. The device should be operated on a level surface to ensure adequate venting and product recovery.
2. Attach a pressure gauge assembly to the inlet of the device.
3. Attach tubing to the sanitary connections on both the inlet port and outlet port on the device. Tubing may be attached to the barb on the vent valve and routed to a waste vessel to prevent dripping.

Note
Flow direction is indicated on the unit label and by arrows molded into the unit.

Viresolve Pro Magnus Device

1. The Viresolve Pro Magnus device must be installed in a Viresolve Pro Magnus Holder. Refer to the user guide supplied with the holder for installation instructions.

Flushing and Wetting

1. Attach a pressure gauge assembly to the inlet side of the device.
2. Open the vent valve to remove any air in the device. Tubing may be attached to the vent valve and the tubing end placed into a waste vessel to prevent dripping.

Caution
Do not close outlet valve while venting. Device may be damaged if pressurized in the reverse direction.

3. Connect the inlet to flushing or wetting fluid.
4. Flow fluid into the inlet of the device at 0.3 bar(d) (5 psid), allowing the device to vent. Close the vent valve after a continuous stream of liquid is observed exiting from the vent.
5. Raise the flushing/wetting pressure for the duration of the flushing/wetting period. Flush the device with:

Device	Flush Volume
Viresolve Pro Modus 1.1	0.85 L
Viresolve Pro Modus 1.2	3.5 L
Viresolve Pro Modus 1.3	11 L
Viresolve Pro Magnus	50 L/m^2

or for 15 minutes at 2.1 bar(d) (30 psid) (typical wetting pressures are 0.7 to 4.1 bar(d) (10 to 60 psid)

Note
Wetting below the recommended wetting pressure range may result in integrity test failure or reduced permeability due to incomplete wetting.

Flow Rate Calculation

1. Measure the flow rate through the device using a flow meter, graduated cylinder and stop watch, or by placing the outlet tubing into a collection vessel on a balance.
2. Record the flow rate until a stable flow rate is observed for three consecutive minutes. Record water temperature.
3. Calculate the temperature-corrected flow rate ($Q_{25^\circ C}$) using the following equation:

$$Q_{25^\circ C} = Q_p * F$$

Where:
Q_p is the filtrate flow rate in mL/min (assumes a density of:
1 g/cc for water to convert weight to volume).
F is the Temperature Correction Factor from Table 1.

4. Depressurize the system and empty the feed vessel.
5. The device installation may be pre-use integrity tested. See the Integrity Testing section in this User Guide for instructions.

Table 1. Temperature Correction Factor (F)*

Temperature		F	Temperature		F
°F	°C		°F	°C	
125.6	52	0.595	82.4	28	0.935
123.8	51	0.605	80.6	27	0.956
122.0	50	0.615	78.8	26	0.978
120.2	49	0.625	77.0	25	1.000
118.4	48	0.636	75.2	24	1.023
116.6	47	0.647	73.4	23	1.047
114.8	46	0.658	71.6	22	1.072
113.0	45	0.670	69.8	21	1.098
111.2	44	0.682	68.0	20	1.125
109.4	43	0.694	66.2	19	1.152
107.6	42	0.707	64.4	18	1.181
105.8	41	0.720	62.6	17	1.212
104.0	40	0.734	60.8	16	1.243
102.2	39	0.748	59.0	15	1.276
100.4	38	0.762	57.2	14	1.310
98.6	37	0.777	55.4	13	1.346
96.8	36	0.793	53.6	12	1.383
95.0	35	0.808	51.8	11	1.422
93.2	34	0.825	50.0	10	1.463
91.4	33	0.842	48.2	9	1.506
89.6	32	0.859	46.4	8	1.551
87.8	31	0.877	44.6	7	1.598
86.0	30	0.896	42.8	6	1.648
84.2	29	0.915	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 $(\mu_{T°F} / \mu_{77°F})$

Typical temperature corrected flow rate range for Viresolve Pro devices at 2.1 bar(d) (30 psid) and 25 °C is:

Device	Flow Range
Viresolve Pro Modus 1.1	80 to 220 mL/min
Viresolve Pro Modus 1.2	320 to 880 mL/min
Viresolve Pro Modus 1.3	1040 to 2860 mL/min
Viresolve Pro Magnus	145 to 363 LMH/bar (10 to 25 LMH/psi)

If the device installation does not meet the specification listed above, check the water temperature and wetting pressure, and repeat the $Q_{25° C}$ measurement. The device may be rewet at a higher wetting pressure, up to 4.1 bar(d) (60 psid) to ensure adequate wetting.

Sanitization (optional)

1. If sanitizing the device, the initial wetting and flushing can be performed with only 50 L/m^2 of wetting fluid or for two minutes at 2.1 bar(d) (30 psid).
2. Flow 0.5N NaOH at room temperature through the device for up to 60 minutes at 0.7 and 4.1 bar(d) (10 to 60 psid). The caustic solution may be left in the device for a static soak at room temperature for up to 16 hours.
3. Rinse the device after sanitization with (150 L/m^2) of flushing fluid. Conductivity of the filtrate may be monitored to reduce the flushing volume as required.

Measuring Buffer Flux

1. Fill the feed vessel with the appropriate volume of buffer. Perform the venting procedure as described in the Flushing and Wetting section of this User Guide. Filter buffer through the device at the selected processing pressure.
2. Measure the flow rate through the device using a flow meter, graduated cylinder and stop watch, or by placing the outlet tubing into a collection vessel on a balance.
3. Record elapsed time and the volume or weight of filtrate collected. Record the flow rate until a stable flow rate is observed for three consecutive minutes. Record buffer temperature.
4. Close the inlet valve and depressurize the feed vessel.
5. Calculate the $Q_{25^\circ C}$ (See Table 1).

Note
The buffer flux may be different than the water flux due to buffer components. However the buffer flux will establish a baseline relative to the feed stream.

6. Empty buffer from feed vessel.

Filtering Product

1. Add the desired volume of protein to the feed vessel. Record the protein temperature.
2. Attach collection vessel to the holder outlet. Pressurize feed vessel to the selected operating pressure or set the pumping system to the desired flow rate.
3. Open the inlet valve and perform product filtration using process parameters determined during process development. If product flow rate is measured, product flux may be calculated using the procedure described in the previous section, Measuring Buffer Flux.
4. Close the inlet valve and depressurize feed vessel.

Post-Use Buffer Flush (Optional for Product Recovery)

1. Empty any remaining protein from feed vessel and replace with appropriate volume of buffer for product recovery. Pressurize to the selected processing pressure or resume the selected constant flow rate.
2. Open the inlet valve and flush the device installation with the desired volume of buffer.
3. Close the inlet valve and depressurize feed vessel when complete.

Caution
Device may be damaged when exposed to pressure in the reverse flow. Never close the outlet valve and open the inlet valve while devices are under pressure conditions.

Integrity Testing

Test the integrity of the installation by measuring the diffusional flow rate of air through the water wetted membrane. Refer to the Certificate of Quality supplied with the device for the diffusion flow rate specification. For multi Viresolve Pro Magnus device installations, add the individual diffusion specifications to obtain the specification for the entire installation.

The integrity test may be performed manually using a graduated cylinder inverted in a vessel of water, or an automated integrity tester or a downstream mass flowmeter.

Note
If decreased permeability is noted after the pre-use integrity test, rewet the device at 2.1 bar(d) (30 psid) to a minimum of 50 L/m^2 to ensure the removal of any air trapped in the device.

Automated Integrity Testing

1. For post-use testing, after product recovery, flush WFI or Milli-Q water through the device installation at a minimum of 0.7 bar (10 psid) for a minimum of 10 L/m^2.
2. The Integritest® 4 Series Automated Filter Integrity Test Instruments from Millipore are recommended. Refer to the instrument user guide for instructions. Contact Millipore for guidance with other integrity testers.
3. If the installation fails the integrity test, rewet the device at 2.1 bar(d) (30 psid), ensuring proper venting, and check the integrity test protocols used. Although wetting at 0.7 bar(d) (10 psid) may be adequate, wetting at 2.1 bar(d) (30 psid) ensures a fully wetted membrane.

Manual Integrity Testing

1. For post-use testing, after product recovery, flush WFI or Milli-Q water through the device installation at a minimum of 0.7 bar(d) (10 psid) for a minimum of 10 L/m^2.
2. Connect process air line to the inlet side of the device.
3. Increase air pressure to 3.4 bar(g) (50 psig).
4. Drain water through the outlet line. After the filtrate flow is reduced to slow dripping, start a timer and allow the system to stabilize for at least 20 minutes.
5. Measure the diffusion flow rate using a downstream mass flow meter or inverted cylinder. If using the inverted cylinder, place the outlet line into a vessel of water. Wait until a few air bubbles are seen exiting the filtrate tubing. Start measuring the diffusion flow rate using an inverted graduated cylinder for one to five minutes.
6. Compare the test results to the specifications.
7. Release the pressure in the feed vessel. Disconnect the device.
8. If the installation fails the integrity test, rewet the device at 2.1 bar(d) (30 psid), ensuring proper venting. Although wetting at 0.7 bar(d) (10 psid) may be adequate, wetting at 2.1 bar(d) (30 psid) ensures a fully wetted membrane.

Note
Integrity testing introduces air into the device. If integrity testing the device prior to use, ensure the device is fully wetted after the integrity test by wetting with 50 L/m^2 of WFI or buffer after the integrity test.

General Limited Warranty

Millipore Corporation ("Millipore") warrants its products will meet their applicable published specifications when used in accordance with their applicable instructions for a period of one year from shipment of the products. MILLIPORE MAKES NO OTHER WARRANTY, EXPRESSED OR IMPLIED. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The warranty provided herein and the data, specifications and descriptions of Millipore products appearing in Millipore's published catalogues and product literature may not be altered except by express written agreement signed by an officer of Millipore. Representations, oral or written, which are inconsistent with this warranty or such publications are not authorized and if given, should not be relied upon.

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Technical Assistance

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