Fluid Management Solutions for Planova™ Virus Filtration

Multi-use and single-use systems
Built For You.

Asahi Kasei Bioprocess is dedicated to unlocking efficiencies and driving productivity within your biopharmaceutical and plasma derivative virus filtration processes.

Viral safety is a fundamental regulatory requirement for the production of mammalian cell-based or plasma-based protein therapeutics. Our virus filtration fluid management solutions help process development scientists and engineers perform virus filtration with our trusted Planova™ 15N, 20N, 35N or BioEX filters.

Multi-Use Systems

For large-scale production of monoclonal antibodies in batch or fed-batch mode, or within high-volume plasma derivative facilities, stainless steel systems remain the preferred type of unit. From manual holders to fully automated GMP-compliant systems, we offer a range of multi-use systems for your large-scale virus filtration needs — and even a small-scale Planova Pressure Reservoir for your lab-scale virus filtration studies.
Planova™ Virus Filtration Rack (VFR)

The Planova VFR is a portable holder that can be used to ergonomically mount 4.0 and 1.0 m² Planova or Planova BioEX filters. The Planova VFR is designed to securely hold the filter(s) in place and is a suitable solution when you are performing virus filtration manually without a skid during pilot or clinical-scale virus filtration operation.

Product Features

» Dimensions: 838 mm (33 in.) diameter x 1540 mm (61 in.) height
» Durable 304L stainless steel with welded and polished construction
» Pressure gauge, drip pan and parts tray included
» Two (2) 4.0 m² Planova filter holders

When manual virus filtration will suffice.

Operating ranges

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Number and Size of Filters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planova 15N, 20N, 35N or BioEX</td>
<td>1 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>2 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>1 x 4.0 m²</td>
</tr>
<tr>
<td></td>
<td>2 x 4.0 m²</td>
</tr>
</tbody>
</table>

Using the Planova VFR

For those instances when manual Planova virus filtration will suffice, the Planova VFR is a cost-effective way to easily mount up to two Planova virus filters, obviating the need for homemade or unsafe filter holders. Connect your existing product feed to the filter(s) mounted on the Planova VFR for simplified operation. The Planova VFR normally holds the filters in a vertical position, and can also pivot to hold the filters at +10° from vertical, thereby facilitating the execution of the pre- and post-use VLT, or -10° from vertical to minimize product dilution during post recovery flush. Instructions for Use are included in the supporting documentation.

Ordering Information

Planova VFR

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VFR008</td>
<td>Planova Virus Filtration Rack</td>
</tr>
<tr>
<td>VFR051</td>
<td>Pre-Filter Mounting Bracket</td>
</tr>
</tbody>
</table>
Planova™ Virus Filtration Controller (VFC)

For problem-free virus filtration, our updated Planova VFC automates your virus filtration unit operation. With a wider operating range, 21CFR Part 11 compliant automation platform, and integrated VLT, the Planova VFC is a standard system that enables reliable virus filtration for Planova 15N, 20N, 35N and BioEX filters in a small format for clinical and commercial cGMP manufacturing areas.

The Planova VFC includes several risk-mitigating features and design elements to ensure that your high-value biotherapeutic is safely, reproducibly and reliably filtered batch after batch. Pre-use and post-use VLTs can be performed on the VFC, minimizing filter handling. Automation permits seamless transfer between virus filtration and buffer chase (Figure 1). Bar code scanning enables filter identification information to be automatically populated in the batch report.

Product Features

- Dimensions: 864 mm (34 in.) W x 686 mm (27 in.) D x 1930 mm (76 in.)
- Operating system flow rate: 0.08 to 10.00 L/min
- Maximum operating pressure: 4.41 barg at 40° C
- Material of Construction: 316L SS / 0.5 µm Ra
- Connections: Five (5) inlets and three (3) outlets
- Product feed: By separate pressurized tank or onboard diaphragm pump
- Control method: Filter differential pressure control or flow control
- Operator interface: Local touchscreen display
- Software compliance: 21CFR Part 11 compliant
- Qualification package: Asahi IQ/OQ package available, CE Declaration of Conformity available

Operating ranges

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Number</th>
<th>Effective Surface Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planova 15N or 20N</td>
<td>1 or 2 in parallel</td>
<td>1.0 m²</td>
</tr>
<tr>
<td></td>
<td>1 or 2 in parallel</td>
<td>4.0 m²</td>
</tr>
<tr>
<td>Planova 35N</td>
<td>1 or 2 in parallel</td>
<td>1.0 m²</td>
</tr>
<tr>
<td>Planova BioEX</td>
<td>1 or 2 in parallel</td>
<td>1.0 m²</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>4.0 m²</td>
</tr>
</tbody>
</table>

Ordering Information

Planova VFC

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>VFC008</td>
<td>Planova Virus Filtration Controller, SS</td>
</tr>
<tr>
<td>VFC009</td>
<td>Spare parts kit (wear parts) for VFC</td>
</tr>
<tr>
<td>20055-0010</td>
<td>Filter holder for 1.0 m² Planova filter</td>
</tr>
<tr>
<td>VFC310</td>
<td>Hose kit for 1.0 m² Planova filter</td>
</tr>
<tr>
<td>VFC340</td>
<td>Hose kit for 4.0 m² Planova filter</td>
</tr>
<tr>
<td>VFC510</td>
<td>Optional pre-filter, 10 in. Code 7 housing</td>
</tr>
<tr>
<td>VFC402</td>
<td>Optional conductivity monitoring</td>
</tr>
<tr>
<td>SRV302</td>
<td>GMP system documentation package</td>
</tr>
<tr>
<td>VFC705</td>
<td>50 L pressurized tank with accessories</td>
</tr>
<tr>
<td>VFC710</td>
<td>100 L pressurized tank with accessories</td>
</tr>
<tr>
<td>VFC720</td>
<td>200 L pressurized tank with accessories</td>
</tr>
<tr>
<td>VFC112</td>
<td>VFC IQ/OQ package</td>
</tr>
</tbody>
</table>
Planova™ Virus Filtration System (VFS)

When you have a large-scale virus filtration application that exceeds the capacity of our standard Planova VFC, the stainless steel Planova VFS platform is the appropriate solution. Customized systems are available with capacity to hold four (4), six (6) or ten (10) Planova 15N, 20N, 35N or BioEX filters in parallel. Zero static valve manifolds are installed on the filter feed side and permeate side to minimize pressure loss and reduce hold-up volume within the multi-filter system.

The Planova VFS design also includes several risk-mitigating features and design elements to ensure that your high-value biotherapeutic is safely, reproducibly and reliably filtered batch after batch.

Planova VFS Options

» Constant pressure or pump operation
» Prefilter
» Bubble traps
» Positioning for VLT
» Conductivity monitoring
» Steam-in-place (SIP) configurations
» Automation platform (Siemens, Allen-Bradley, DeltaV™)

DeltaV is a trademark of Emerson Process Management.

Typical System Phases

Planova VFS software can be configured to operate the following steps:

» System pressure test and SIP*
» Deaeration
» WFI flush
» Pre-use VLT
» Buffer equilibration
» Product filtration
» Product recovery flush
» Post-use VLT
» Filter wash
» Gold particle test (GPT) pre-wash steps (for Planova 15N, 20N and 35N filters only)
» System CIP

*Only for Planova BioEX filters and stainless steel Planova Virus Filtration Systems.
### Ordering Information

#### Planova VFS

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Planova Filter Effective Surface Area</th>
<th>Number of Planova 15N or 20N Filters</th>
<th>Number of Planova 35N Filters</th>
<th>Number of Planova BioEX Filters</th>
</tr>
</thead>
<tbody>
<tr>
<td>VFS106</td>
<td>1.0 m²</td>
<td>3 – 4</td>
<td>1 – 2</td>
<td>2 – 4</td>
</tr>
<tr>
<td></td>
<td>4.0 m²</td>
<td>1 – 4</td>
<td>1</td>
<td>1 – 2</td>
</tr>
<tr>
<td>VFS108</td>
<td>1.0 m²</td>
<td>4 – 6</td>
<td>1 – 2</td>
<td>2 – 6</td>
</tr>
<tr>
<td></td>
<td>4.0 m²</td>
<td>1 – 6</td>
<td>1</td>
<td>1 – 3</td>
</tr>
<tr>
<td>VFS110</td>
<td>1.0 m²</td>
<td>8 – 10</td>
<td>2</td>
<td>4 – 5</td>
</tr>
<tr>
<td></td>
<td>4.0 m²</td>
<td>2 – 10</td>
<td>1 – 2</td>
<td>1 – 5</td>
</tr>
</tbody>
</table>

Note: Planova Virus Filtration Systems can be optimized for the Planova filter type of your choice.

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#### Planova™ Pressure Reservoir (PPR)

The Planova PPR is designed to support small-scale laboratory filtrations with Planova filters. This feed vessel is constructed of high strength, translucent polysulfone for excellent chemical compatibility and easy cleaning.

### Product Features

- Freestanding unit for flexible placement
- Hassle-free push-to-connect and Luer connections
- Easy disassembly for sterilization

### Vessel Specifications

**Operating conditions:**

- Maximum allowable working pressure: 3.5 barg
- pH 2 – 9
- Temperature: 2 – 40 °C
- Maximum volume: 850 mL

### Ordering Information

#### Planova PPR

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AKB-PPR-085</td>
<td>Planova Pressure Reservoir – complete assembly</td>
</tr>
<tr>
<td>AKB-PPR-009</td>
<td>Spare O-ring kit – includes two O-rings</td>
</tr>
</tbody>
</table>

Note: For research use only. This product is currently only available in the U.S. market.
Asahi Kasei Bioprocess understands that the flexibility and reduced capital expense afforded by single-use systems are preferred in many new facilities.

By uniting single-use technology with our viral safety know-how, we can help you successfully implement Planova 15N, 20N, 35N or BioEX filters in single-use mode.

Single-Use Systems

In today’s clinical and multi-product manufacturing facilities, having flexibility for fast changeover is paramount. Therefore, Asahi Kasei Bioprocess has launched a suite of single-use fluid management solutions to support the Planova virus filter. From cost-effective semi-automated systems to fully automated and 21CFR Part 11 capable units, we offer a range of single-use systems for mid- and large-scale virus filtration.
Planova™ Single-Use Virus Filtration Rack (SU-VFR)

Ideal for pilot plant or early clinical phase single-use facilities, the Planova SU-VFR is a cost-effective semi-automated single-use virus filtration and data acquisition system housed on a compact portable cart. The Planova SU-VFR can be used in non-GMP or GMP open system processes which do not require electronic record-keeping for Planova 15N, 20N or 35N filters.

Product Features

» PlanovaDAQ data acquisition software and Microsoft Surface Pro 3 tablet
» Dimensions: 720 mm (28") width x 760 mm (30") depth x 1800 mm (71") height
» Three (3) inlets with automated valves: WFI, Buffer and Product
» End-of-stream air sensor on feed line
» Single-use quaternary diaphragm pump
» Single-use flowmeter on feed line
» Two (2) single-use pressure sensors, one (1) each on feed line and permeate line
» Automated transmembrane pressure control with optional flow control
» Ability to interface to your RS-232 compatible weigh scale
» Holders tilt filters +10° for VLT and -10° for reduced filtrate volume
» Mounting bracket for optional pre-filter
» USP Class VI product-contact materials of construction
» VLT capability with on-screen timer

Operating ranges

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Number and Size of Filters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planova 15N</td>
<td>1 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>2 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>1 x 4.0 m²</td>
</tr>
<tr>
<td>Planova 20N</td>
<td>1 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>2 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>1 x 4.0 m²</td>
</tr>
<tr>
<td>Planova 35N</td>
<td>1 x 1.0 m²</td>
</tr>
<tr>
<td></td>
<td>2 x 1.0 m²</td>
</tr>
</tbody>
</table>

Using the Planova SU-VFR

The SU-VFR offers many advancements over homemade pump-and-tubing filter systems. Tubing sets for 1 x 1.0 m², 2 x 1.0 m², and 1 x 4.0 m² configurations are available. An optional pre-filter also acts as a bubble trap to remove air bubbles. Flow can be delivered to the filters with the onboard diaphragm pump, or alternatively by your pressurized tank. The PlanovaDAQ data acquisition software is housed on a modern tablet interface and provides both system setup and automated compilation of flux decay data. In order to optimize efficiency, the SU-VFR offers flexibility to mount Planova filters in one of three positions: vertical, +10°, or -10°. A User Guide, component manuals and product-contact material certificates are included in the supporting documentation.

Ordering Information

Planova SU-VFR

<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>Product Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVF004</td>
<td>Planova Single-Use Virus Filtration Rack (SU-VFR)</td>
</tr>
<tr>
<td>VFC110</td>
<td>1.0 m² Planova filter holder adaptor</td>
</tr>
<tr>
<td>SVF110</td>
<td>Single filter 1.0 m² tubing/pump head/sensor/clamp kit for SU-VFR</td>
</tr>
<tr>
<td>SVF210</td>
<td>Dual filter 1.0 m² tubing/pump head/sensor/clamp kit for SU-VFR</td>
</tr>
<tr>
<td>SVF140</td>
<td>Single filter 4.0 m² tubing/pump head/sensor/clamp kit for SU-VFR</td>
</tr>
</tbody>
</table>
Planova™ Single-Use Virus Filtration Controller (SU-VFC)

Our Planova SU-VFC automates the virus filtration unit operation in a single-use format. With a flexible operating range, 21CFR Part 11 compliant automation platform, and gamma-irradiated tubing sets, the Planova SU-VFC enables reliable virus filtration for Planova 15N, 20N, 35N and BioEX filters in a small footprint that is ideal for single-use cGMP manufacturing areas.

The Planova SU-VFC includes several risk-mitigating features and design elements to ensure that your high-value biotherapeutic is safely, reproducibly and reliably filtered batch after batch.

Transfer seamlessly between product and buffer chase, minimizing the pause after product filtration. With a footprint of a modest 864 mm x 686 mm (34 in. x 27 in.), the Planova SU-VFC can be installed in almost any downstream processing area and is fully 21CFR Part 11 capable. Universal gamma-irradiated tubing sets can be used for any of the compatible Planova filters. By incorporating the capability to perform integrity testing, the Planova SU-VFC permits simplified implementation of Planova filters in your process.

Software

Planova SU-VFC software can be configured to operate the following steps:

» System integrity test prior to operation
» Deaeration
» WFI flush
» Pre-use VLT
» Buffer equilibration
» Product filtration
» Product recovery flush
» Post-use VLT
» Filter wash
» Gold particle test (GPT) pre-wash steps  
  (for Planova 15N, 20N and 35N filters only)

Product Features

» Dimensions: 864 mm (34 in.) W x 686 mm (27 in.) D x 1930 mm (76 in.)
» Operating system flow rate: 0.08 to 10.00 L/min
» Maximum operating pressure: 4.41 barg at 40° C
» Material of Construction: C-Flex thermoplastic elastomer (TPE) tubing; braided and unbraided
» Connections: Three (3) inlets and four (4) outlets
» Product feed: By onboard single-use diaphragm pump
» Control method: Filter differential pressure control or flow control
» Operator interface: Local touchscreen display
» Software compliance: 21CFR Part 11 compliant
» Qualification package: Asahi IQ/OQ package available and CE Declaration of Conformity available
Using the Planova SU-VFC

The SU-VFC is a modern single-use system designed with universal, gamma-irradiated tubing sets to permit cost-effective inventory management. After loading the tubing sets, the control software can be quickly configured to set up the controlled delivery of WFI, buffer and product to the filter with the onboard diaphragm pump. The 21CFR Part 11 data acquisition software provides automated compilation of flux data and logs all user interventions. To optimize efficiency, the SU-VFC offers flexibility to mount Planova filters in one of three positions: vertical, + 10°, or -10°. A User Guide, component manuals and product-contact material certificates are included in the supporting documentation.

Operating ranges

<table>
<thead>
<tr>
<th>Filter Type</th>
<th>Number</th>
<th>Effective Surface Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Planova 15N, 20N or BioEX</td>
<td>1</td>
<td>1.0 m²</td>
</tr>
<tr>
<td>Planova 35N</td>
<td>1</td>
<td>4.0 m²</td>
</tr>
</tbody>
</table>

Note: Universal tubing sets accommodate the full operating range of the SU-VFC.

Planova™ Single-Use Virus Filtration System (SU-VFS)

When you have a large-scale single-use virus filtration application that exceeds the capacity of our standard Planova Single-Use Virus Filtration Controller (SU-VFC), or if you require customized features for your application, the Planova SU-VFS platform is the appropriate selection for you. Available in capacities of two (2) pieces or four (4) pieces of 4.0 m² in parallel, these customized systems allow you to tailor the implementation of Planova filters to your specific needs while enjoying the benefits of single-use technology at scale. Like all of our automated virus filtration system, the Planova SU-VFS design also includes several risk-mitigating features and design elements to ensure that your high-value biotherapeutic is safely, reproducibly and reliably filtered batch after batch.

The Planova SU-VFS can be designed for your unique requirements, balancing your current production levels against anticipated future demand. We can design customized gamma-irradiated tubing sets specific to your application (minimum orders may apply for customized tubing sets).

Figure 4. Transfer seamlessly between product and buffer chase, minimizing the pause between product filtration and buffer chase.
Software
Planova SU-VFS software can be configured to operate the following steps:
» Deaeration
» WFI flush
» Pre-use VLT
» Buffer equilibration
» Product filtration
» Product recovery flush
» Post-use VLT
» Filter wash
» Gold particle test (GPT) pre-wash steps (for Planova 15N, 20N and 35N filters only)
» System integrity test prior to operation

Planova SU-VFS Options
» Capability to manage both Planova N series and Planova BioEX filters
» Pump with flow rate range to meet your application needs
» Prefilter
» Positioning for VLT
» Conductivity monitoring
» Automation platform (Siemens, Allen-Bradley, DeltaV)

Typical System Phases
Planova SU-VFS software can be configured to operate the following steps:
» System integrity test prior to operation
» Deaeration
» WFI flush
» Pre-use VLT
» Buffer equilibration
» Product filtration
» Product recovery flush
» Post-use VLT
» Filter wash
» Gold particle test (GPT) pre-wash steps (for Planova 15N, 20N and 35N filters only)
A reliable technical support network is available throughout the United States, Europe and Asia.

We offer an extendable 1-year warranty, service contracts and a personalized level of service for peace of mind and timely support when you need it.

For more information, please visit:
www.ak-bio.com

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