Filtration, Separation & Preparation



Mobius® FlexReady Solution for Large Scale Virus Filtration

Fast setup. Maximum adaptability. Pre-designed and optimized.

The Mobius® FlexReady Solution for Large Scale Virus Filtration is an easy-to-use system featuring an optimized single-use flow path designed to fully support your parvovirus filtration needs.

It features Viresolve® Pro and Pro+ Magnus devices, a next-generation parvovirus safety solution that delivers robust parvovirus clearance capable of processing up to 5 kg of protein or 2000 L volumes at 2.5 g/L expression.

The Mobius® FlexReady Solution for Large Scale Virus Filtration consists of single-use Flexware® assemblies, innovative Viresolve® Pro Solution devices and process-ready hardware systems to deliver optimal operational flexibility. The disposable nature of the flow path eliminates cleaning validation requirements. Accompanied by our extensive support and services, the Mobius® FlexReady Solution for Large Scale Virus Filtration can help you maximize resource productivity and reduce risk.



Benefits

- Fast setup of hardware with easy installation of optimally designed Flexware[®] assemblies
- Maximum adaptability to your changing operational needs with single-use flow paths
- Pre-designed and optimized for parvovirus filtration to give you confidence and peace of mind



Parvovirus filtration for large scale production

Mobius® FlexReady Solution for Large Scale Virus Filtration is designed for volumes ranging from 5 kg of protein or 2000 L volumes at 2.5 g/L expression, across a membrane area of 0.51 m² to 3.06 m².

Each system has the following unique design features:

- Low pulsation single-use pump chamber
- ullet Constant pressure operation using Viresolve® Prosolution Δ pressure feedback and pump speed control or constant flow rate operation using pressure feedback and pump speed control
- High-pressure cut-off switch for operator safety
- Feed temperature (resistance thermometer),
 Viresolve® Pro Magnus device feed temperature
 (Device filtrate temperature only available with
 optional pH and conductivity).
- Optional Viresolve® Pro+ Shield and device or Viresolve® Pre-filter (Pod design)
- Optional filtrate scale for flow rate measurement and cumulative volume during flushing and processing
- Optional filtrate flow meter multi-use for flow rate measurement and cumulative volume during flushing and processing

- Process end-point via cumulative volume/weight or processing time, or conductivity for flushing operations
- Innovative low dead volume t-connectors enabling the use of traditional pressure transducers
- Flexware® assemblies designed to fit the hardware and install quickly and easily
- Ease of operation with an intuitive touch screen interface, user-defined process and alarm set points

Viresolve® Pro Magnus Holder

The Viresolve® Pro Magnus holder was designed specifically for large volume processing using the Magnus devices. Loading and unloading of devices is quick and easy. The innovative design of the holder allows drug manufacturers to process several runs with minimum down time between changeovers.

- No product contact eliminates need for cleaning validation
- Ergonomic and easy-to-clean design fits into your facility
- Vertical orientation minimizes holder footprint
- One rod sized to fit from 0.51 m² to 3.06 m²



Virus Large Scale Specifications

| Descript | tion | VF3 5 LPM | VF3 20 LPM | VF3 40 LPM | | |
|--|--|--|---|--|--|--|
| Feed Ski | id Unit Overall Dimensions | | | | | |
| | (H x W x D) mm: | VF3 skid: 1657 x 1875 x 861 (- | +/- 10 mm) | | | |
| | | POD cart: 1138 x 1129 x 650 (+/- 10 mm) | | | | |
| Total Weight (approx.) | | 390 kg | | | | |
| Wheels | | | | | | |
| | No. Total: | 4 | | | | |
| | No. Locking: | 2 | | | | |
| Utility Re | equirements: | 110 or 230 V 50/60 Hz (1 phase, + N, + G) | | | | |
| | | Power consumption: 1.4 kW | | | | |
| Universal Power Supply (UPS) | | In case of power loss, system shuts down properly (no data loss) | | | | |
| Electrical Enclosure: | | IP 65 | | | | |
| Regulatory Compliance: | | CE (2014/30/UE, 2006/42/CE) | | | | |
| Environmental Temperature Range: | | | | | | |
| Humidity: | | 10 – 90% (non-condensing) | | | | |
| | e Rating: | Up to 4.1 bar (60 psig), 2.1 bar | r (30 psi) with POD prefilter | | | |
| | Fluid Temperature Range: | 4 to 30 °C | | | | |
| | Connection Type: | TC 3/4" | | | | |
| Materials | s of Construction | | | | | |
| | Flowpath: | - | propylene, Nylon, EPDM, Santoprene | ® resin, Polysulfone (for SUC) | | |
| | Frame: | Painted Stainless Steel 304 | | | | |
| | Holder plate: | Stainless Steel 316 L | | | | |
| | Regulatory Information: | Sealing materials and plastics in contact with the product meet USP <88> biological reactivity test for Class VI Plastics and are Title 21 CFR 177.2600 and 177.1550 compliant. | | | | |
| Tubing S | Sizes: | 3/8" ID | 5/8" ID | 3/4" ID | | |
| | | | | | | |
| Inlets: | | Up to 4 inlets on manifold (TC 3 | 3/4") | | | |
| | | Up to 2 drain lines (TC or colde | <u> </u> | | | |
| Outlets: Max Mer | mbrane Holder Capacity nus filter device: | · · · · · · · · · · · · · · · · · · · | <u> </u> | | | |
| Outlets: Max Mer for Magr | mbrane Holder Capacity nus filter device: | Up to 2 drain lines (TC or colde | <u> </u> | | | |
| Outlets: Max Mer for Magr | nbrane Holder Capacity nus filter device: ne Holder Capacity Viresolve® Pro Magnus/ | Up to 2 drain lines (TC or colde | <u> </u> | | | |
| Outlets: Max Mer for Magr | mbrane Holder Capacity nus filter device: ne Holder Capacity | Up to 2 drain lines (TC or colde | <u> </u> | 1.53 – 3.06 m² | | |
| Outlets: Max Mer for Magr Membra | nbrane Holder Capacity nus filter device: ne Holder Capacity Viresolve® Pro Magnus/ | Up to 2 drain lines (TC or colde Up to 3.06 m ² | r) + 1 collection (TC) | 1.53 - 3.06 m ² for 1.53 m ² | | |
| Outlets: Max Mer for Magr Membra | nbrane Holder Capacity nus filter device: ne Holder Capacity Viresolve® Pro Magnus/ | Up to 2 drain lines (TC or colde) Up to 3.06 m ² 0.51 m ² 420 - 660 LMH @ 30 psig 490 - 665 LMH @ 35 psig | r) + 1 collection (TC) 0.51 - 1.53 m ² | | | |
| Outlets: Max Mer for Magr Membra | nbrane Holder Capacity nus filter device: ne Holder Capacity Viresolve® Pro Magnus/ | Up to 2 drain lines (TC or colde Up to 3.06 m ² 0.51 m ² 420 - 660 LMH @ 30 psig | 0.51 - 1.53 m ² for 1.02 m ² 480 - 660 LMH @ 30 psig 490 - 1100 LMH | for 1.53 m ² | | |
| Outlets: Max Mer for Magr Membra | nbrane Holder Capacity nus filter device: ne Holder Capacity Viresolve® Pro Magnus/ | Up to 2 drain lines (TC or colde) Up to 3.06 m ² 0.51 m ² 420 - 660 LMH @ 30 psig 490 - 665 LMH @ 35 psig | 0.51 - 1.53 m ² for 1.02 m ² 480 - 660 LMH @ 30 psig | for 1.53 m ² 630 – 770 LMH @ 35 psig | | |
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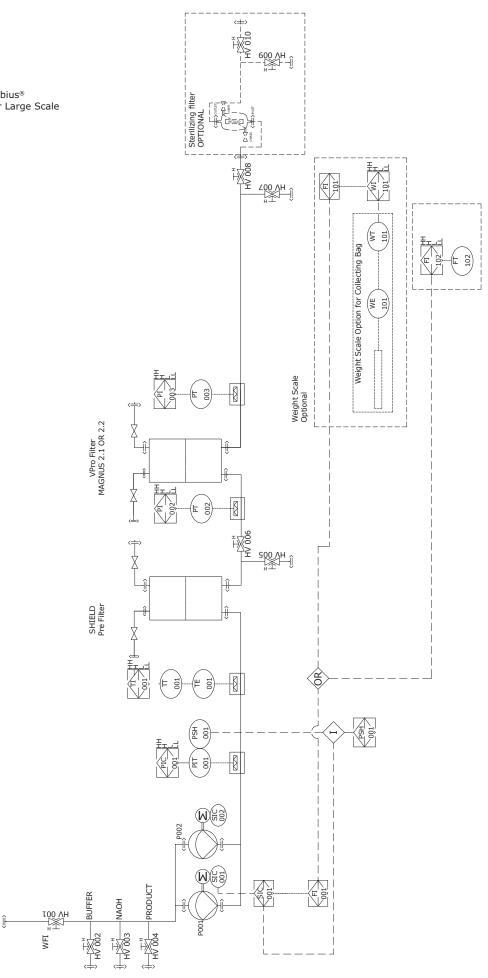
| Location: Beform Brand: Labor Model: CC 66 Range: 0 - 6 Loop accuracy: ±0.2 Pressure: Type: Non i Location: After Brand: Labor Model: CC 66 Range: 0 - 6 Loop accuracy: ±0.2 Temperature: Type: Non i Location: After Brand: Labor Model: Type: Non i Location: After Brand: Labor Model: Type: Non i Location: After Brand: Labor Model: Type: Non i Loop accuracy: ±2°C Filtrate pH (Optional): Type: Single Location: After Brand: Fines Model: True Range: 1 to 3 Loop accuracy: ±0.1 Filtrate Conductivity (Optional): Type: Single Location: After Brand: Optel Model: ACF6 Range: 0 - 1 Loop accuracy: ±2% Filtrate Flowmeter (Optional): Electric Range: Custon Siltrate Rand: Notel Range: Custon Siltrate Rand: Custon Siltrate Weight scale: Location: Filtrate Rand: Custon Model: Deckel Range: 0 - 6 | 0 5 bar 2 bar 3 bar 2 bar 3 bar 4 bar 5 bar 5 bar 6 bar 6 bar 7 bar 6 bar 6 bar 7 bar 6 ba | Non intrusive Before Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After pumps Labom Type Series GA270 -40°C / + 85°C ± 2°C Single-use cell using glass pH probe After Viresolve® Pro Magnus device Finesse True pH 1 to 14 pH ± 0.1 pH (b/w pH 3 to 9) Single-use cell | Non intrusive Before Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After pumps Labom Type Series GA270 -40°C / + 85°C ± 2°C Single-use cell using glass pH probe After Viresolve® Pro Magnus device Finesse True pH 1 to 14 pH ± 0.1 pH (b/w pH 3 to 9) | | | |
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| Type: Non i Location: Befor Brand: Labor Model: CC 60 Range: 0 - 6 Loop accuracy: ±0.2 Pressure: Type: Non i Location: After Brand: Labor Model: CC 60 Range: 0 - 6 Loop accuracy: ±0.2 Temperature: Type: Non i Location: After Brand: Labor Model: Type: Non i Location: After Brand: Labor Model: Type: Non i Location: After Brand: Labor Model: Type Range: -40 °0 Loop accuracy: ±2 °0 Filtrate pH (Optional): Type: Single Location: After Brand: Fines Model: True Range: 1 to 1 Loop accuracy: ±0.1 Filtrate Conductivity (Optional): Type: Single Location: After Brand: Optel Model: ACF6 Range: 0 - 1 Loop accuracy: ±2 % Filtrate Flowmeter (Optional): Filtrate Flowmeter (Optional): Filtrate Range: 0 - 1 Loop accuracy: ±2 % Filtrate Weight scale: Location: Filtrat Brand: Custo Model: Deckel | re Viresolve® Pro Magnus device im 0 5 bar 2 bar intrusive Viresolve® Pro Magnus device im 0 5 bar 2 bar intrusive of bar 2 bar | Before Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After pumps Labom Type Series GA270 -40°C / + 85°C ± 2°C Single-use cell using glass pH probe After Viresolve® Pro Magnus device Finesse True pH 1 to 14 pH ± 0.1 pH (b/w pH 3 to 9) Single-use cell | Before Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After Viresolve® Pro Magnus device Labom CC 60 0 - 6 bar ± 0.2 bar Non intrusive After pumps Labom Type Series GA270 -40 °C / + 85 °C ± 2 °C Single-use cell using glass pH probe After Viresolve® Pro Magnus device Finesse True pH 1 to 14 pH ± 0.1 pH (b/w pH 3 to 9) | | | |
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| Filtrate Weight scale: Location: Filtrate Brand: Custo Model: Decki | | ±2% FS | ±2% FS | | | |
| Filtrate Weight scale: Location: Filtrate Brand: Custo Model: Decki | oriant annualitation and table 600 | Electrical consenting available for | Electrical connection available for | | | |
| Filtrate Weight scale: Location: Filtrate Brand: Custo Model: Decki | rical connection available for stomer filtrate flowmeter | Electrical connection available for a customer filtrate flowmeter | Electrical connection available for a customer filtrate flowmeter | | | |
| Brand: Custo Model: Decki | stomer made nowmeter | a castomer intrace nowineter | a castomer intrace nowineter | | | |
| Model: Decki | ate line for recovery bag | Filtrate line for recovery bag | Filtrate line for recovery bag | | | |
| Range: 0 - 6 | omer balance or Metler Toledo | Customer balance or Metler Toledo | Customer balance or Metler Toledo | | | |
| | mate 2888 Portable | Deckmate 2888 Portable or PFA579-FM3000 | PFA579-FM3000 | | | |
| | 500 kg | 0 – 600 kg or 0 – 3000 kg | 0 – 3000 kg | | | |
| Loop accuracy: 0.1% | % FS | 0.1% FS | 0.1% FS | | | |
| | | | | | | |
| | Calculated feed flow ($\pm 10\%$ measured value) | | | | | |
| | Constant Magnus Delta Δ | | | | | |
| | stant flow rate stant flow followed by constant | Dolta A | | | | |
| | | | | | | |
| | Semi-automated system with manual valves actuation Reports generation (analog values, alarms and events) with checksum | | | | | |
| | ally compliant with 21CFR Part | | | | | |
| | Siemens CPU | | | | | |
| | Siemens Simatic | | | | | |
| | | | | | | |
| <u> </u> | On MMC card, on external computer | | | | | |
| | NICR V-CatowayIM Ethornot ada | | | | | |
| | ous® x-Gateway™ Ethernet adap | \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ | User Manual: 1 paper copy + on CD Technical Documentation: on CD | | | |
| | Manual: 1 paper copy + on CD |) | | | | |
| | | | | | | |

| Description | Dimensions | |
|---|--------------------------|--|
| Viresolve® Pre-filter Pod Holder | | |
| Overall Dimensions (H x W x D) mm (optional): | 660 x 640 x 1090 | |
| Total Weight | 140 kg | |
| Wheels | | |
| No. Total: No. Locking: | 4 2 | |
| Viresolve® Pre-filter Membrane Holder Recommended Capacity (optional): | Up to 5.5 m ² | |

Figure 2.

Diagram Example: Mobius® FlexReady Solution for Large Scale

Virus Filtration



To place an order or receive technical assistance

In Europe, please call Customer Service:

France: 0825 045 645 Spain: 901 516 645 Option 1
Germany: 069 86798021 Switzerland: 0848 645 645
Italy: 848 845 645 United Kingdom: 0870 900 4645

For other countries across Europe, please call: +44 (0) 115 943 0840

Or visit: MerckMillipore.com/offices

For Technical Service visit: MerckMillipore.com/techservice

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