

УСТАНОВКИ MOBIUS FLEXREADY VF3



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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
- Constant pressure operation using Viresolve® Pro solution 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



Figure 1.

Viresolve® Pro and Pro+ magnus and shield device

Virus Large Scale Specifications

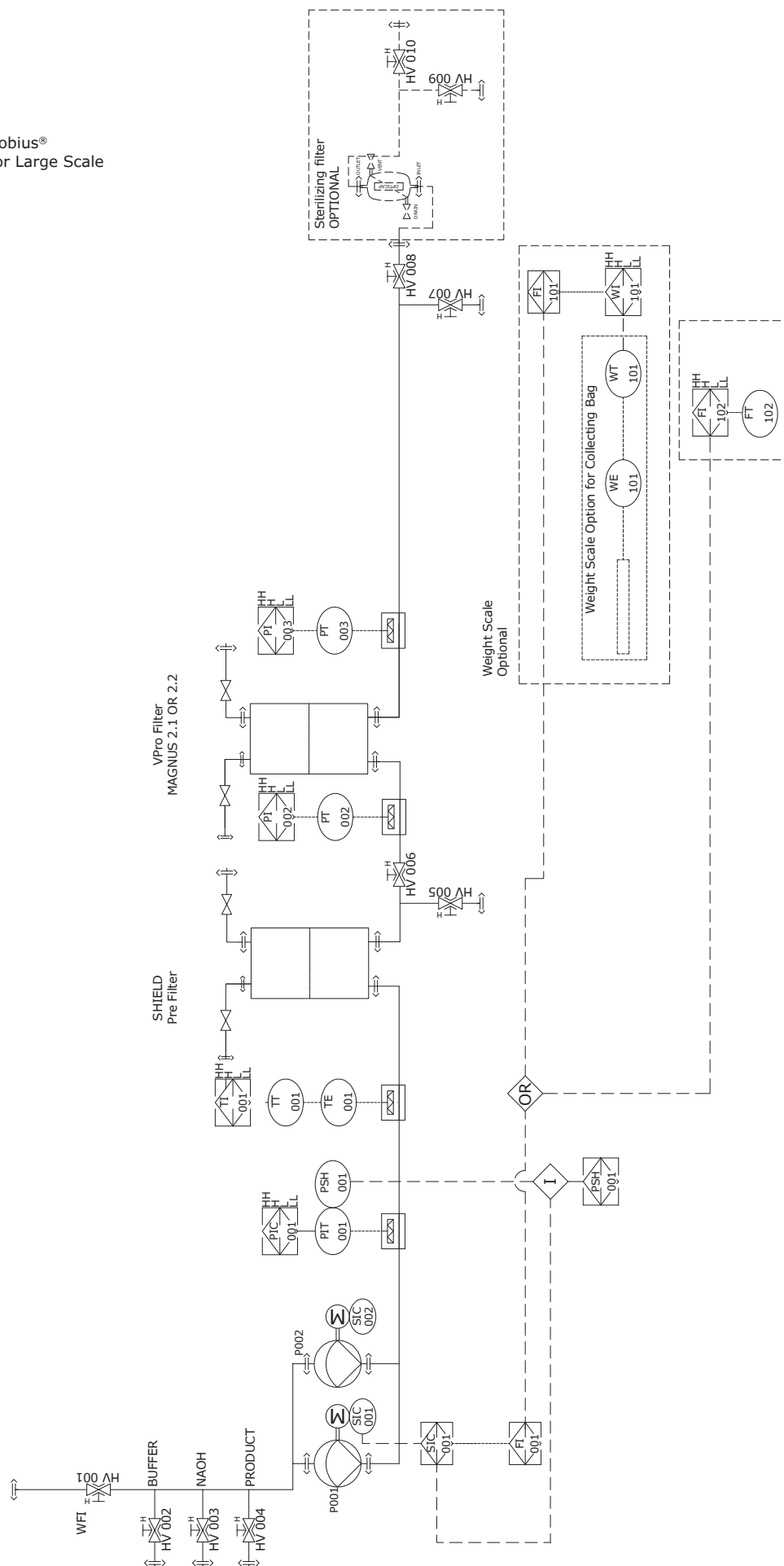
Description	VF3 5 LPM	VF3 20 LPM	VF3 40 LPM
Feed Skid Unit Overall Dimensions			
(H x W x D) mm:	VF3 skid: 1657 x 1875 x 861 (+/- 10 mm) POD cart: 1138 x 1129 x 650 (+/- 10 mm)		
Total Weight (approx.)	390 kg		
Wheels			
No. Total:	4		
No. Locking:	2		
Utility Requirements:	110 or 230 V 50/60 Hz (1 phase, + 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:	4 to 25°C		
Humidity:	10 – 90% (non-condensing)		
Pressure Rating:	Up to 4.1 bar (60 psig), 2.1 bar (30 psi) with POD prefilter		
Process Fluid Temperature Range:	4 to 30°C		
Process Connection Type:	TC 3/4"		
Materials of Construction			
Flowpath:	Different grade of silicone, polypropylene, 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 Sizes:	3/8" ID	5/8" ID	3/4" ID
Inlets:	Up to 4 inlets on manifold (TC 3/4")		
Outlets:	Up to 2 drain lines (TC or colder) + 1 collection (TC)		
Max Membrane Holder Capacity for Magnus filter device:	Up to 3.06 m²		
Membrane Holder Capacity Viresolve® Pro Magnus/ Shield Device:	0.51 m²	0.51 – 1.53 m²	1.53 – 3.06 m²
Flux:	420 – 660 LMH @ 30 psig 490 – 665 LMH @ 35 psig 560 – 680 LMH @ 40 psig	for 1.02 m² 480 – 660 LMH @ 30 psig 490 – 1100 LMH (b/w 35 – 50 psig)	for 1.53 m² 630 – 770 LMH @ 35 psig 640 – 880 LMH @ 40 psig 700 – 1100 LMH @ 50 psig
Pumps			
Brand:	Quattroflow™/Almatech	Quattroflow™/Almatech	Quattroflow™/Almatech
Model:	150S	1200S	1200S
Quantity	2	1	2
Flow range:	0.2 – 5 LPM	2 – 20 LPM	4 – 40 LPM
Valves			
Hardware Valves			
Type:	Manual pinch valve	Manual pinch valve	Manual pinch valve
Brand:	Pinch Valve Biovalve	Pinch Valve Biovalve	Pinch Valve Biovalve
Model:	3/8	1/2-1	1/2-1
Pressure Switch			
Location:	After pumps	After pumps	After pumps
Brand:	Labom	Labom	Labom
Model:	Pascal CV3110	Pascal CV3110	Pascal CV3110
Range:	0 – 4 bar	0 – 4 bar	0 – 4 bar
Loop accuracy:	±0.2 bar	±0.2 bar	±0.2 bar

Description	VF3 5 LPM	VF3 20 LPM	VF3 40 LPM
Sensors			
Pressure (Optional):			
Type:	Non intrusive	Non intrusive	Non intrusive
Location:	Before Viresolve® Pro Magnus device	Before Viresolve® Pro Magnus device	Before Viresolve® Pro Magnus device
Brand:	Labom	Labom	Labom
Model:	CC 60	CC 60	CC 60
Range:	0 – 6 bar	0 – 6 bar	0 – 6 bar
Loop accuracy:	± 0.2 bar	± 0.2 bar	± 0.2 bar
Pressure:			
Type:	Non intrusive	Non intrusive	Non intrusive
Location:	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device
Brand:	Labom	Labom	Labom
Model:	CC 60	CC 60	CC 60
Range:	0 – 6 bar	0 – 6 bar	0 – 6 bar
Loop accuracy:	± 0.2 bar	± 0.2 bar	± 0.2 bar
Temperature:			
Type:	Non intrusive	Non intrusive	Non intrusive
Location:	After pumps	After pumps	After pumps
Brand:	Labom	Labom	Labom
Model:	Type Series GA270	Type Series GA270	Type Series GA270
Range:	-40 °C / + 85 °C	-40 °C / + 85 °C	-40 °C / + 85 °C
Loop accuracy:	± 2 °C	± 2 °C	± 2 °C
Filtrate pH (Optional):			
Type:	Single-use cell using glass pH probe	Single-use cell using glass pH probe	Single-use cell using glass pH probe
Location:	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device
Brand:	Finesse	Finesse	Finesse
Model:	True pH	True pH	True pH
Range:	1 to 14 pH	1 to 14 pH	1 to 14 pH
Loop accuracy:	± 0.1 pH (b/w pH 3 to 9)	± 0.1 pH (b/w pH 3 to 9)	± 0.1 pH (b/w pH 3 to 9)
Filtrate Conductivity (Optional):			
Type:	Single-use cell	Single-use cell	Single-use cell
Location:	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device	After Viresolve® Pro Magnus device
Brand:	Optek	Optek	Optek
Model:	ACF60	ACF60	ACF60
Range:	0 – 150 mS/cm	0 – 150 mS/cm	0 – 150 mS/cm
Loop accuracy:	± 2% FS	± 2% FS	± 2% FS
Filtrate Flowmeter (Optional):			
	Electrical connection available for a customer filtrate flowmeter	Electrical connection available for a customer filtrate flowmeter	Electrical connection available for a customer filtrate flowmeter
Filtrate Weight scale:			
Location:	Filtrate line for recovery bag	Filtrate line for recovery bag	Filtrate line for recovery bag
Brand:	Customer balance or Metler Toledo	Customer balance or Metler Toledo	Customer balance or Metler Toledo
Model:	Deckmate 2888 Portable	Deckmate 2888 Portable or PFA579-FM3000	PFA579-FM3000
Range:	0 – 600 kg	0 – 600 kg or 0 – 3000 kg	0 – 3000 kg
Loop accuracy:	0.1 % FS	0.1 % FS	0.1 % FS
Control Loops:	Calculated feed flow (± 10 % measured value) Constant Magnus Delta Δ Constant flow rate Constant flow followed by constant Delta Δ		
Automation:	Semi-automated system with manual valves actuation Reports generation (analog values, alarms and events) with checksum Partially compliant with 21CFR Part 11		
CPU:	Siemens CPU		
Screen:	Siemens Simatic		
Data export:	On MMC card, on external computer		
Ethernet IP connection (optional):	Anybus® x-Gateway™ Ethernet adapter		
Documentation:	User Manual: 1 paper copy + on CD Technical Documentation: on CD QA documentation: 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:	4
No. Locking:	2
Viresolve® Pre-filter Membrane Holder	
Recommended Capacity (optional):	Up to 5.5 m²

Figure 2.

Diagram Example: Mobius®
FlexReady Solution for Large Scale
Virus Filtration





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