

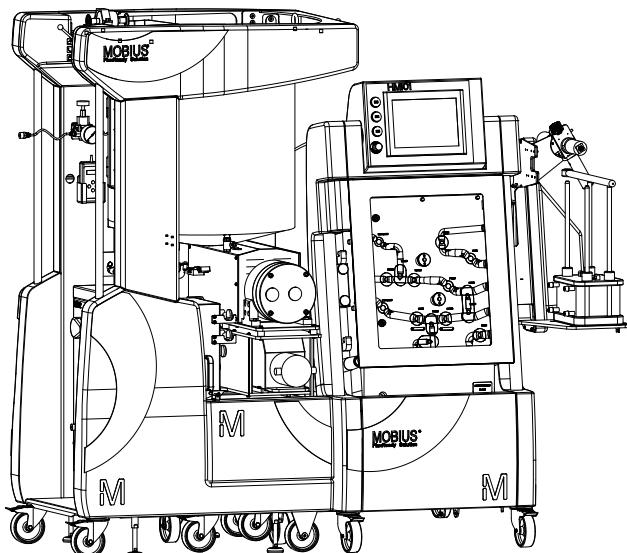
Mobius[®] FlexReady Solution with Smart Flexware[®] Assemblies for TFF

Features

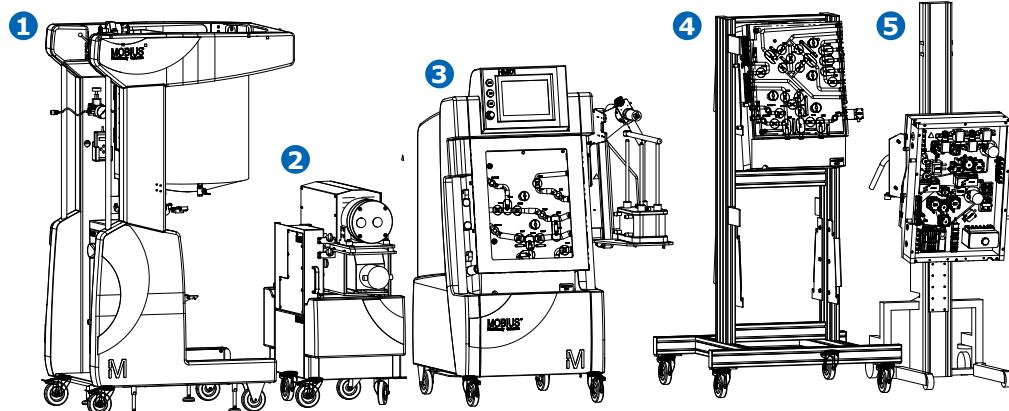
- Flexible design options
- Unique feed tank design and performance
- Smart Flexware[®] full single-use flow paths
- Excellent product recovery and purification
- Implement with ease and lower risks
- Full process automation with flexible recipes using the Common Control Platform[®] (CCP[®])

Benefits

- Ability to produce higher final concentrations
- Consistently deliver safety and quality with less cleaning validation and lower risk of cross contamination
- Ability to meet unique requirements
- Agile system able to perform at multiple scales for both TFF and Chromatography
- Simplified training requirements



TF2S: 18L/min – 0.5 to 5.0 m² Pellicon[®] cassettes or similar



1. Tank cart
2. Pump and manifold cart
3. Smart cart with exchangeable clamshell
4. Clamshell storage rack
5. Clamshell lift

General Specifications

System Dimensions

Carts connected H x L x W in. (mm)	2022 x 2160 x 974 +/- 20 mm
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Net Weight

Tank cart 50 L	280 kg
Tank cart 100 L	310 kg
Tank cart 200 L	330 kg
Smart cart with clamshell	430 kg
Pump cart with 2 pumps and manifold	200 kg

Environmental Operating Conditions

Product temperature range	2 to 45 °C
System operation temperature	2 to 30 °C
Operating humidity	10%–90% (non-condensing)
Operating pressure	4 bar max: feed / retentate assemblies 2 bar max: transfer / filtrate assemblies Atmospheric pressure: feed bag

Fluidic Sections

Feed Section

Feed container volume	50 L/100 L/200 L in LLDPE or stainless steel container with jacket
Tank jacket volume	50 L tank 3.3 L 100 L tank 6.0 L 200 L tank 7.8 L
Pump model	Quattroflow 1200 SU
Flow at 4 bar max	2 to 20 L/min
Minimal working volume (w/o cassettes feed volume)	0,7 L -1,8 L from 2 to 18 L/min*
Maximum viscosity	35cP
Pressure sensor	Non-intrusive 0-4 bar +/-0.2 bar; Security switch set at 4.4 bar
Tank weight	0.3% FS
Control on feed pump	Fixed position (speed in %) or flow control or pressure drop control
Precision of calculated feed flow	+/-10% with feed pressure at least 1 bar
Temperature sensor feed container	2-45 °C +/- 2 °C

*May vary slightly depending on the configuration system and other parameters.

Transfer Section

Pump model	Quattroflow™ 1200 SU
Flow at 2 bar	5m ² : 2 to 9 L/min
Transfer pump control	Fixed position (speed in %) or level control
Pressure sensor	0-4 bar +/-0.2 bar; Security switch set at 2.3 bar

Retentate Section

Pressure sensor	Non-intrusive	0-4 bar +/-0.2bar
Sampling		Optional zero dead leg device – NovaSeptum® sampling solution compatible
Volume factor concentration	VCF	Precision better than 2%
Retentate PCV control		Fixed position (% of closure) or TMP control or retentate pressure control

Filtrate Section

Pressure sensor	Non-intrusive	0-4 bar +/-0.2bar
Conductivity and UV	In-line Single-use Cell (Optek) and Multi-use	Conductivity: 0 to 100 µS/cm +/-2% FS UV: 0 to 2 AU +/-2% FS OPL: 10 mm Wavelength: 280 nm / 300 nm
Weight with Mobius® weight scale		0 to 600 Kg +/-0.3 % FS
Weight with user supplied weight scale		0 to 1000 Kg (accuracy linked to component connected)
Flowmeter	Non intrusive (ultrasonic by Emtec)	From 2LPM: +/-5% MV Below 2LMP: +/-0,12 LPM
Sampling		Optional zero dead leg device NovaSeptum® sampling solution compatible
Filtre PCV control		Fixed position (% of opening) or TMP

Important Note:

The single-use cell (SUC) is factory calibrated by Optek and for best performance the end-user should enter in the C8000 transmitter, the K factor delivered with each new sensor assembly.

As calibration is dependent on each SUC installed, the calibration loop should be verified by the end-user prior and/or after each batch (as per customer internal standard operating procedures.)

In consequence, during internal release test, only the proper wiring of the loops is tested using:

- Calibrated UV filters
- A conductivity tester supplied by Optek to simulate a conductivity value

Documentation

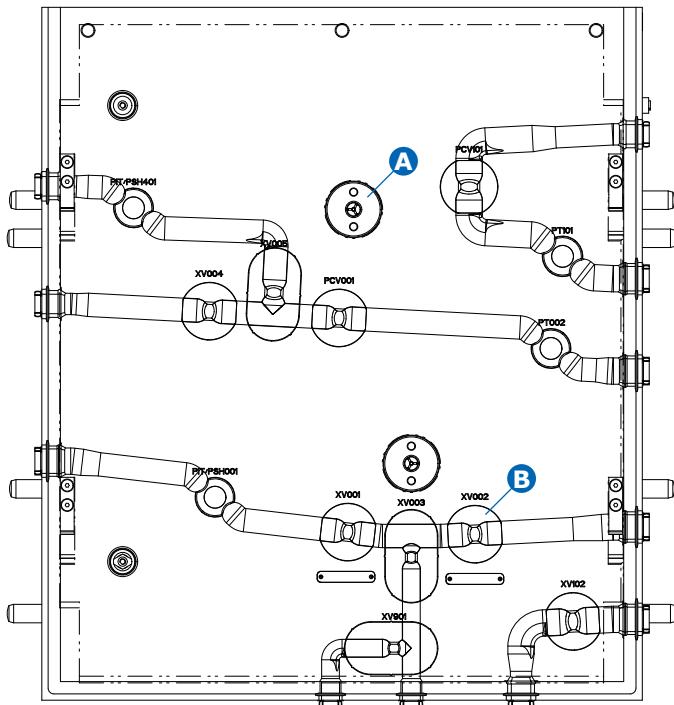
User guide on CD

Access to template recipes upon request

1. FDA Guidance for Industry Process Validation: General Principles and Practices – January 2011
2. Annex 15 to the EU Guide to Good Manufacturing Practice Qualification and Validation – July 2001
3. Mobius® FlexReady solution with Smart Flexware Assemblies for tangential – Flow Filtration Performance Guide – AN4465EN00

Smart Flowpath

The smart flowpath is a unique and patented fluid management device featuring fewer connections than other designs. Fewer connections provide improved process effectiveness through reduced working volume and protein shearing, reduced leak risks, and maximum product recovery.



Feed

XV001, XV002: Normally Closed Valves
PIT/PSH001 : High Pressure Switch Sensor

Retentate

PCV001: Normally Opened Control Valve
XV004: Normally Opened Valve
PT002: Retentate Pressure Sensor

Filtrate

PCV101: Normally Closed Control Valve
PT101: Filtrate Pressure Sensor

Transfer

XV005: Normally Closed Valve
PIT/PSH401: High Pressure Switch Sensor

Drain/recovery

XV901, XV003: Normally Closed Valves

Filtrate drain

XV102: Normally Closed Valve

A: Internal door locks and sensors

B: Silicone Valve Pads

Endurance

Active process time	12 h at 50 cycles per valve
Valve pads longevity	2500 cycles / 6 months

Wetted Materials

Tubing	Silicone
Smart Flexware® Assembly	Pureflex™ film and PE fittings
Feed Bag Assembly	Pureflex™ film
Pump Head	EPDM, Santoprene® and Polypropylene
Liners	Polysulfone
Connectors	Polypropylene and Polysulfone
Multi-use UV & Conductivity Sensors	Quartz, EPDM and stainless steel 316 L
Single Use UV & Conductivity Sensors	Polysulfone Quartz, EPDM and stainless steel 316 L (pins only)
Retentate Low Dead Volume TC Sampler	DMDA-1250 NT 7, sampler: HDPE O-ring: silicone
TFF Mixer Vortex Breaker & Diverter Plate	HDPE

Regulatory and Quality Compliance

USP <87> Biological reactivity <i>in vitro</i> , USP <88> Biological Reactivity <i>in vivo</i> , Plastic Class VI	Compliant
Irradiation dose	25–40 kG
21 CFR Part 11	Compliant ready
2004/108/CE Electromagnetic Compatibility (EMC)	Compliant
2006/42/CE Machinery Directive	Compliant
PSE	Exempt
ASME U-1 code	Tank Jacket is compliant

Data and System Control

PLC	Allen-Bradley CompactLogix™
Control software system	Microsoft® Windows® 7
Operator interface panel type	iFix®
Operator interface	12.1" tiltable touch screen
Languages	English, German, Spanish, Japanese, French, Italian, Chinese, Korean
Security	Based on Microsoft® Windows® operating system Configurable user access group levels (4 pre-configured)
Data acquisition	Stored in Read Only Database
PC	B&R
Data	21 CFR Part 11 compliance ready
Manufacturing	GMP compliance ready

Utilities Connections

OPC server	RJ45
Keyboard	USB
External storage media	USB
Mouse	USB
Air	6–10 bar oil free at 4 L/min max

Power Supply

Smart Cart	220–240 VAC, 50/60 Hz, 1 phase, 3.9 A Or 100–120 VAC, 50/60 Hz, 1 phase, 8.4 A Maximum power consumption 1 kW
Tank Cart	220–240 VAC, 50/60 Hz, 1 phase, 0.4 A (50 L) – 1.8 A (100/200 L) Or 100–120 VAC, 50/60 Hz, 1 phase, 0.8 A (50 L) – 3.7 A (100/200 L) Maximum power consumption 0.1 kW (50L) to 0.4 kW (100/200L)
Pump cart	3 x 200–240 VAC, 50/60 Hz, 3 phases + neutral + ground, 10 A Or 3 x 400–460 VAC, 50/60 Hz, 3 phases + neutral + ground, 5 A Maximum power consumption 3 kW

Services Packages

We offer a wide range of comprehensive packages to meet your unique manufacturing requirements, resulting in peace of mind and maximum operational flexibility.

	Operator Training	SAT	IQ/OQ	CCP® Recipe Design	CCP® Training	Support for PQ
Qualification package non-cGMP	●	●				
Qualification package GMP	●	●	●			●
Single molecule non cGMP package	●	●	●	●		
Multi Molecule cGMP package	●	●	●		●	
Single Molecule cGMP package	●	●	●	●		●
Full cGMP package	●	●	●	●	●	●

Full cGMP Package is designed for 2 to 4 attendees at manufacturing site and delivered by a Qualified Field Service Engineer and/or a Biomanufacturing Science Engineer. Upon completion a Certificate of Achievement will be delivered.

Basic operator/system training is recommended prior to any FAT/SAT to ensure proper focus on the FAT/SAT objectives.

For additional information, visit

SigmaAldrich.com

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

