Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Mobius® Multi Column Capture System

The most comprehensive multi-column capture system for intensified fed-batch or perfusion monoclonal antibody bioproduction

The Mobius® Multi Column Capture system is designed as a fully automated, single-use solution to operate continuous closed capture chromatography.

The system manages process parameters in real time with reference to changing column load, surge feed tank load, and monitoring resin performance. Coupled with an in-line dilution capability and intuitive software, the 3 columns system allows complete control of the capture step of your fed-batch or perfusion bioprocess. The Mobius® Multi Column Capture system is suitable for bioreactor volumes ranging from 50 L to 2000 L.

Resin usage optimization for continuous chromatography

In traditional capture chromatography, the resin is only utilized at 60–70% of its capacity to minimize potential product loss. Continuous loading of multiple columns in series allows for improved resin usage, decreasing the volume of resin required by up to 99%, improving overall productivity and decreasing volume of buffer required for a process. A cost analysis is available on demand, please contact your sales representative to access our interactive PDF calculator.

MilliporeSigma is the U.S. and Canada Life Science business of Merck KGaA, Darmstadt, Germany.

MilliporeSigma

Time saving and cost-efficient features:

Real-time automated control for minimized operator intervention and enhanced process reproducibility

- In-process **real-time adjustment** to variation in feed concentration for a reproducible quantity of protein loaded
- **Flow rate adjustment** to upstream feed
- Automated continuous **HETP frontal analysis** for column performance and stability monitoring
- **In-line dilution** minimizes time and resources required for buffer preparation. Results have demonstrated the capabilities of the system to run two modes of dilutions respecting a mixing error below **4.4% in percentage** mode and below **2.3% in conductivity** mode for all total flowrates and dilution rates tested
- Process data recording: configuration and exportation of graphs and images representative of the data

Designed for diverse process modes and scales

- Flow rates from **1–120 L/h** provide flexibility and adjustability across scales to enable seamless scale up from early clinical development (50 L bioreactors) to commercial manufacturing (2000 L bioreactors)
- Accommodation of **fed-batch** and **perfusion** process streams
- The CCP® Software is very intuitive with low training time and includes **recipe editor with preconfigured** steps and phases for fast continuous process creation and control
- Best-in-class architecture for cleanability and set up

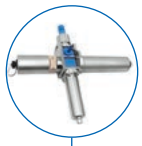
A fully closed continuous process without the need for interruption

- Recalibration of **pH probes** during the continuous process, and ability to **adjust flowrates real-time** with respect to upstream feed enable the process to be truly continuous for days
- Our offering of Flexware® assembly configurations have been qualified for continuous processing for **20 days**
- A large consumable offering of **100% single-use** assemblies suits the needs for both traditional and closed processes. Our filters, equipped with AseptiQuick® connectors eliminate contamination and carry-over risks

System Components

1 concentrate/buffer line and 1 diluent line allowing for dilution of up to 6 buffers.

Optional pre-column filter to protect the column.



3 x 2 pre-column sensors (pH and conductivity) and 3 x 3 post-column sensors (pH, UV, and conductivity). All instruments are fully single-use. pH probe can be single- or multi-use.

Product and buffer lines running in parallel, allowing to load the product continuously over 20 days.

We offer 3 possible UV configurations:

- 280 nm
- 280–308 nm
- 254–280 nm

and 2 possible optical path length configurations on the Flexware® assembly:

- 1 mm
- 2.5 mm

Select between a Flexware® assembly with TC and CPC® MPC connectors, and a Flexware® assembly with CPC® AseptiQuik® connectors, enabling closed processing.

Pre-packed columns can be placed on the system trolley for further footprint optimization.

Flexware® assembly installation has been streamlined through color-coding, direction indicators, and labels to reduce errors.

Gamma irradiated, 100% single-use Flexware® assemblies

The single-use Flexware® assemblies are **USP class VI and Animal-Free and EMA/410/01**-compliant, delivering equivalent performance to that of traditional stainless-steel systems, while maximizing system flexibility.

Components designed for closed processing

In addition, we offer a flowpath designed to enable closed processing, including pre-column and waste filter providing the necessary segregation from potential contaminating factors present in the environment, thanks to CPC® AseptiQuik® connectors. It prevents contamination while reducing or eliminating reliance on environmental controls, enabling reduced area classification.

Common Control Platform® (CCP®) Software

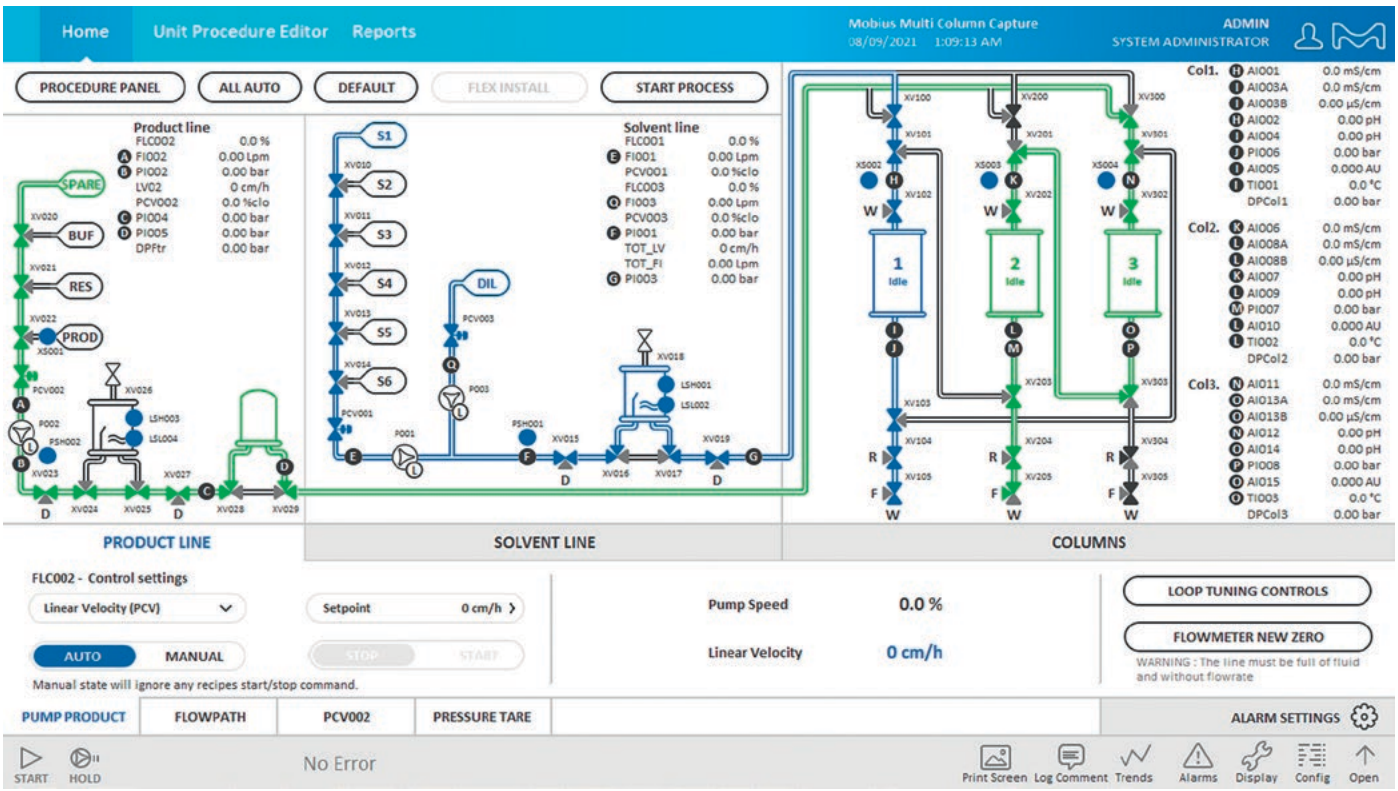
The Common Control Platform® (CCP®) is a powerful automation software with an intuitive graphical interface on a 19 inch touch screen that provides real-time monitoring and in-depth control of the process.

A software developed for fast continuous process set up and recipe creation.

Each aspect of the process can be monitored and controlled from the home screen through the interactive P&ID. Process operations can be created using the **recipe editor**. There are **pre-defined steps** for continuous chromatography. Together with **6 programmable phases**, make recipe creation very simple. Reports can be easily created using the configurable report generator.

CCP® software is designed for cGMP facilities, developed in line with GAMP® 5 recommendations for automation software, and fulfills EU GMP annex 11 & FDA guideline 21 CFR Part 11 requirements for electronic records and signatures.

Our CCP® software provides one software platform across our portfolio of automated systems for a familiar look and feel at each step of the process.



Related Products to Support your Intensified Chromatography Process

OPUS® Pre-packed Columns

OPUS® pre-packed columns are a convenient and flexible solution suitable for biomanufacturing processes at any stage of development. Ranging in size from 5 cm to 80 cm internal diameter and a bed height from 5 cm to 30 cm configurable to the nearest millimeter, OPUS® GMP columns can handle resin volumes from 0.5 L to 150 L. The Mobius® Multi Column Capture system can accommodate OPUS® columns from 10 cm to 25 cm diameter. Please contact your local sales representative for more information.

QuikScale® Chromatography Columns

Designed to achieve maximized throughput, our QuikScale® columns are easily packed to deliver optimal resolution across a wide range of chromatographic applications, accommodating all media types. The flow distributor assures full, uniform media utilization within the column, assuring reproducible and reliable separations. QuikScale® chromatography columns offer fast packing and unpacking, predictable and scalable performances, and flow adjuster seal technology for fail-safe operation in a choice of column tube materials for any application. Check the QuikScale® Columns data sheet for more information (DS1224EN00).

Eshmuno® A Resin

Eshmuno® A affinity chromatography resin has a high dynamic binding capacity for primary mAb capture. The rigid base bead and novel ligand combination is optimized for acid and alkaline resistance for efficient cleaning and sanitization while still maintaining high capacity for improved throughput of processed mAb by resin volume. Check our website for more information.

Buffer Concentrates

As a trusted partner in your biopharmaceutical supply chain, we bring together products and services to offer the industry's highest quality sterile liquid capabilities. We manufacture a broad range of ready to use, pre-titrated buffer concentrates, that require minimal adjustment, post dilution. Concentration factors >30x are achievable, allowing for significant reductions in operational footprint. Check our website for more information.

Mobius® Multi Column Capture System Services

The pharmaceutical and biotechnology industries are highly regulated and, to help you navigate this challenging environment, we offer a wide range of services. These services help you save time, lower costs, and comply with regulations. For your peace of mind, all our services are performed by our global experts who have an intimate knowledge of our equipment backed by decades of experience.

Qualification Services

Our qualification services are designed to make the integration of our system into your process as seamless as possible and ensure your equipment is properly installed and functioning per your pre-defined requirements.

- Factory acceptance test (FAT)
- Installation qualification/operational qualification (IQ/OQ)
- Full test package: this service is an alternative to standard IQ/OQ for customers who wish to have tests from FAT performed again at their site
- Performance qualification support (PQ)

Training Services

Appropriate training for users is not only a GMP requirement, it also ensures your staff has the expertise to operate and manage the system as part of your manufacturing process.

Our training offering has been designed to make your staff more autonomous in managing your system and your process while saving time and money. Our training services cover system use and programming with interactive hands-on sessions and, depending on the training you select, may also include:

- Installing the Flexware® assemblies
- Interacting with the human machine interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

These trainings can be delivered either at your site or in our M Lab™ Collaboration Centers. Please contact your local representative or email ilearn@milliporesigma.com to discuss our training offering.

Specialized Services

CCP® Software Recipe Design

Every process is unique and to ensure that your system is optimized to deliver the best performance, our biomanufacturing engineers will configure your process into your own CCP® software recipe. This allows your system to run fully automatically, resulting in consistency and reduced operator error.

Application Support

Our chromatography experts can help you design your process and scale-up, ensuring smooth operations and efficient process.

System Service Reliance Plans

To support you in ensuring optimum equipment uptime and regulatory compliance while mitigating risks, we have developed a complete range of services for your systems and equipment: System Service Reliance Plans. These comprehensive packages offer priority access to a wide range of services and support, ensuring your equipment is properly maintained and allowing you to select a coverage level that best fits your needs. For additional details, please refer to the System Service Reliance Plans Data Sheet (MK_DS7881EN).

Spare parts & Repair Services

Repair services

In the unlikely case your system does experience a problem, our worldwide engineering organization will provide on-site technical support to get you back up and running as quickly as possible.

Spare parts

Purchasing spare parts directly from us is the only way we can guarantee that you get the right parts every time, with the same level of performance as the original. For details and ordering information, please check the illustrated spare parts list (MK_CA9082EN).

Learn more on our systems services at **SigmaAldrich.com/product-services**

System and Flexware® Assemblies Specifications

General System specifications

Specifications	Mobius® Multi Column Capture System	
Pumps	Model	Quattroflow® QF150SU x 3
	Pump Control	Pump speed, flow rate, linear velocity
	Maximum Pressure	4 bar
Valves	On/Off 3-way valves	Automatic Asco pinch valves $^{1}/_{4}$" x 32
	On/Off valves (2-way)	Automatic Acro Pinch Valve 934 $^{1}/_{4}$" x 2 (venting BBT)
	Drain valve	Automatic Gemü Sumondo $^{3}/_{8}$" ID x 4
	Pressure Control Valves (PCV)	Automatic Acro pinch valve 934 $^{1}/_{4}$" with pressure regulator x 3
	Bubble trap (BBT) vent valve	Acro pinch valve 934 x 2

Mechanical Specifications

Specifications	Mobius® Multi Column Capture System	
System dimensions (±12 mm) (without Flexware® assemblies)	Pump cart (H x W x D)	1788 x 1091 x 855 mm (70.39 x 42.95 x 33.66 in.)
	Instrumentation cart (H x W x D)	1445 x 1251 x 855 mm (56.89 x 49.25 x 33.66 in.)
	Columns trolley (H x W x D)	769 x 630 x 845 mm (30.28 x 24.80 x 33.27 in.)
	All carts connected (H x W x D)	1788 x 2342 x 855 mm (70.39 x 92.20 x 33.66 in.)
Net weight	Pump cart	405 kg
	Instrumentation cart	283 kg
	Columns trolley	59 kg
Materials of construction	**Wetted Components**	
	Tubing	Silicone
	Pump chambers	EPDM, Santoprene® and Polypropylene
	AseptiQuik® connectors	Polycarbonate
	MPC connectors	Polysulfone
	Flowmeter	Polypropylene
	UV, conductivity (SUC)	Polysulfone Quartz, EPDM and Stainless Steel 316L (pins only)
	pH probes (SU and MU)	Glass and VMQ (Silicone elastomer)
	Drain valves	Body: PP-R Natural (Bormed RF830MO) Diaphragm: TPE (Thermolast TM9MED)
	Filters (pre-column and waste)	Membrane: Hydrophilic polyethersulfone Film edge: Polypropylene Vent O-rings: Silicone
	BBT bag	PureFlex™ film (ULDPE)
	Non-Wetted Components	
	Carts	Stainless steel 304L minimum
Casters	Pump cart	4 including 2 with locking
	Instrumentation cart	4 including 2 with locking
	Trolley	4 including 2 with locking
Aseptic connections	Inlets (x6 and x3 and x1)	Colder AseptiQuik® S $^{1}/_{4}$ in.
	Outlets (x5)	Colder AseptiQuik® S $^{1}/_{4}$ in.
	Filter pre-column	Colder AseptiQuik® G $^{1}/_{4}$ in.
Connections	Inlets (x6 and x3 and x1)	MPC $^{1}/_{4}$ in.
	Outlets (x5)	MPC $^{1}/_{4}$ in.
	Filter pre-column	TC 1 in. $^{1}/_{2}$
	Columns	TC $^{3}/_{4}$ in.

Operating Specifications

Specifications	Mobius® Multi Column Capture System
Pump flow range	1 to 120 L/h
Dilution	Conductivity: ±3 mS/cm Percentage/volume: ±6%
Total operating time	Valves operations: Min 10000 actuations
	Up to 20 days under worst conditions: 4 bars, 2 L/min, fluid at 20 °C*
Fluid temperature range	15–30 °C
Fluid pressure range	Max 4 bar
Fluid operating viscosity	Max 2 Cp
System operating temperature range	Ambient (15–30 °C)
Pressure pulsations after the pumps	Max 0.2 bar
System operating humidity	30–85%, non-condensing
Power supply	Universal power supply compatible from 100 VAC to 240 VAC at 50 Hz and 60 Hz. Max consumption 500 W.
Pneumatic supply	Compressed air ≥6 bar, instrument air filtered to ≤5 mm, –20 °C dew point, oil free
Pneumatic connection	Quick connector with pneumatic fitting (flexible hose Ø12 mm OD supplied by customer)

*Additional information can be found in the performance guide doc XXX

Instrument Specifications

Specification	Tags	Range/Setting/Type/Accuracy	Process Connection
Pressure Sensors Pendotech PRESS-N-025-W	PE003 PE004 PE005 PE006 PE007 PE008	Range: from 0 to 4.2 bar Accuracy: ±0.1 bar from 0.0 to 2.0 bar ±0.2 bar from 2.0 to 4.0 bar	Non-intrusive
High Pressure Switches Pendotech PRESS-N-025-W	PE/PSH001 PE/PSH002		Non-intrusive
Flowmeters Ultrasonic Levitronix® 100-30374	FE001 FE002 FE003	Range: 0.016 to 2.000 L/min Accuracy in standard condition (water, 20 °C, 1 cp): • from 16 to <75 mL/min: ±1.75 mL/min • from ≥75 to 2000 mL/min: ±3% MV	Single-use flow cells Inline
Temperature Sensors (Included in conductivity sensor)	TE001 TE002 TE003	Process range: 0–40 °C Process accuracy: ±1 °C	Combined with conductivity sensors
Conductivity Sensors Optek® ACF60	AE001 AE006 AE011 AE003 AE008 AE013	0 to 50 µS/cm (cleaning): Accuracy: ±3% MV ±0.4 µS/cm 0 to 200 mS/cm (process) Accuracy: ±3% MV ±0.4 mS/cm	Single-use flow cells Inline
pH Sensor MU: Hamilton 243632-2313	AT002 AT007 AT012 AT004 AT009 AT014	**Multi-use:** Process range: 2–13 pH Process accuracy: ±0.10 pH after calibration on pH range from 2 to 11	Multi-use pH probes must be ordered separatly
pH Sensor SU: Hamilton 243236	AT002 AT007 AT012 AT004 AT009 AT014	**SU:** Process range: 2–12 pH Process accuracy*: • from 2 to 10: ±0.10 pH after process calibration at ±1 pH around calibration point • from 10 to 12: ±0.30 pH after process calibration	Single-use pH probes are included in the Flexware® assembly
Air Sensors Ultrasonic Sonotec® ABD06.95	XS001 XS002 XS003 XS004	Switch instrument, accuracy is not applicable	Non-intrusive
UV Sensors Optek® AF46	AE005 AE010 AE015 AE016 AE017 AE018	**Single Wavelength:** • Process range: 0–3 AU • Process accuracy: ±0.06 AU • Wavelength: 280 nm **Dual Wavelength:** • Process range: 0–2 AU • Process accuracy: ±0.04 AU • Wavelength: 254/280 nm or 280/308 nm For OPL options, please refer to Flexware® assemblies kits	Single-use flow cells Inline
BBT Optical Level Sensor IFM KG5065	LSH001 LSH003 LSL002 LSL004	Switch instrument, accuracy is not applicable	Non-intrusive

* Accuracy for process conditions: pressure <10 psi and conductivity >2.5 mS/cm

Ordering Information

Hardware

Catalogue Number	Description	Wavelength Option		
		Single: 280 nm	Dual: 280 nm & 308 nm	Dual: 280 nm & 254 nm
Switzerland				
MCPMCC02CH1	Mobius® MCC System CH 280 nm	X		
MCPMCC02CH2	Mobius® MCC System CH 280–308 nm		X	
MCPMCC02CH3	Mobius® MCC System CH 280–254 nm			X
China				
MCPMCC02CN1	Mobius® MCC System CN 280 nm	X		
MCPMCC02CN2	Mobius® MCC System CN 280–308 nm		X	
MCPMCC02CN3	Mobius® MCC System CN 280–254 nm			X
Europe				
MCPMCC02EU1	Mobius® MCC System EU 280 nm	X		
MCPMCC02EU2	Mobius® MCC System EU 280–308 nm		X	
MCPMCC02EU3	Mobius® MCC System EU 280–254 nm			X
Japan				
MCPMCC02JP1	Mobius® MCC System JP 280 nm	X		
MCPMCC02JP2	Mobius® MCC System JP 280–308 nm		X	
MCPMCC02JP3	Mobius® MCC System JP 280–254 nm			X
Korea				
MCPMCC02KR1	Mobius® MCC System KR 280 nm	X		
MCPMCC02KR2	Mobius® MCC System KR 280–308 nm		X	
MCPMCC02KR3	Mobius® MCC System KR 280–254 nm			X
North America				
MCPMCC02NA1	Mobius® MCC System NA 280 nm	X		
MCPMCC02NA2	Mobius® MCC System NA 280–308 nm		X	
MCPMCC02NA3	Mobius® MCC System NA 280–254 nm			X
UK				
MCPMCC02UK1	Mobius® MCC System UK 280 nm	X		
MCPMCC02UK2	Mobius® MCC System UK 280–308 nm		X	
MCPMCC02UK3	Mobius® MCC System UK 280–254 nm			X
EAC countries				
MCPMCC02UR1	Mobius® MCC System UR 280 nm	X		
MCPMCC02UR2	Mobius® MCC System UR 280–308 nm		X	
MCPMCC02UR3	Mobius® MCC System UR 280–254 nm			X

Accessories

Catalogue number	Description	Comment
MCPMCC02SUPH	Mobius® Multi Column Capture system arc modules for single-use pH probe (this item contains 6 arc modules)	To be ordered when using Flexware® assemblies kit with single-use pH probe
MCPMCC02MUPH	Mobius® Multi Column Capture system multi-use pH probes (this item contains 6 multi-use pH probes)	To be ordered when using Flexware® kit that does not contain a pH probe
MCPMCC02KBS	Mobius® Multi Column Capture system keyboard support	

Flexware® assemblies kit

Catalogue number	Description	Closed processing ready	With Single Use pH probe	With Dilution line	OPL 2.5 mm	OPL 1.0 mm
FXWMCC0PND1	Mobius® MCC FXW Kit Open WOPH WDIL OPL1	✘	✘[2]	✔	✘	✔
FXWMCC0PNN1	Mobius® MCC FXW Kit Open WOPH WODIL OPL1	✘	✘[2]	✘	✘	✔
FXWMCC0PND2	Mobius® MCC FXW Kit Open WOPH WDIL OPL25	✘	✘[2]	✔	✔	✘
FXWMCC0PNN2	Mobius® MCC FXW Kit Open WOPH WODIL OPL25	✘	✘[2]	✘	✔	✘
FXWMCC0PPD1	Mobius® MCC FXW Kit Open WPH WDIL OPL1	✘	✔[1]	✔	✘	✔
FXWMCC0PPN1	Mobius® MCC FXW Kit Open WPH WODIL OPL1	✘	✔[1]	✘	✘	✔
FXWMCC0PPD2	Mobius® MCC FXW Kit Open WPH WDIL OPL25	✘	✔[1]	✔	✔	✘
FXWMCC0PPN2	Mobius® MCC FXW Kit Open WPH WODIL OPL25	✘	✔[1]	✘	✔	✘
FXWMCCCLND1	Mobius® MCC FXW Kit Closed WOPH WDIL OPL1	✔	✘[2]	✔	✘	✔
FXWMCCCLNN1	Mobius® MCC FXW Kt Closed WOPH WODIL OPL1	✔	✘[2]	✘	✘	✔
FXWMCCCLND2	Mobius® MCC FXW Kit Closed WOPH WDIL OPL25	✔	✘[2]	✔	✔	✘
FXWMCCCLNN2	Mobius® MCC FXW Kit Closed WOPH WODIL OPL25	✔	✘[2]	✘	✔	✘
FXWMCCCLPD1	Mobius® MCC FXW Kit Closed WPH WDIL OPL1	✔	✔[1]	✔	✘	✔
FXWMCCCLPN1	Mobius® MCC FXW Kit Closed WPH WODIL OPL1	✔	✔[1]	✘	✘	✔
FXWMCCCLPD2	Mobius® MCC FXW Kit Closed WPH WDIL OPL25	✔	✔[1]	✔	✔	✘
FXWMCCCLPN2	Mobius® MCC FXW Kt Closed WPH WODIL OPL25	✔	✔[1]	✘	✔	✘

[1] Requires adding an Arc Module: MCPMCC02SUPH
[2] Requires ordering multi-use pH probe separately: MCPMCC02MUPH

Flexware® assemblies accessories to enable closed processing

Catalogue number	Description
FXWMCCSCLF20	Mobius® Multi Column Capture system Flexware® assemblies kit closed pre-column filter 20 inch
FXWMCCSCLF30	Mobius® Multi Column Capture system Flexware® assemblies kit closed pre-column filter 30 inch
FXWMCCSCLWF5	Mobius® Multi Column Capture system Flexware® assemblies kit closed waste filter 5 inch
FXWMCCSCLWF10	Mobius® Multi Column Capture system Flexware® assemblies kit closed waste filter 10 inch
Spare Parts	
FXWMCCSCLBBT	Mobius® Multi Column Capture system Flexware® assemblies kit spare closed bubble trap
FXWMCCS0PBBT	Mobius® Multi Column Capture system Flexware® assemblies kit spare open bubble trap

System Services

Catalogue number	Description
Qualification	
SSVFATSFC	FAT execution for Mobius Chromatography system, included protocol in English
SSVQUAMCC	Mobius® Multi Column Capture system—IQ/OQ execution protocol in English and travel
SSVFTPMCC	Mobius® Multi Column Capture system—Full Test Package execution incl. protocol in English and travel
Specialized support	
SSVRPCCPB	CCP® recipe design, Qt 3
Maintenance and repair[1]	
SSVESPMCC	Mobius® Multi Column Capture system—Essential Service Reliance Plan
SSVESPMCC + SSVADCMCC	Mobius® Multi Column Capture system—Advanced Service Reliance Plan
SSVESPMCC + SSVTOCMCC	Mobius® Multi Column Capture system—Total Service Reliance Plan
Spare parts & kits[2]	
PMFXWKITMCC*	Mobius® Multi Column Capture system—Service kit

[1] For additional information, please visit **SigmaAldrich.com/services-plans**

[2] Please refer to spare part list MK_CA9082EN available at **SigmaAldrich.com/chrom-systems**

Note: PMFXWKITMCC kit should be ordered separately prior to qualification and maintenance services

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Learn more at
SigmaAldrich.com/chrom-systems

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