

Mobius® Chrom Systems

For Purification of Clinical and Process Scale Biologics

The Mobius® Chrom systems are flexible, automated, single-use chromatography systems that enable consistent and reliable separation and purification of mAbs, vaccines, plasma, and therapeutic proteins at clinical and process scales.

The innovative single-use flowpath reduces contamination risk and gives you the confidence to tackle any chromatography challenge, while the flexible design featuring a standard hardware platform that can be combined with a selection of options, empowers you to meet your unique process requirements.

The systems deliver optimal operational flexibility for processes from 50 to 2,000 L with flow rates from 0.1 to 20 L/min, a 5:1 turn down ratio at process scale and enhanced isocratic and linear gradient accuracy. Its single-use flow path offers the flexibility to operate in functionally or fully closed mode.

Benefits

- Manufacturing flexibility
- Fully automated & user friendly
- Safe and reliable process
- Enables high resolution separation

Mobius® Chrom 2



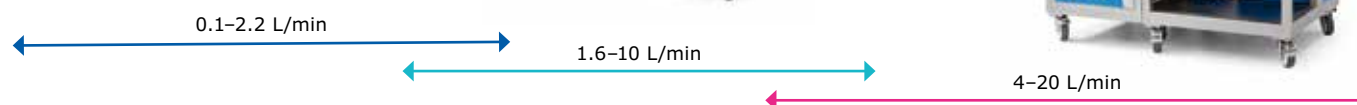
+

Mobius® Chrom 10



+

Mobius® Chrom 20
In-line dilution optional



Benefits

Manufacturing Flexibility

- One family of chromatography systems with harmonized design and linear performance ensures successful and seamless scale-up or scale-down.
- The design of the single-use systems is focused on flexibility, reducing preparation, process time and labour.
- Adapts to multi-products and multi-processing modes (open and closed modes of operation are possible with specifically designed flow path, reducing contamination risk.
- To optimize facility utilization and footprint, an in-line dilution module is available for the Mobius® Chrom 20 system.

Safe and reliable process

The systems and flow paths are extremely robust and enable Good Manufacturing Practices. Superior performance, support & services will meet your expectations to implement and process purifications steps with peace of mind.

Fully automated & user friendly

- Full automation with step edition CCP® software.
- Mobius® Chrom systems designed with operator comfort and safety in mind, featuring a movable screen for operator convenience.
- The stainless-steel surface is easy to clean and the accessible components facilitate maintenance.
- Easy installation of the flowpaths with unique clamshell design.

Enables high resolution separation

The high gradient accuracy of the system enhances separation performance making it ideal for challenging processes.

System Components

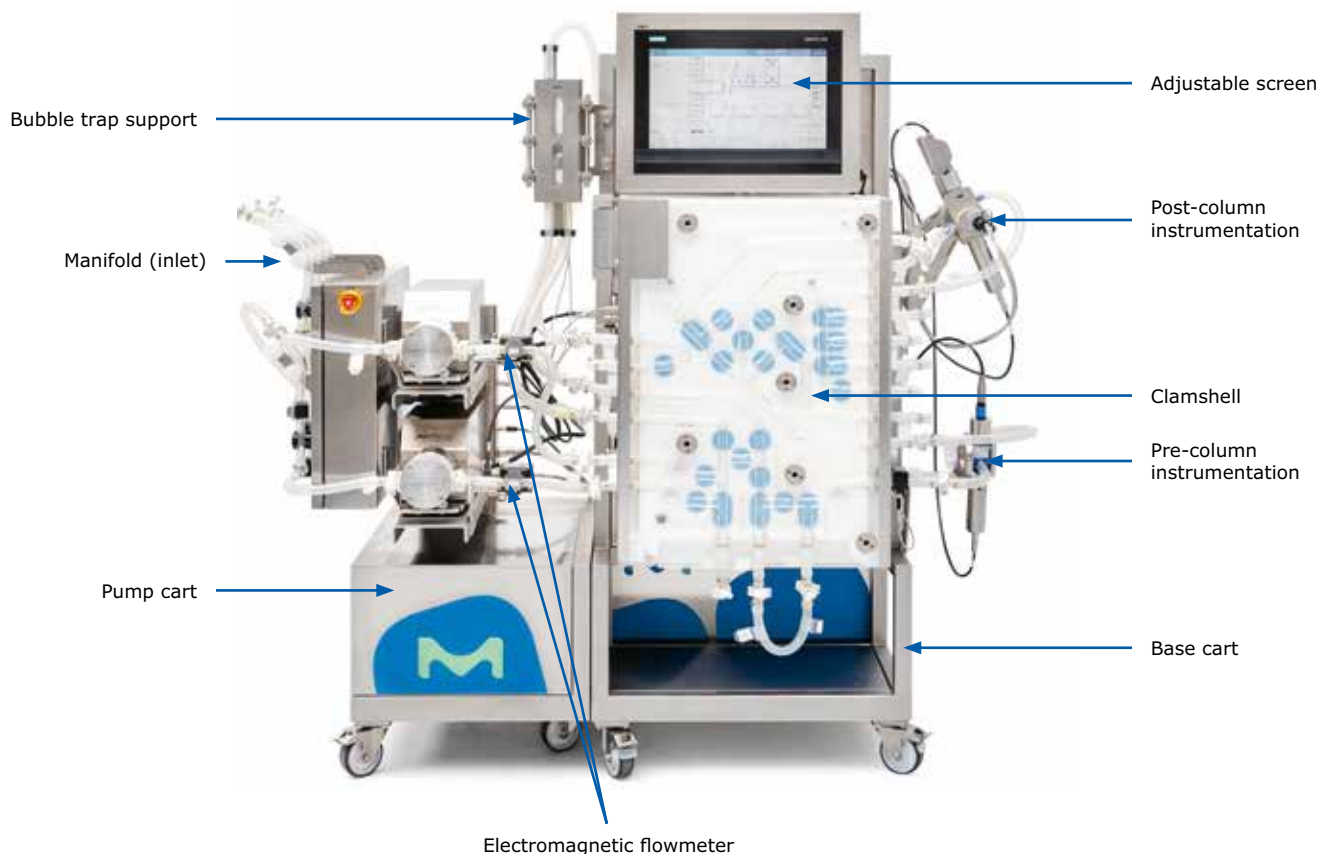
The Mobius® Chrom systems are made up of a base system and configurable options that can be added to design a system that best meets your purification process and challenges.

The base cart is the heart of the system and houses the clamshell and automation software.

Mobius® Chrom Systems Configurations

The basic configuration includes:

- Clamshell
- Pump cart
- Base cart
- Post-column instrumentation

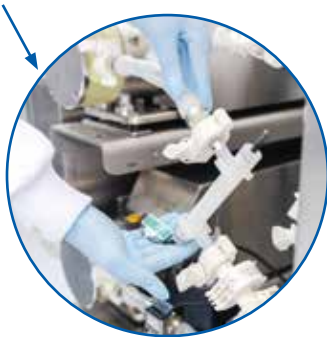


The system options and accessories include:

For Mobius® Chrom 20 system only



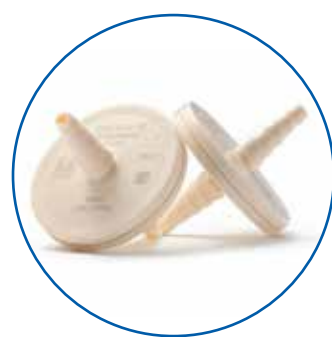
Pre-column 0.2 µm filter and its support for protecting the column



Ultrasonic flowmeter enabling in-line dilution



Pre-column instrumentation for conductivity and pH measurement



Bubble trap vent

Mobius® Chrom Systems standard offering and options

Mobius® Chrom 2	Mobius® Chrom 10	Mobius® Chrom 20 (in-line dilution optional)
Base cart + Bubble trap + Pumps cart + Clamshell		
Magnetic flowmeter		Ultrasonic flowmeter
Single-Use post column instrumentation: conductivity/UV		
254/280 nm		280/300 nm
pH probes*		
Single-Use (pre-installed)		Multi-Use (self installed)

* Please refer to accessories section

Standard offering

Options

Mobius® Chrom Systems Flexware® Assemblies

Single-use Flexware® assemblies deliver equivalent performance to that of traditional stainless-steel systems, while providing maximized contamination control.

Assemblies minimize dead space, decreasing the risk of contamination to virtually zero, while ensuring high gradient accuracy. The assemblies are delivered gamma-irradiated, ready-to-use, and are clearly labeled, significantly reducing the risk of installation error and the challenges typically associated with installing single-use flow paths.

Benefits of our 100% Single-use Flowpaths

- Fast changeover and reduced contamination risk from previous batches in multi-product and multi-scale productions.
- Combination of clamshell and Flexware® clamshell assembly offers easy installation compared to classic tubing.
- Reduced hold-up volume contributes to the enhanced accuracy of the system.
- Reduced number of connections versus traditional single-use assemblies decreases the risk of integrity failure.
- The clamshell assemblies are 100% integrity tested during manufacturing, ensuring reliable performance.

Closed and open modes

All modes of operation are enabled with specifically designed flow path, allowing to reduce contamination risk and protect operators. The switch between modes of operation is straightforward.



Flexware® clamshell assembly labels.



Mobius® Chrom 20 system clamshell and Flexware® clamshell assembly.

Related products to support your chromatography process

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.



IsoPak™ Chromatography Process Columns

Recognized for their proven chromatographic performance, IsoPak™ columns provide faster, cleaner, and more consistent packing and unpacking for reproducible results. IsoPak™ columns are available in a variety of options including IsoPak™ valves, antijet, hydraulic assist, and proven flow cell distribution to provide consistent performance and scalability across a wide range of column diameters.



Industry-Leading Affinity and Ion Exchange Chromatography Medias

Eshmuno® Resin

This unique family of ion-exchange and affinity resins is specifically designed for highly productive downstream purification.

Fractogel® Resin

This tentacle-modified synthetic polymer resin is designed for ion exchange, hydrophobic interaction, size exclusion and metal chelate affinity.

Supply Robustness and Control. Stay Ahead.

Mega-trends are contributing to a boom in the biopharmaceutical industry. As a leading partner and supplier to the industry, we continue to strengthen our supply chain to support our commitment of on-time delivery reliability and product quality to help you stay ahead.



Mobius® Chrom Systems 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 and lower costs. 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).

For additional information on tests performed, please contact us to get the detailed test matrix document (CA11658EN).

Training Services

Appropriate training for users is to ensure 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 training sessions can be delivered either at your site or in our M Lab™ Collaboration Centers. Please contact your local representative or email ilearn@merckgroup.com to discuss our training offering.

System Service Reliance Plans

To help you ensure optimum equipment uptime while mitigating risks, we have developed a wide range of services and support that allow you to select a coverage level that best fits your needs. Our System Service Reliance Plans, a complete range of services for your systems, offer priority access while ensuring your equipment is properly maintained.

For additional details, please refer to the System Service Reliance Plans Data Sheet (DS7881EN). Available at SigmaAldrich.com/services-plans

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 automatic, resulting in consistency and reduced operator error.

For catalogue numbers, please refer to the ordering information at the end of the document.

Repair Services and Spare Parts

Repair Services

In the event your system experiences a problem, our worldwide engineering organization will provide on-site or repair center 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, check the illustrated spare parts list (CA12829EN).

Mobius® Chrom System and Flexware® Assemblies Specifications

General system specifications

Specification	Mobius® Chrom 2 System	Mobius® Chrom 10 System	Mobius® Chrom 20 System	Mobius® Chrom 20 System (with in-line dilution option)
Process range	6–132 L/h	96–600 L/h	In gradient mode within accuracy specifications: 240–1,200 L/h In Isocratic mode: 24–1,200 L/h	

Mechanical Specifications: System and Assemblies

Specification		Mobius® Chrom 2 System	Mobius® Chrom 10 System	Mobius® Chrom 20 System	Mobius® Chrom 20 System (with in-line dilution option)
System Dimensions	Pump & Base carts connected W × H × D in mm	1,836 × 1,697* × 1,104 mm 72.3 × 66.8* × 43.5 inch *when screen is in lower position			
Net Weight	Base cart with Clamshell	Total: 527 kg Base Cart with Clamshell: 365 kg Pump cart with two pump + manifold: 162 kg			
Materials of Construction	Wetted Components meet the criteria for Biological Reactivity Testing. These tests can be any or a combination of the following test methods: USP <88> class VI (<i>in vivo</i>), USP <87> (<i>in vitro</i>), ISO 10993-5 (<i>in vitro</i>).				
	Tubing	Silicone			
	Flexware® Clamshell Assembly	Pureflex™ Film, polyethylene fittings and silicone gaskets, polypropylene			
	Pump Head	EPDM, Santoprene® and Polypropylene			
	Connectors	Polypropylene, polysulfone			
	Magnetic flowmeter	Polysulfone/Nickel			
	Ultrasonic flowmeter	–	–	–	Polypropylene
	UV, Conductivity (Single-Use Cell)	Polyphenylsulfone Quartz, EPDM and Stainless Steel 316 L (pins only)			
	pH probes MU/SU	Glass and VMQ (Silicone elastomer)			
	Non-Wetted Components				
	Base cart, pump cart and cover	Stainless steel 304 (minimum)			
	Clamshell (rear)	POM			
	Clamshell (front)	PMMA			
	Valve Pads	Silicone			
Connections	Inlets (10 = 2 × 5 inlets)	2 × 5 on TC ¾" ¼" tube	2 × 5 on TC ¾" ⅜" tube	2 × 5 on TC ¾" ⅝" tube	
	Outlets, 3 Fractions + 1 Waste	<ul style="list-style-type: none">• 3 Fractions and 1 Waste on MPC connector• Drain line on MPC connector• Vent line on MPC connector• ¼" tube	<ul style="list-style-type: none">• 3 Fractions and 1 Waste on MPC connector• Drain line on MPC connector• Vent line on MPC connector• ⅜" tube	<ul style="list-style-type: none">• 3 Fractions and 1 Waste on TC ¾"• Drain line on TC ¾"• Vent line on TC ¾"• ⅝" tube	
	Filters	¾" TC			
	Column	¾" TC			

Specification		Mobius® Chrom 2 System	Mobius® Chrom 10 System	Mobius® Chrom 20 System	Mobius® Chrom 20 System (ILD)
Power requirements	Base cart	220–240 VAC, 50/60 Hz, 1 phase, 6.5 A OR 100–120 VAC, 50/60 Hz, 1 phase, 13.6 A Maximum consumption 1.6 kW			
	Pump cart	24–48 V Powered by Base cart			
	Clamshell	24 V Powered by Base cart			
General information		6 bar (87 psi, oil free) min – 10 bar (145 psi) maximum			

Instrument Specifications and Performances

Specification	Tag*	Range/Setting/Type/Accuracy	Process Connection
Pressure Indicators	PIT001 PIT002 PT003	0–4 bar (0–58 psi) ±0.2 bar (2.9 psi)	Non-intrusive
High Pressure Switches	PSH001 PSH002	4.2 bar (60 psi)	Non-intrusive
Single-Use Magnetic Flowmeters	FT001 FT002	<ul style="list-style-type: none"> Chrom 2: 0.1 to 0.3 LPM: +/- 10 mL/min >0.3 to 2.2 LPM: +/-2% MV Chrom 10: 1.6 to 10 LPM: +/-2% MV Chrom 20: 4 to 20 LPM: +/-2% MV 	In-line
Single-Use Ultrasonic Flowmeters	FT002	<ul style="list-style-type: none"> Chrom 20 (in-line dilution option): 4 to 20 LPM: +/-5% MV 	In-line
Temperature Sensors	TE201	4–30 °C (39.2 °F to 86 °F) ±1 °C (1.8 °F)	Combined with conductivity sensor
Single-Use Conductivity Sensors	AE102 AE201A AE201B	Process: 0.001–200 mS/cm ± (3% MV + 0.4 mS/cm) Cleaning: 1–50 µS/cm ± (3% MV + 0.4 µS/cm)	In-line
pH Sensors	AE103 AE202	3–9 pH ± 0.1 pH after process calibration at ±1 pH around calibration point	In-line
Air Sensors	XS001 XS002	N/A	Non-intrusive
UV Sensors	AE203/204	AF46: 0–2 AU ±2% FS OPL: 1 or 2.5 mm Wavelength: Dual 254/280 nm or 280/300 nm	In-line

Do not use UV Sensors in a condensing atmosphere. Condensation may lead to erroneous sensor readings.

*Refers to the labels on the system hardware.

Operating specifications

Specification		Mobius® Chrom Systems
Total Operating Time	Flexware® Assemblies	Max active duration: 24 hours continuously Max wetted duration batch: 24 hours
	Valve Pads	50 cycles (50 valve openings and 50 valve closings) per valve. The integrity of the installation may be compromised if used for more than 50 cycles
		Do not exceed 1,200 cycles or 6 months of operation
Product Temperature Range		4 to 30 °C (39 to 86 °F)
Maximum Pressure	Pump 1 Manifold	0 to 2 bar (0 to 29 psi)
	Pump 2 Manifold	0 to 2 bar (0 to 29 psi)
	Pump Assembly	0 to 4 bar (0 to 58 psi)
	Bubble Trap Assembly	0 to 4 bar (0 to 58 psi)
	Clamshell assembly	0 to 4 bar (0 to 58 psi)
	Precolumn Filter Assembly	0 to 4 bar (0 to 58 psi)
	Pre-column Instrumentation Assembly	0 to 4 bar (0 to 58 psi)
	Post-column Instrumentation Assembly	0 to 2 bar (0 to 29 psi)
	Column Assembly	0 to 4 bar (0 to 58 psi)
System Operating Temperature		20 to 30 °C (68 to 86 °F)
Operating Humidity		10 to 90% (non condensing)

Power Cord

Description	Part number
Switzerland	SPKMBPWCCCH
China	SPKMBPWCCN
Europe	SPKMBPWCEU
Japan	SPKMBPWCJP
Korea	SPKMBPWCKR
North America	SPKMBPWCNA
United Kingdom	SPKMBPWCUK

Power cord to connect base cart.

Accessories

Part number	Description	Additional information
MBCLAMLIFT110V	Clamshell lift 110V	For use with Mobius® TFF 80 & Mobius® Chrom systems
MBCLAMLIFT230V	Clamshell lift 230V	For use with Mobius® TFF 80 & Mobius® Chrom systems
MBCLAMSTORE	Storage rack for clamshell	To store Mobius® TFF 80 & Mobius® Chrom systems clamshells
MBSPKB	Keyboard support	–
MBCLAMCABLE	Maintenance cable	–
SPKGENINS012	Multi-use pH Arc probe – address#1	To be inserted in pre-column Single-Use Cell
SPKGENINS013	Multi-use pH Arc probe – address#2	To be inserted in post-column Single-Use Cell
SPKGENINS015	Single-use pH Arc module – address#1	To be connected to pre-column SU pH probe
SPKGENINS016	Single-use pH Arc module – address#2	To be connected to post-column SU pH probe
MBSPTXM20	Pre-column filter support	For use with Mobius® Chrom 20 system

Ordering Information

Hardware

To tailor the Mobius® Chrom systems to your needs select:

- A configuration based on the flow range, processing modes and options needed for your process
- The system power cord and accessories
- The Flexware® assemblies kits according to your system configuration and processing mode

		Chrom 2				Chrom 10				Chrom 2				Chrom 20 (ILD)			
		MCPXM02SB01	MCPXM02SB02	MCPXM02SBS1	MCPXM02SBS2	MCPXM10SB01	MCPXM10SB02	MCPXM10SBS1	MCPXM10SBS2	MCPXM20SB01	MCPXM20SB02	MCPXM20SBS1	MCPXM20SBS2	MCPXM20SB01D	MCPXM20SB02D	MCPXM20SBS1D	MCPXM20SBS2D
Base Cart + BBT + Pump cat + Clamshell		Included •															
SU Post column instrumentation: conductivity/UV	254/280 nm	•		•		•		•		•		•		•		•	
	280/300 nm		•		•		•		•		•		•		•		•
Flowmeter	Magnetic flowmeter (units)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (2)	• (1)	• (1)	• (1)	• (1)
	Ultrasonic flowmeter (units)													• (1)	• (1)	• (1)	• (1)
Option	SU Pre-column instrumentation			•	•			•	•			•	•			•	•

Flexware® assemblies kits according to system configuration and processing mode

	System part numbers	Flexware® assemblies kits part numbers	
		Traditional mode	Fully closed mode
Chrom 2	MCPXM02SB01 MCPXM02SB02	FXWXM02K0001	FXWCLXM02K0001P
		FXWXM02K0002	FXWCLXM02K0002P
		FXWXM02K0003	FXWCLXM02K0003P
		FXWXM02K0004	FXWCLXM02K0004P
	MCPXM02SBS1 MCPXM02SBS2	FXWXM02K0005	FXWCLXM02K0005P
		FXWXM02K0006	FXWCLXM02K0006P
		FXWXM02K0007	FXWCLXM02K0007P
		FXWXM02K0008	FXWCLXM02K0008P
Chrom 10	MCPXM10SB01 MCPXM10SB02	FXWXM10K0001	FXWCLXM10K0001P
		FXWXM10K0002	FXWCLXM10K0002P
		FXWXM10K0003	FXWCLXM10K0003P
		FXWXM10K0004	FXWCLXM10K0004P
	MCPXM10SBS1 MCPXM10SBS2	FXWXM10K0005	FXWCLXM10K0005P
		FXWXM10K0006	FXWCLXM10K0006P
		FXWXM10K0007	FXWCLXM10K0007P
		FXWXM10K0008	FXWCLXM10K0008P
Chrom 20	MCPXM20SB01 MCPXM20SB02	FXWXM20K0001	FXWCLXM20K0001P FXWCLXM20BUBBL
		FXWXM20K0002	FXWCLXM20K0002P FXWCLXM20BUBBL
		FXWXM20K0003	FXWCLXM20K0003P FXWCLXM20BUBBL
		FXWXM20K0004	FXWCLXM20K0004P FXWCLXM20BUBBL
	MCPXM20SBS1 MCPXM20SBS2	FXWXM20K0005	FXWCLXM20K0005P FXWCLXM20BUBBL
		FXWXM20K0006	FXWCLXM20K0006P FXWCLXM20BUBBL
		FXWXM20K0007	FXWCLXM20K0007P FXWCLXM20BUBBL
		FXWXM20K0008	FXWCLXM20K0008P FXWCLXM20BUBBL
Chrom 20 ILD	MCPXM20SB01D MCPXM20SB02D	FXWXM20K0001D	FXWCLXM20K0001DP FXWCLXM20BUBBL
		FXWXM20K0002D	FXWCLXM20K0002DP FXWCLXM20BUBBL
		FXWXM20K0003D	FXWCLXM20K0003DP FXWCLXM20BUBBL
		FXWXM20K0004D	FXWCLXM20K0004DP FXWCLXM20BUBBL
	MCPXM20SBS1D MCPXM20SBS2D	FXWXM20K0005D	FXWCLXM20K0005DP FXWCLXM20BUBBL
		FXWXM20K0006D	FXWCLXM20K0006DP FXWCLXM20BUBBL
		FXWXM20K0007D	FXWCLXM20K0007DP FXWCLXM20BUBBL
		FXWXM20K0008D	FXWCLXM20K0008DP FXWCLXM20BUBBL

Services

Qualification Services	
Mobius® Chrom Systems – FAT execution including protocol in English	SSVFATSFC
Mobius® Chrom Systems – IQOQ execution including protocol in English and travel	SSVQUAM201
Mobius® Chrom Systems – Full test package execution including protocol in English and travel	SSVQUAM202
Training Services	
Mobius® Chrom Systems – Operator training	PTRSMRCHROP
Mobius® Chrom Systems – CCP® software V.6 training	PTRSMRCHRCCP1
Mobius® Chrom Systems – CCP® software V.6, system use and troubleshooting training	PTRSMRCHRCCP2
Mobius® Chrom Systems – CCP® software V.6, system use and troubleshooting and process design training	PTRSMRCHRCCP3
Specialized Support	
CCP® recipe design (3 recipes)	CNMSAT003
System Service Reliance Plans	
Mobius® Chrom Systems – Essential Service Plan execution including protocol in English and travel	SSVESPM20
Mobius® Chrom Systems – Advanced Service Plan execution including protocol in English and travel	SSVESPM20 + SSVADCM20
Mobius® Chrom Systems – Total Service Plan execution including protocol in English and travel	SSVESPM20 + SSVTOCM20
Mobius® Chrom Systems Preventive Maintenance – additional to service plan	SSVPRMM20
Repair and spare parts	
Please refer to spare part list CA12829EN available at SigmaAldrich.com	
Contact your local representative for repairs.	

Flexware® assemblies kits to be purchased prior to qualification and preventive maintenance service:

Description	Mobius® Chrom 2 Flexware service kit	Mobius® Chrom 10 Flexware service kit	Mobius® Chrom 20 Flexware service kit	Mobius® Chrom 20 ILD Flexware service kit
Catalogue numbers	SERFXWKITXM02	SERFXWKITXM10	SERFXWKITXM20	SERFXWKITXM20ILD

Note: Service kits to be ordered separately prior the qualification services (FAT or IQ/OQ or Full Test Package) or yearly maintenance services included in the System Service Reliance Plans.

For additional information, please visit [SigmaAldrich.com/chrom-systems](https://www.sigmaaldrich.com/chrom-systems)
To place an order or receive technical assistance, please visit [SigmaAldrich.com/offices](https://www.sigmaaldrich.com/offices)

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