

# **Mobius® Chrom Systems**

# For Purification of Clinical and Process Scale Biologics

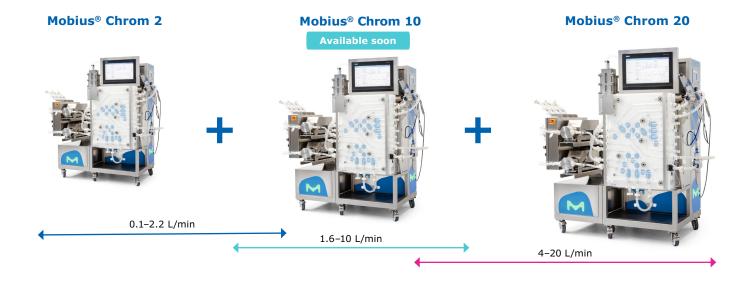
The Mobius® Chrom systems are flexible, automated, single-chromatography systems that enable consistent and reliable separation and purification of mAbs, vaccines, plasma, and therapeutic proteins at clinical and process scale.

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. The single-use flow path offers the flexibility to operate in functionally or fully closed mode.

#### **Benefits**

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





#### **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 mutli-products and multi-processing modes (open and closed modes of operation is possible with specifically designed flow path, allowing to reduce contamination risk).
- To optimize facility utilization and footprint, an in-line dilution option is available for the Mobius® Chrom 20 system.

#### Safe and reliable process

The systems and flow paths are extremely robust and GMP compliant. Superior performances, 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 and features 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**

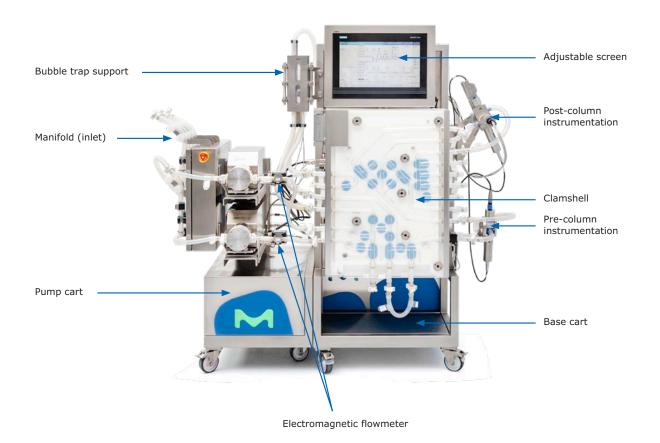
The Mobius® Chrom systems are made up of a base system and configurable options that can be added to design a system that best meets your purification process and challenges.

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:



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 dlilution optional)

Base cart + Bubble trap + Pump 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 multiscale 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,  $IsoPak^{TM}$  columns provide faster, cleaner, and more consistent packing and unpacking for reproducible results.  $IsoPak^{TM}$  columns are available in a variety of options including  $IsoPak^{TM}$  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.

To learn more about our program, please visit our website at **SigmaAldrich.com** 





## **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 predefined 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 MS\_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 trainings can be delivered either at your site or in our M Lab™ Collaboration Centers. Please contact your local representative or email ilearn@milliporesigmagroup.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 (MS\_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 (MS\_CA12829EN).

# **Mobius® Chrom Systems and Flexware® Assemblies Specifications**

# **General system specifications**

Specification	Mobius® Chrom 2 System	Mobius® Chrom 10 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® System	Chrom 10	Mobius® Chro System	om 20	Mobius® Chrom 20 System (with in-line dilution option)		
System Dimensions	Pump & Base carts connected W $\times$ H $\times$ D in mm	$1,836 \times 1,697^* \times 1,104$ mm $72.3 \times 66.8^* \times 43.5$ inch *when screen is in lower position							
Net Weight	Base cart with Clamshell	Total: 527 Base Cart with Clamshell: 365 Pump cart with two pumps + manifold: 162							
Materials of	Wetted Components USP<88>	Class VI compliant mat	erial						
Construction	Tubing			Silio	cone				
	Flexware® Clamshell Assembly	Pureflex™ Filr	m, polyethy	lene fittings	s and silicone ga	skets,	polypropylene		
	Pump Head		EPDM, 9	Santoprene	® and Polypropy	lene			
	Connectors		Po	olypropylen	e, polysulfone				
	Magnetic flowmeter	Polysulfone/Nickel							
	Ultrasonic flowmeter						Polypropylene		
	UV, Conductivity (Single Use Cell)	Polyphenyls	ulfone Qua	rtz, EPDM a	nd Stainless Ste	eel 316	L (pins only)		
	pH probes MU/SU		Glass	and VMQ (S	Silicone elastom	er)			
	Non-Wetted Components								
	Base cart, pump cart and cover			Stainless	steel 304 (minim	num)			
	Clamshell (rear)			P	OM				
	Clamshell (front)			PM	IMA				
	Valve Pads			Silio	cone				
Connections	Inlets $(10 = 2 \times 5 \text{ inlets})$	2 × 5 on TC 3/4 1/4" tube	4"		on TC 3/4" " tube		2 × 5 on TC 3/4" 5/8" tube		
	Outlets, 3 Fractions + 1 waste	Vent line on MPC connector connector				TC :	3/4" in line on TC 3/4" t line on TC 3/4"		
	Filters			3/4"	TC				
Column 34" 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 informa	ation	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	Chrom 2: 0.1 to 0.3 LPM: +/- 10mL/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 Flowmeter	FT002	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: $0.001-200 \text{ mS/cm} \pm (3\% \text{ MV} + 0.4 \text{ mS/cm})$ Cleaning: $1-50  \mu\text{S/cm} \pm (3\% \text{ MV} + 0.4  \mu\text{S/cm})$	In-line
pH Sensors	AE103 AE202	$3-9~\mathrm{pH}\pm0.1~\mathrm{pH}$ after process calibration at $\pm1~\mathrm{pH}$ 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.  $\ast$  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			
		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			
	Valve Pads	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	SPKMBPWCCH	
China	SPKMBPWCCN	
Europe	SPKMBPWCEU	
Japan	SPKMBPWCJP	
Korea	SPKMBPWCKR	
North America	SPKMBPWCNA	
United Kingdom	SPKMBPWCUK	

Power cord to connect base cart.

### **Accessories**

Part number	Descripton	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
MBCLAMST0RE	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
MBSPFTXM20	Pre-column filter support	For use with Mobius® Chrom 20 system

# **Ordering Information**

### **Hardware**

To taylor 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

	assemblies kies according	, ,		,		9			. Ф.		····9						
	Chron			om 2			Chro	m 10		Chrom 20				Chrom 20 (ILD)			.D)
		MCPXM02SB01	MCPXM02SB02	MCPXM02SBS1	MCPXM02SBS2	MCPXM10SB01	MCPXM10SB02	MCPXM10SBS1	MCPXM10SBS2	MCPXM20SB01	MCPXM20SB02	MCPXM20SBS1	MCPXM20SBS2	MCPXM20SB01D	MCPXM20SB02D	MCPXM20SBS1D	MCPXM20SBS2D
Base Cart + Bubble trap + Pump cart + Clamshell Included •																	
SU Post column	254/280 nm	•		•		•		•		•		•		•		•	
instrumentation: conductivity/UV	280/300 nm		•		•		•		•		•		•		•		•
Flowmeters	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			•	•			•	•			•	•			•	•

# $\textbf{Flexware}^{\textcircled{\textbf{8}}} \textbf{ assemblies kits according to system configuration and processing mode}$

		Flexware® assemblies kits part numbers		
	System part numbers	Tradtional mode	Fully closed mode	
		FXWXM02K0001	FXWCLXM02K0001P	
	MCPXM02SB01	FXWXM02K0002	FXWCLXM02K0002P	
N	MCPXM02SB02	FXWXM02K0003	FXWCLXM02K0003P	
Chrom 2		FXWXM02K0004	FXWCLXM02K0004P	
hro		FXWXM02K0005	FXWCLXM02K0005P	
O	MCPXM02SBS1	FXWXM02K0006	FXWCLXM02K0006P	
	MCPXM02SBS2	FXWXM02K0007	FXWCLXM02K0007P	
		FXWXM02K0008	FXWCLXM02K0008P	
		FXWXM10K0001	FXWCLXM10K0001P	
	MCPXM10SB01	FXWXM10K0002	FXWCLXM10K0002P	
10	MCPXM10SB02	FXWXM10K0003	FXWCLXM10K0003P	
Ë		FXWXM10K0004	FXWCLXM10K0004P	
Chrom 10		FXWXM10K0005	FXWCLXM10K0005P	
<del>5</del>	MCPXM10SBS1	FXWXM10K0006	FXWCLXM10K0006P	
	MCPXM10SBS2	FXWXM10K0007	FXWCLXM10K0007P	
		FXWXM10K0008	FXWCLXM10K0008P	
		FXWXM20K0001	FXWCLXM20K0001P FXWCLXM20BUBBL	
	MCPXM20SB01	FXWXM20K0002	FXWCLXM20K0002P FXWCLXM20BUBBL	
	MCPXM20SB02	FXWXM20K0003	FXWCLXM20K0003P FXWCLXM20BUBBL	
n 20		FXWXM20K0004	FXWCLXM20K0004P FXWCLXM20BUBBL	
Chrom 20		FXWXM20K0005	FXWCLXM20K0005P FXWCLXM20BUBBL	
	MCPXM20SBS1	FXWXM20K0006	FXWCLXM20K0006P FXWCLXM20BUBBL	
	MCPXM20SBS2	FXWXM20K0007	FXWCLXM20K0007P FXWCLXM20BUBBL	
		FXWXM20K0008	FXWCLXM20K0008P FXWCLXM20BUBBL	
		FXWXM20K0001D	FXWCLXM20K0001DP FXWCLXM20BUBBL	
	MCPXM20SB01D	FXWXM20K0002D	FXWCLXM20K0002DP FXWCLXM20BUBBL	
9	MCPXM20SB02D	FXWXM20K0003D	FXWCLXM20K0003DP FXWCLXM20BUBBL	
20 I		FXWXM20K0004D	FXWCLXM20K0004DP FXWCLXM20BUBBL	
Chrom 20 ILD		FXWXM20K0005D	FXWCLXM20K0005DP FXWCLXM20BUBBL	
ō	MCPXM20SBS1D	FXWXM20K0006D	FXWCLXM20K0006DP FXWCLXM20BUBBL	
	MCPXM20SBS2D	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)	SSVRPCCPB
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 MS_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	Mobius® Chrom 10	Mobius® Chrom 20	Mobius® Chrom 20 ILD
	Flexware service kit	Flexware service kit	Flexware service kit	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.

MilliporeSigma 400 Summit Drive Burlington, MA 01803

For additional information, please visit SigmaAldrich.com
To place an order or receive technical assistance, please visit SigmaAldrich.com/contactAF

