SARTORIUS

Product Datasheet

Multi-Use Membrane Chromatography System – MU RCC

Implementation of Membrane Chromatography Based on Rapid Cycling Chromatography (RCC)

Product Information

The Multi-Use Membrane Chromatography System – MU RCC is a liquid chromatography system intended for small scale production and process development in purification of biomolecules. Designed to achieve optimum purification of mAbs, ADCs, vaccines, viral vectors, and recombinant proteins, the system provides a tailored design and configuration for the implementation of membrane chromatography based on Rapid Cycling Chromatography (RCC).

Compared to traditional and multi-column chromatography in mAb bioprocessing, RCC offers extremely high productivity and enables a consistent performance together with Sartobind® membrane chromatography products. This optimized skid addresses the challenges of running many cycles in a short time – with fast flow rates, rapid buffer changes, data handling and real time analytics powered by Umetrics® and supported by full-spectrum pre-post UV.

Features and Benefits

Features	Benefits	RCC Solution (Optimized system, device membrane)
▪ Small footprint (700 × 1000 × 1830 mm) ▪ Two modes for bind-elute and flow-through ▪ Rotatable HMI, keyboard and touchscreen	Easier Installation and operation for new facilities	Flexibility
▪ Positive displacement pump with low pulsation ▪ Small void volume (overall system: 190 mL) ▪ Defined fluid inlet: Mixing point of feed and buffer lines close to the membrane adsorber	Efficient processing by quick ramp-up, less back mixing and concentration dilution	Time and cost saving
▪ Optimized valve with very short switching time: 0.5 s ▪ Full-spectrum UV sensors ▪ Real-time monitoring and prediction by Umetrics®	Reliable process control and advanced analytics	Consistency of product quality

Technical Specifications

System Specifications

Description	Specification
Version	Main module (Batch configuration)
Footprint W × L × H (mm)	700 × 1000 × 1830
Weight (kg)	300
Hold-up Volume (mL)	< 200 (without bubble trap)
Electrical Cabinet Location	Embedded
Distance between Electrical cabinet & the system (only when remote cabinet option is selected)	N/A (Electrical cabinet is embedded onto the pumping module)
Distance between Electrical cabinet & the supervision (only when remote supervision option is selected)	N/A (Supervision is embedded onto the pumping module)
Automation Device Location	In the electrical cabinet
HMI Display Location	Embedded onto the skid

Operating Environment

Description	Specification
Ambient temperature range	10 – 25°C
Humidity	20% to 70% Rh (non-condensing)

Enclosure Protection Class

Description	Specification
Main Electrical Cabinet ▪ Electrical Protection Classes	IP55 (EN-60529)
Field Mounted Electrical parts ▪ Electrical Protection Classes	IP66 (EN-60529)

Electrical Requirements

Description	Specification	
Version	North American version	European version
Voltage Type AC/DC	AC	AC
Nominal Power supply	208Y 120V	230V
Frequency	60 Hz	50 Hz
Power required	2 kW	2 kW
Phase Numbers	3 phases	1 phase
Switching current capacity (kA r.m.s)	N/A	55
Short-circuit current rating SCCR (kA)	10	N/A
Neutral System | Distributed	Wye phases midpoint Grounded with neutral	TN-S

Process Utilities Requirements

Description	Specification
Process fluids	
Pressure	Operating pressure: 5 bar max Inlets: 0.15 barge max Outlets: >0 and <1 bar
Capacity	5 to 150 L/h (83 to 2500 mL/min)
Quality	> 2 µm filtered
Temperature	Operating span: 4 – 50°C
Compressed Air pressure	
Pressure	6 - 7 bar
Capacity	< 5 Nm^3/h
Quality	40 µm filtered, oil free & dry
Temperature	10 – 30°C

Material of Construction

Description	Specification
Tubing material	Polypropylene stainless steel 316L
Frame	stainless steel 304 Painted stainless steel (powder coating)
Gasket Material & other Wetted Part	PPSU Radel®, stainless steel (316L), quartz, glass, ceramic, PP, PTFE, PEEK, EPDM, EPDM-PP or platinum silicon
Electrical cabinet	Painted stainless steel (powder coating)
Tubing internal roughness	Electro polished < 0.6 µm Ra (71 µ-inches Ra)
Valves internal roughness	N/A
Pumps internal roughness	Electro polished < 0.6 µm Ra (71 µ-inches Ra)
Frame external roughness	Grit 200 (about 1.6 µm Ra / 62 µ-inches Ra)
Pipe & Welding Specification	Refer to Novasep URS CC-866
Passivation Procedure	Refer to Novasep URS CC-1078 & CC-1042
Insulation	No
Tagging	Color: silver. Material: polyester with solvent resistant protective film.

Interface Requirements

Type	Description
Instrumentation compressed air	10 mm push-in fitting
Buffers and feed Inlets	⅜" Micro-Clamp®
Collection valves	⅜" Micro-Clamp®
Membrane connection	⅜" Micro-Clamp®

Standards & Norms

Description	Specification
Electrical Design	EC Machine Directive EC Low Voltage Directive EC Electro Magnetic Compatibility Directive RoHS Directive Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)
Explosion proof design (Depending of the selected options)	Not designed for hazardous area
Material certificates for wetted parts	3.1 for stainless steel FDA USP Class VI for polymers
Software & Automation standards	GAMP guidelines and FDA CFR 21 Part 11 regulations
Tagging	English language. Compliant with UL/CSA, 2005/618/EC MCV amendment to RoHS Directive 2002/95/EC
Documentation provided	Refer to Novasep Quality Plan 1SO-MANL

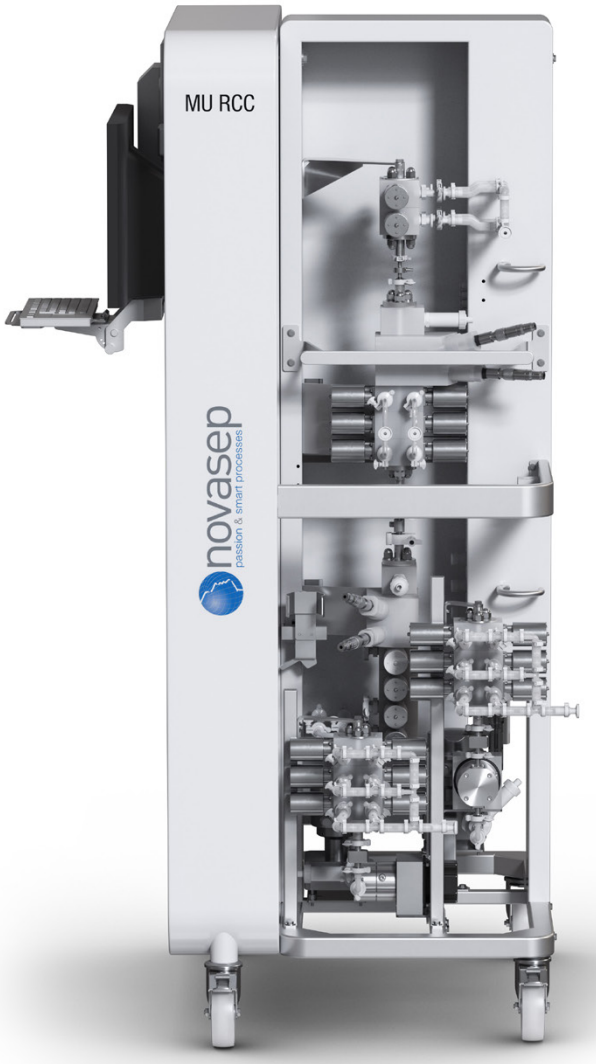
Selection of Membrane Adsorbers

Bind-Elute

Sartobind® Q and S		
Membrane volume (MV)	150 mL	400 mL
Nominal membrane area	5,500 cm^2	14,600 cm^2
Bed height	8 mm	8 mm
Design	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	0.5 (0.05, 7)	0.5 (0.05, 7)
Sartobind® Phenyl		
Membrane volume (MV)	150 mL	400 mL
Nominal membrane area	5,500 cm^2	14,600 cm^2
Bed height	8 mm	8 mm
Design	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	0.5 (0.05, 7)	0.5 (0.05, 7)

Flow-Through

Sartobind® Q and S		
Membrane volume (MV)	75 mL	200 mL
Nominal membrane area	2,700 cm^2	7,300 cm^2
Bed height	4 mm	4 mm
Design	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	0.5 (0.05, 7)	0.5 (0.05, 7)
Sartobind STIC® PA		
Membrane volume (MV)	75 mL	200 mL
Nominal membrane area	2,700 cm^2	7,300 cm^2
Bed height	4 mm	4 mm
Design	Cylindrical	Cylindrical
Maximum pressure bar (MPa, psig) at 20°C	4 (0.4, 58)	4 (0.4, 58)
Maximum pressure during venting bar (MPa, psig) at 20°C	0.5 (0.05, 7)	0.5 (0.05, 7)



Ordering Information

Configuration	Description		Order Number
Capture The System can be mechanically and electrically configured as a Batch to be used for Capture.	**Feed line** 4 Inlets, 1 Air Sensor, 1 Pump A, 1 Flowmeter, 1 Pressure Post Pump A, 1 Pressure Post Pre-Filter, 1 pH/Cd Pre-Membrane, 1 Air Sensor Pre-Membrane, 1 UV Pre-Membrane, 1 Membrane w/ Bypass, 1 pH/Cd Post-Membrane, 1 pressure Post-Membrane, 1 UV Post-Membrane, 4 Fractions **Buffer line** 6 Inlets, 1 Air Sensor, 1 Pump B (Gradient/ILD), 1 Flowmeter, 1 Pressure Post Pump B, 1 Novasep Display	**Capture CE** **Capture UL**	MCSCEB46NAK MCSULB46NAK
Flow-through The System can be mechanically and electrically configured as a Batch to be used for Polishing.	**Feed line** 4 Inlets, 1 Air Sensor, 1 Pump, 1 Flowmeter, 1 Pressure Post Pump, 1 Pre-Filter w/ Bypass, 1 Pressure Post Pre-Filter, 1 Air Sensor Pre-Membrane, 1 UV Pre-Membrane, 1 Membrane w/ Bypass, 1 pH/Cd Post-Membrane, 1 Pressure Post-Membrane, 1 UV Post-Membrane, 4 Fractions 1 Novasep Display	**Flow-through CE** **Flow-through UL**	MCSCEB4NNAK MCSULB4NNAK
Capture with Bubble trap The System can be mechanically and electrically configured as a Batch to be used for Capture.	**Feed line** 4 Inlets, 1 Air Sensor, 1 Pump A, 1 Flowmeter, 1 Pressure Post Pump A, 1 Pressure Post Pre-Filter, 1 pH/Cd Pre-Membrane, 1 Air Sensor Pre-Membrane, 1 UV Pre-Membrane, 1 Membrane w/ Bypass, 1 pH/Cd Post-Membrane, 1 Pressure Post-Membrane, 1 UV Post-Membrane, 4 Fractions **Buffer line** 6 Inlets, 1 Air Sensor, 1 Pump B (Gradient/ILD), 1 Flowmeter, 1 Pressure Post Pump B, 1 Novasep Display, 1 Bubble trap	**Capture with Bubble trap CE** **Capture with Bubble trap UL**	MCSCEB46AAK MCSULB46AAK

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