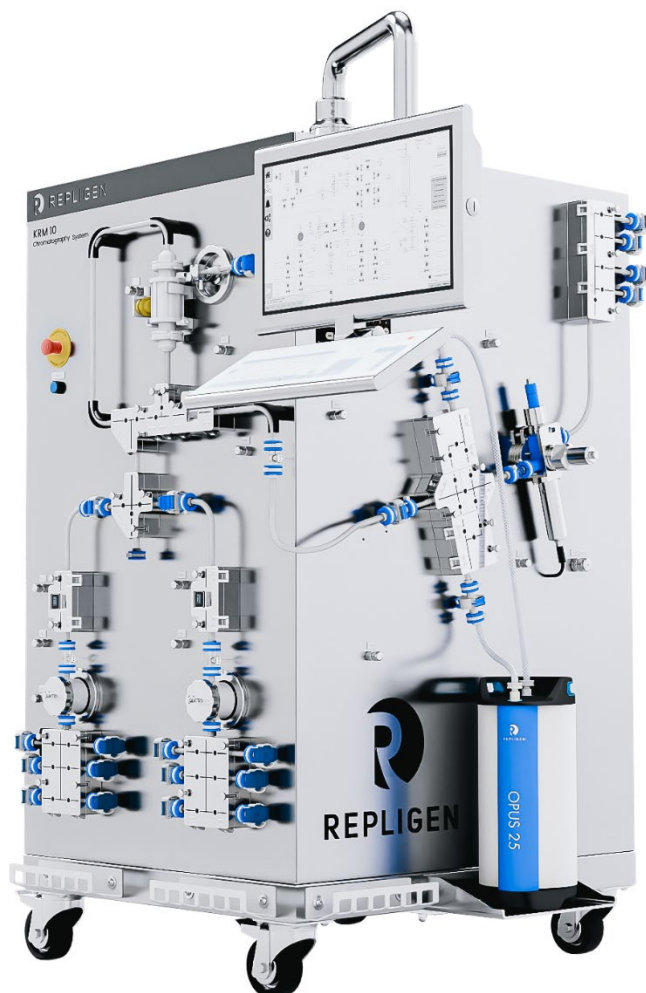


KRM® 10 Chromatography System

Technical Specifications



TD0082_AUG2026

General Functionality Overview

KRM® 10 Chromatography System	The fully automated and single-use system can run both isocratic and gradient chromatographic batch purification processes operating in bind & elute or flow-through modes. The system's two pumps provide inline buffer dilution (IBD) capability for isocratic chromatographic processes. Each single-use system can be configured to meet customer-specific process requirements. The exact functionality of each system depends on selected accessories and the installed configuration. Please refer to the System Configurations & Options table and consult with your sales representative for details.
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System Overview

Model	KRM10
Skid design	cGMP clean room washdown design with skid structure and control panel made of stainless steel 304L, brushed finish #3A
Approximate dimensions (H x W x D)	Assembled System: 2.00 m x 1.22 m x 1.24 m
System Max Weight (Empty)	520 kg (The exact value will vary depending on the hardware configuration)
Column type accepted	Repligen; Millipore; Sartorius; Pall
Column diameter range	8 – 25 cm
Column bed height	5 – 30 cm
Single-use system flow path kit	¼" ID platinum-cured silicone with integrated single-use sensors, connectors, bubble trap filter, and pump heads

Pumps

Inlet pump 1	Diaphragm pump operating flow range: 0.03 – 3 LPM
Inlet pump 2	Diaphragm pump operating flow range: 0.03 – 3 LPM

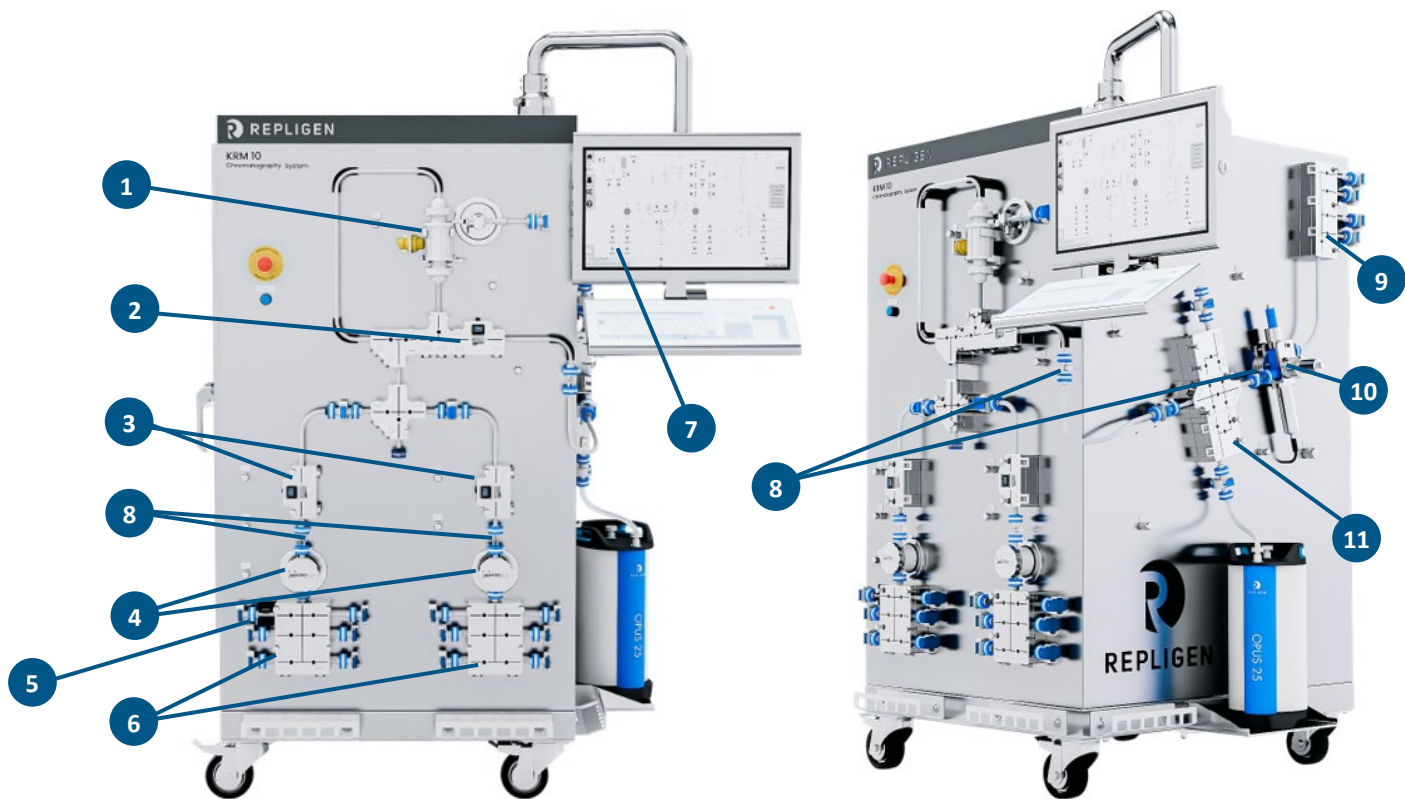
Process Valves

Number of automated valves	• 33 ON/OFF valves (standard), or • 33 ON/OFF valves and 1 control valve (option on the outlet valve block), or • 37 ON/OFF valves (4 optional on the post-column outlet line), or • 37 ON/OFF valves (4 optional on the post-column outlet line) and 1 control valve (option on the outlet valve block)
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Operating Parameters (Flow Kit)

Fluid pressure upper limit	4 barg
Temperature range	4°C – 40°C

Figure 1. KRM 10 Chromatography System Components



Components

1. Filter and level sensor assembly

2. Pre-column bubble detection

3. Ultrasonic flow meters (2)

4. 4-chamber diaphragm pumps (2)

5. Inlet air sensor

6. Inlet valve blocks (2)
7. HMI, touch screen, and glass keyboard

8. Single-use pressure sensors (4)

9. Outlet valve block

10. Multi-sensor flow cell (UV, pH, conductivity)

11. Column valve block

Environmental Conditions	
Ambient temperature	17°C – 27°C
Ambient humidity	20% to 80% relative humidity, non-condensing
Storage temperature	-5°C – 50°C
Installation	Category II (over voltage) in accordance with IEC 664
Degree of Protection	IP 54

Extra Column Volume	
KRM10 with bubble trap filter bypass	≤0.18 L
KRM10 with bubble trap filter inline	≤0.45 L

Note: The exact value will vary depending on the hardware configuration. However, the values provided represent the maximum possible volume. Extra column volume refers to the standard flow kit of the KRM System starting from the inlet valve to the outlet valve. It excludes connections from the column valve block to the column and back and external connections.

Automation

Standard platform	• KlariFi™ System Platform/Allen Bradley PLC • Data Historian • Automatic Recipes and Reports • Built for facilities with 21CFR-P11/ALCOA+ requirements
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Utilities

Power	Instrument power: 120 – 230 VAC (±10%), single-phase, 50/60 Hz, 15 A Main power: 120 – 230 VAC (±10%), single-phase, 50/60 Hz, 15 A
Compressed air	Instrument air: 5.8 – 8 barg (max), Festo 10 mm push-in connector
Network connection	RJ45 Network for PLC RJ45 Network for HMI

Process Connections

Inlet Connections

Inlet Pump 1	Inlet Pump 2	Other
• Inlet 1 • Inlet 2 • Inlet 3 • Inlet 4 • Inlet 5 • Inlet 6	• Inlet 7 • Inlet 8 • Inlet 9 • Inlet 10 • Inlet 11 • Inlet 12	N/A

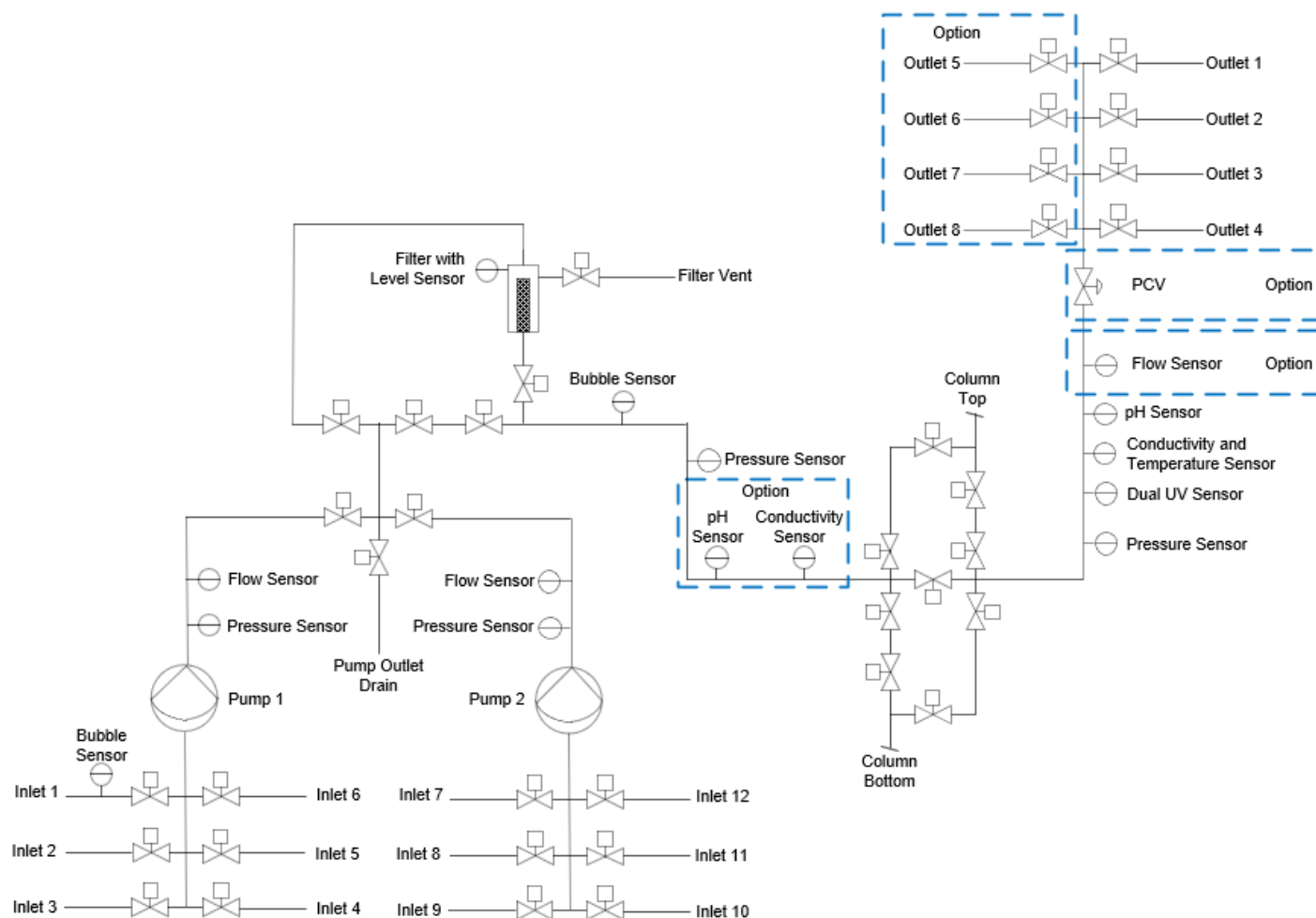
Outlet Connections

Pump Outlet Line	Bubble Trap Filter Line	Post-column Line
Pump outlet drain	Filter vent	• Outlet 1 • Outlet 2 • Outlet 3 • Outlet 4 • Outlet 5 (optional) • Outlet 6 (optional) • Outlet 7 (optional) • Outlet 8 (optional)

Compliance

Electrical and chemical	System is compliant with UL508A, CE, RoHS, REACH
Single-use product component	All flexible tubing and product-contact components are USP Class VI and comply with EMA 410/01 Rev. 3

Figure 3. Process Flow Diagram



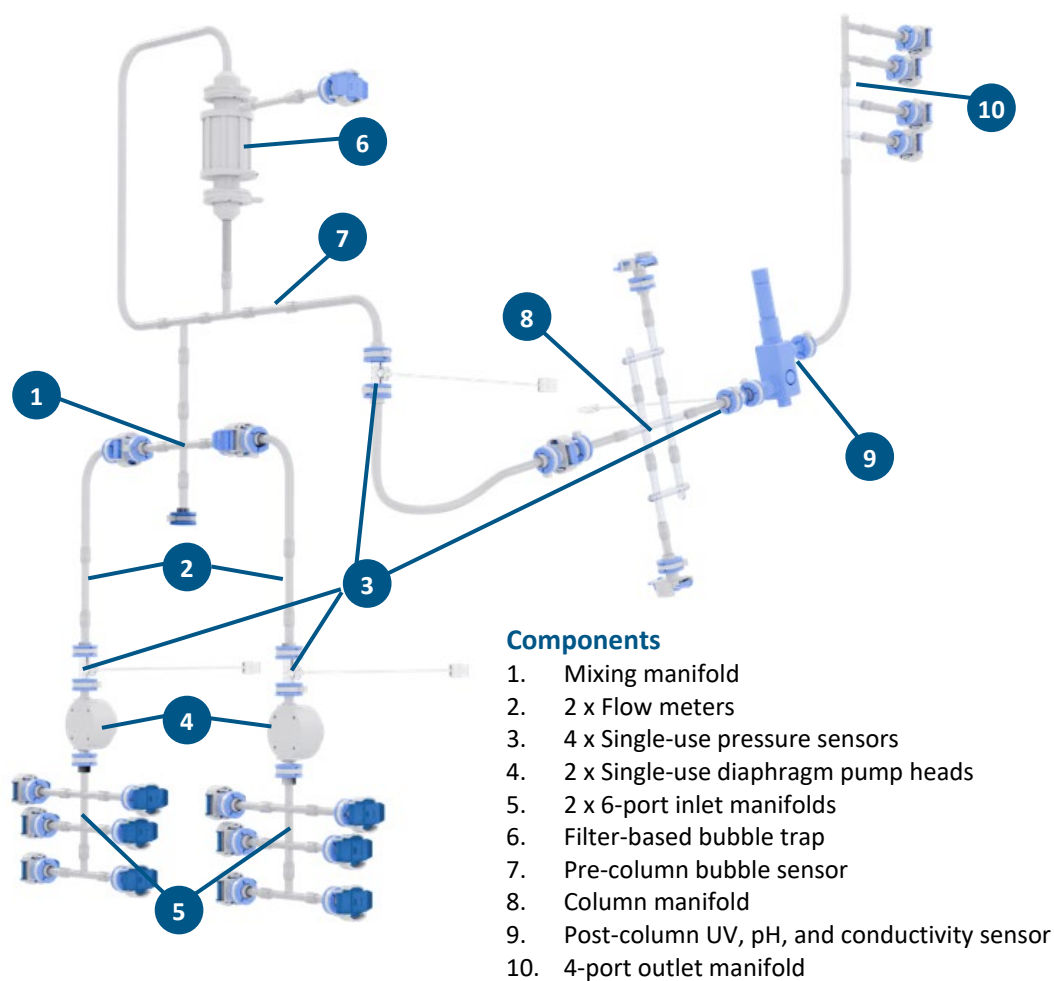
KRM 10 Chromatography System: System Configurations & Options

Hardware Part Number	Description
KRM10	Single-use Chromatography System (¼" D)
CHR025BASE	CHROM025 base assembly ☒ System main unit module with linear and step gradient capability ☒ Two (2) 4-chamber diaphragm pumps (line 1, line 2) ☒ Two (2) Repligen valve manifolds with six (6) inlets each (12 Inlets per system) ☒ Non-product contact air/liquid interface sensor (inlet 1) ☒ Two (2) non-product contact ultrasonic flow meters (line 1, line 2) ☒ Four (4) pressure sensors (line 1, line 2, pre-column, post-column) ☒ Bubble trap filter assembly with liquid level detector ☒ Non-product-contact ultrasonic bubble detector (pre-column) ☒ Repligen chromatography valve manifold ☒ Conductivity/temperature sensor (post-column) ☒ pH sensor (post-column) ☒ HMI touchscreen, swingarm, and glass keyboard ☒ 21 CFR Part 11- and ALCOA+- compliant system software ☒ System CE and UL Certifications

CHR025HW01	Isocratic hardware configuration (single pump and 6 inlets only)
CHR025HW02	Post-column pressure control valve
CHR025HW03*	Post-column UV sensor wavelength 280/300 nm
CHR025HW04*	Post-column UV sensor wavelength 254/280 nm
CHR025HW05	Post-column ultrasonic flow meter assembly
CHR025HW06	Pre-column conductivity, temperature, and pH sensor hardware
CHR025HW07	Alarm beacon/status light tower on top of the skid
CHR025HW08	Repligen valve manifold with eight (8) outlets (post-column)
CHR025HW09	Power configuration: US
CHR025HW10	Power configuration: EU
CHR025HW11	Power configuration: UK

*Either CHR025HW03 or CHR025HW04 should be selected. These two options cannot be chosen together.

Figure 2. Single-use System Flow Path Kit



Single-Use Flow Path Kit

Overview	- The complete single-use flow path kit consists of all required ¼" ID molded silicone tubing valve liner sub-assemblies, ¼" ID braided silicone tubing segments, single-use sensors, pump heads, bubble trap filter, and connectors per the selected flow path kit configuration. - The assembled single-use flow path kits will be double-bagged, gamma irradiated, and carefully boxed and inspected prior to shipping. - All flexible tubing and product-contact components are USP Class VI and comply with EMA 410/01 Rev. 3 pertaining to minimizing risk of transmitting animal spongiform encephalopathy agents via human and veterinary products.
Materials of Construction (product contact tubing)	- High pressure lines encased in XO® and low pressure lines not encased in XO: Platinum-cured, non-braided silicone - High pressure lines not encased in XO: Platinum-cured nylon braided silicone
Operating temperature	4°C – 40°C
Operating pressure	- High Pressure Lines (non-braided silicone lines encased in XO or braided silicone lines not encased in XO; e.g., post-pump lines and outlet lines): max 4 barg - Low Pressure Lines (non-braided silicone lines that are not encased in XO; e.g., inlet lines and pre-pump lines): no pressure rating available.

Process Connections

Inlet and outlet connections ¹	CPC AseptiQuik® G (standard) or mini tri-clamp (TC, optional)
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¹Other connector types are available upon request. Please reach out to a sales representative for more details.

Automation Overview

The automation platform is based on the KlariFi Software Platform/Allen-Bradley programmable logic controller (PLC). The various operational processes (e.g., initial flush, inline dilution, column equilibration, load, wash, elution, column cleaning, HETP, etc.) will be selected from a process menu via the HMI (human machine interface). These preconfigured processes will be monitored, controlled, and historically logged via the PLC and SCADA (supervisory control and data acquisition) software of the single-use chromatography system. Additionally, the automation system will be configured to enable bi-directional communications via Ethernet/IP (i.e., batch data collection) between the chromatography system automation platform and the facility distributed control system (DCS).

Control Cabinet

General	Local control panels/control cabinets are a combination of high-quality components from globally available and known brands such as Rockwell/Allen-Bradley, ABB, Schneider Electric, Phoenix Contact, Festo, and others. The design and fabrication of the control panels conform to UL508A and EU Machinery Directive requirements for industrial control panels and machinery.
Enclosure (Main System Enclosure)	Type 1/IP54 stainless steel lockable enclosures with #3 brushed finish. All electrical installations inside the Main System Enclosure are low voltage (<50 VDC). All high voltage components are inside a segregated, lockable enclosure.
Enclosure (High-voltage)	Segregated Type 1/IP54 lockable enclosure for high-voltage components (>50 VAC/VDC). This enclosure is located inside the main unit enclosure.
PLC	Allen-Bradley CompactLogix
Networking	- Antaira LNX-800AG switch - Dedicated customer connections for HMI, PLC, and Service
HMI	Systec Wave 221 with color touch screen and glass keyboard with industrial PC mounted in control cabinet
E-stop	Single push-button E-Stop with reset
VSD(s)	Festo CMMT series drives

Software

Platform	KlariFi Software
Operating System	Windows 10 LTSC
Sequencing	The system will be delivered with a series of standard recipes that demonstrate typical process steps. These recipes are fully configurable and may be adjusted by the end-user to suit their specific needs. The recipes consist of following operational sequences: • System CIP • Column CIP • System WFI Flush • Column equilibration • Product Loading • Wash(es) • Linear/Step Gradient Elution • Post-elution wash(es)/sanitization(s) • HETP The system also allows for custom end-user configured recipes.
Control Option	The system is designed to operate as a standalone unit that does not require any external connectivity to execute required functions. The unit can be operated in both manual and automatic modes. The system has the following options to control the process by authorized users: • Automatic mode: Preconfigured recipes with logic and transitions direct the actions of all devices on the equipment. • Automatic recipes can be developed or modified using the Recipe Editor software. The Recipe Editor implements user security based on Windows credentials, versioning, and a lifecycle that requires recipe approval before allowing operators to run a recipe. Recipes may be shared between skids via export/import functions. • Manual mode: An operator with proper security privileges may direct the action of any individual instrument, pump, valve, or equipment module.
Reporting	The system provides preconfigured electronic batch and recipe reports and access to live data through Ethernet communication via Ethernet IP directly to the PLC. The system stores electronic batch, alarm, and event data in a local Historian that can be queried directly by customer reporting systems.
External Monitoring and Control	• The system is designed to accommodate external monitoring and control functions. As delivered, the standard system has dedicated network connections for both the PLC and the HMI. These can be configured to connect to customer networks with no impact on system operations. • The system may also be joined to a customer Active Directory domain for consolidated logons. • External control, such as starting or controlling recipes from a DCS, is available as an option.
Backups	The system uses Acronis for routine machine-level backups.
Safety	The system can automatically implement predefined safety measures when critical parameters are out of defined limits.
21 CFR Part 11 and ALCOA+	Designed and configured to support customer verification of 21 CFR Part 11 and ALCOA+ compliance

Equipment & Components

Bubble Trap Filter

Manufacturer	Sartorius
Model	Sartopore 2 Gamma Midicaps® (0.1 m ²)
Type	Single-use sterilizing-grade filter
Materials of Construction (product contact materials)	• Membrane: polyethersulfone (PES) • Capsule: polypropylene (PP) • O-rings: silicone • Support fleece: polyester

Filtration area	0.1 m ²
Maximum differential pressure	5 bar @ 20°C in direction of flow
Retention Rating	0.2 µm
Connections	1½" TC (ASME BPE-compliant)
Flow Cell (Post-Column) Single-Use	
Manufacturer	Optek
Model	SUC27
Type	Single-use flow cell
Materials of Construction (product contact materials)	- Windows: Quartz, UV transparent - Gasket: ethylene propylene diene monomer (EPDM, FDA, USP class VI) - Sensor body: polyphenylsulfone (PPSU) - Electrode pins: stainless steel 316L
Connections	Mini TC, ¼" ID
Instruments: Conductivity	See Conductivity and Temperature (Post-column) in the Instruments table
Instruments: pH	See pH (Post-column) in the Instruments table
Instruments: UV	See UV (Post-column) in the Instruments table
Process pressure	0 – 6 barg; May be reduced in combination with pH probe.
Process temperature	2 – 50°C; May be reduced in combination with pH probe.
Automated Pinch Valves	
Manufacturer	Repligen
Type	Repligen pinch valve
Pneumatic actuator	Repligen
Failure position	Fail close
Pump 1 and Pump 2	
Manufacturer	Quattroflow
Model	QF150SU-EZ
Type	4-piston diaphragm pump with ring drive (standard orientation) and pressure plate, 5° eccentric shaft, servo motor, and frame
Materials of construction (product contact materials)	- Pump chamber: PP - Valve plate: PP - Diaphragms: thermoplastic elastomer (TPE) - Valves: EPDM - O-rings: EPDM
Connection	Mini TC, ¼" ID
Flow range	Manufacturer specified: 0.017 – 3 LPM
Pressure	≤4 barg
Control	- Fixed speed - Feed flow - Fixed ratio - Time gradient - Flow gradient - Column volume gradient

Instruments	
Pressure (Pump 1, Pump 2, Pre-column, Post-column)	
Manufacturer	Pendotech
Model	PREPS-N Series
Type	Single-use pressure sensor, non-sterile
Material of Construction	Polysulfone (meet USP Class VI, both pre- and post-gamma radiation)
Pressure range	Installed/Configured: 0 – 4.14 bar
Accuracy	Installed/configured: ± 0.03 bar or $\pm 5\%$ of reading
Multi-use	No
Product contact	Yes
Connection	$\frac{1}{2}$ " TC (ASME BPE-compliant)
Flow Sensor (Pump 1 and Pump 2)	
Manufacturer	Sonotec
Model	SONOFLOW CO.57 series
Type	Stainless steel clamp-on ultrasonic flow sensor
Size	$\frac{1}{4}$ " ID tubing
Materials of Construction	- Housing: stainless steel 1.4305 - Measuring channel: Poly(methyl methacrylate) (PMMA) black - Display protection: PMMA transparent
Flow range	- Manufacturer specified: 0 – 10 LPM - Measurement: 0 – 5 LPM
Accuracy	- Installed/configured for 0 – 1 LPM: ± 0.03 LPM - Installed/configured for 1 – 5 LPM: $\pm 3\%$ of reading (at 1 barg backpressure and viscosity of 1 cP for process fluid) Note: The flowmeter can be tuned to operate with the same accuracy at a different backpressure.
Multi-use	Yes
Product contact	No (non-product contact clamp-on ultrasonic)
Air/Liquid Sensor (Inlet 1)	
Manufacturer	Pendotech
Model	AD Series
Type	Air/liquid sensor and transmitter
Material of Construction	Plastic
Range	Manufacturer specified: - Bubbles that are greater than 50% of the tubing inner diameter will be detected in almost any liquid. - Groups of micro-bubbles or foam will also be detected as bubbles.
Multi-use	Yes (sensor only)
Product contact	No
Bubble Detector (Pre-Column)	
Manufacturer	Sonotec
Model	SONOFLOW CO.57 Series
Type	Stainless steel clamp-on bubble sensor

Materials of Construction	- Housing: stainless steel 1.4305 - Measuring channel: PMMA black - Display protection: PMMA transparent
Range	Manufacturer specified: - Bubble sensitivity : ~3 – 6.3 mm - Max. bubble speed: 1.9 m/s
Multi-use	Yes
Product contact	No

Conductivity and Temperature (Post-Column)

Manufacturer	Optek
Model	ACF60-SU-35
Type	Conductivity sensor with integrated temperature sensor
Materials of Construction (product contact; flow cell only)	- Conductivity electrode pins: stainless steel 1.4435 (SS 316L), delta-ferrite (dF) <1%, BN2 - Gasket: EPDM (FDA, USP Class VI) - Sensor body: PPSU
Conductivity and temperature ranges	- Conductivity: Manufacturer specified: 0 µS/cm – 150 mS/cm - Temperature: Manufacturer/Installed/Configured: 2°C – 50°C
Accuracy	- Conductivity: 0 – 10 mS/cm Accuracy is ±0.5 mS/cm 10 – 150 mS/cm accuracy is ±5% of the actual reading - Temperature: Installed/Configured: ±1°C
Multi-use	No
Product contact	Yes

Converter

Manufacturer	Optek
Model	C8480
Type	Multi-input transmitter for pH, conductivity, temperature, and UV
Materials of Construction	Stainless steel/polyester/silicone/glass/diverse plastics
Inputs	4 detector inputs (Optek) 2 sensor inputs (conductivity) (Optek ACF60 only) 2 sensor inputs (pH)
Outputs	1 failsafe system relay (active) 1 lamp output (Optek) 8 mA outputs (0 – 20 or 4 – 20 mA), galvanically isolated
Multi-use	Yes
Product contact	No

UV (Post-Column)

Manufacturer	Optek
Model	- Sensory assembly: AF46-VB - Wavelength module: AF46
Type	UV absorption sensor
Material construction	SS 316L
Wavelength	Standard dual wavelength: 254/280 nm or 280/300 nm
Optical path length	- Manufacturer specified: 1 – 160 mm - Installed/configured: 2.5 mm
UV range	Manufacturer specified: 0 – 2 AU

Accuracy	Linearity $\pm 1\%$ of respective measuring range (specific to application)
Multi-Use	Yes
Product contact	No. Installed on single-use flow cell (SUC27) with quartz window
pH Sensor (Post-Column)	
Manufacturer	Hamilton
Model	OneFerm pH VP 120 Pt1000
Type	Single use pH sensor
Materials of Construction (product contact)	- Probe: glass - VMQ (silicone elastomer)
Connections	PG 13.5 thread
Range	Manufacturer specified: pH 3 – 10
Process pressure	- Manufacturer range for accuracy: 0 – 2 barg - Operating pressure: 0 – 4 barg
Process temperature	Manufacturer specified: 4°C – 50°C
Accuracy	Installed/configured : ± 0.2 pH units (for pressure up to 2 bar)
Instrument size	- Standard pH probe holder $\varnothing$ 12 mm x 120 mm
Multi-use	No
Product contact	Yes
Pressure Regulator and Transmitter (Instrument Air Line)	
Manufacturer	Festo
Model	MS4-LFR
Type	Pressure regulator, pressure indicator
Materials of Construction	- Bowl: Polycarbonate (PC) - Housing: die-cast aluminum - Filter: Polyethylene (PE) - Diaphragm: Nitrile butadiene rubber (NBR)
Pressure regulation range	0.3 – 7 barg
Grade of filtration	5 μ m
Multi-Use	Yes
Product Contact	No
Level Switch for bubble trap	
Manufacturer	Turck
Model	BC10 Series
Type	Capacitive Sensor
Material Construction	Plastic
Range	Manufacturer specified: - Rated switching distance (flush): 10 mm - Rated switching distance (non-flush) 15 mm
Accuracy	Manufacturer specified: $\leq 2\%$ of full scale
Multi-use	Yes
Product contact	No

Optional: Equipment, Critical Components, and Instruments

Equipment & Components	
Flow Cell (Pre-Column) Single-Use	
Manufacturer	Optek
Model	SUC23
Type	Single-use flow cell
Materials of Construction (product contact materials)	- Gasket: EPDM (FDA, USP class VI) - Sensor body: PPSU - Electrode pins: stainless steel 316 L
Connections	Mini TC, ¼" ID
Instruments - conductivity	See Conductivity (Pre-Column) in the Instruments table
Instruments - pH	See pH (Pre-Column) in the Instruments table
Process pressure	0 – 2 barg; May be reduced in combination with pH probe.
Process temperature	2°C – 50°C; May be reduced in combination with pH probe.
Automated Pinch Valves (8 Outlets)	
Manufacturer	Repligen
Type	Repligen pinch valve
Pneumatic actuator	Repligen
Failure position	Fail close
Pressure Control Valve (Post-column)	
Manufacturer	Repligen
Type	Repligen pinch control valve
Pneumatic actuator	Repligen
Failure position	Fail open
Positioner Manufacturer	Bürkert
Control Algorithms	- Fixed position/ramp - Post-column pressure - Column differential pressure - Adaptive column differential pressure and post-column pressure control

Instruments	
pH (Pre-Column)	
Manufacturer	Hamilton
Model	OneFerm pH VP 120 Pt1000
Type	Single use pH sensor
Materials of Construction (product contact materials)	- Probe: glass - VMQ (silicone elastomer)
Connections	PG 13.5 thread
Range	Manufacturer specified: pH 3 – 10
Process pressure	- Manufacturer range for accuracy: 0 – 2 barg - Operating pressure: 0 – 4 barg
Process temperature	Manufacturer specified: 4°C – 50°C
Accuracy	Installed/configured: ± 0.2 pH units (for pressure up to 2 bar.)
Instrument size	- Standard pH probe holder - Ø 12 mm x 120 mm
Multi-use	No
Product contact	Yes
Conductivity (Pre-Column)	
Model	ACF60-SU-35
Type	Conductivity sensor
Materials of Construction (product contact; flow cell only)	- Conductivity electrode pins: stainless steel 1.4435 (SS 316L), dF <1%, BN2 - Gasket: EPDM (FDA, USP class VI) - Sensor body: PPSU
Conductivity range	Manufacturer specified: 0 – 150 mS/cm
Accuracy	0 – 10 mS/cm accuracy: ±0.5 mS/cm 10 – 150 mS/cm accuracy: ±5% of the actual reading
Multi-use	No
Product contact	Yes

Flow Sensor (Post-Column)	
Manufacturer	Sonotec
Model	SONOFLOW CO.57 series
Type	Stainless steel clamp-on ultrasonic flow sensor
Size	¼" ID tubing
Materials of Construction	- Housing: stainless steel 1.4305 - Measuring channel: PMMA black - Display protection: PMMA transparent
Flow range	- Manufacturer specified: 0 – 10 LPM - Measurement: 0 – 5 LPM
Accuracy	- Installed/configured 0 – 1 LPM accuracy: ± 0.03 LPM - Installed/configured 1 – 5 LPM accuracy: $\pm 3\%$ of reading at 1 barg backpressure and viscosity of 1 cP for process fluid Note: The flowmeter can be tuned to operate with the same accuracy at a different backpressure.
Multi-use	Yes
Product contact	No (non-product-contact clamp-on ultrasonic)

Optional ACCESSORIES: Equipment and Instrument Details

Instrument	
Product Concentration (Post-column)	
Manufacturer	Repligen
Model	PATsmart™ FlowVPX® System
Type	Inline measurements using variable pathlength
Note	For further details, please refer to the FlowVPX Technical Specification document.



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