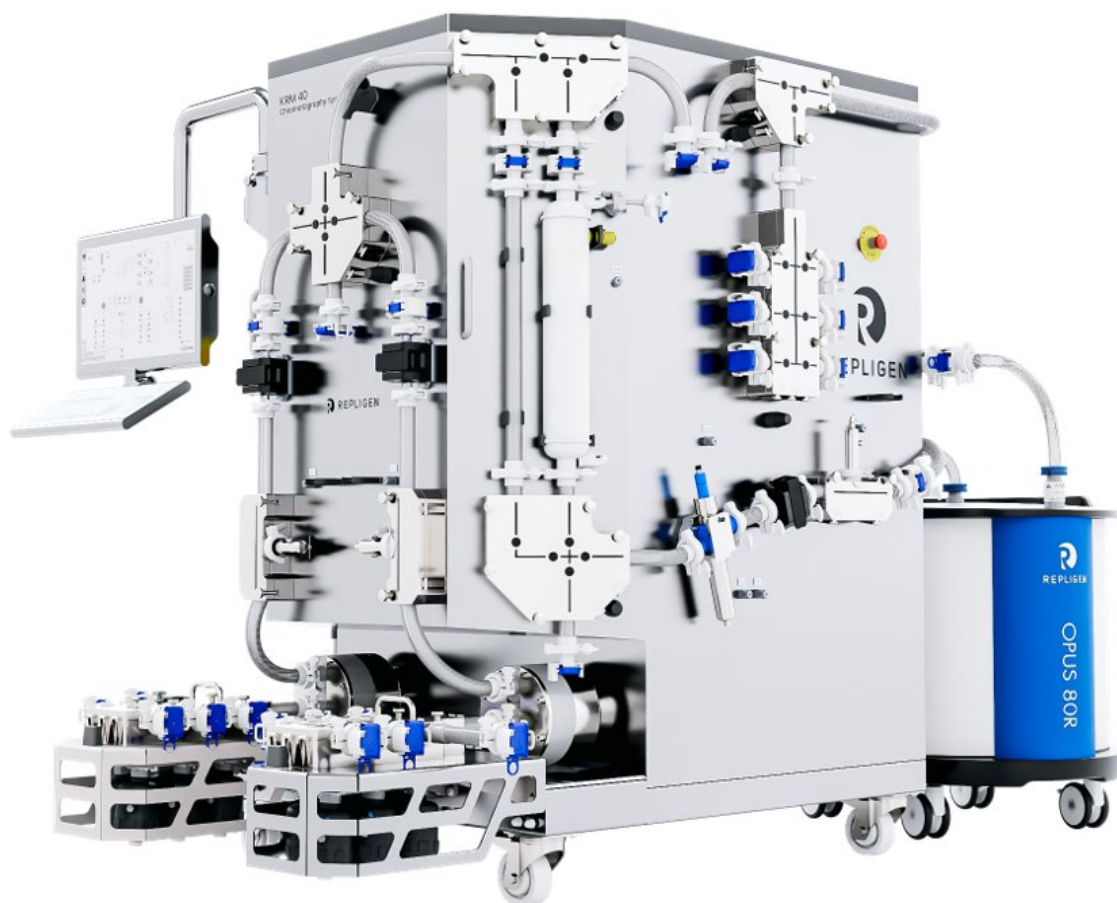


KRM® 40 Chromatography System

Technical Specifications



TD0082_AUG2026

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General Functionality Overview

KRM® 30 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	KRM 40
Skid design	cGMP clean room washdown design with skid structure and control panel made of stainless steel 304L, brushed finish #3A
Approximate dimensions (W x D x H)	System: 2.15 m x 1.84 m x 2.08 m
System max. weight (empty)	930 kg (The exact value will vary depending on the hardware configuration.)
Column type accepted	Repligen; Millipore; Sartorius; Cytiva
Column diameter range	40 – 100 cm
Column bed height	5 – 30 cm
Single-use system flow path kit	1" 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: 1* – 60 LPM
Inlet pump 2	Diaphragm pump - operating flow range: 1* – 60 LPM

*1 LPM is the lowest flowrate that system can control with 2% max-to-avg fluctuation error

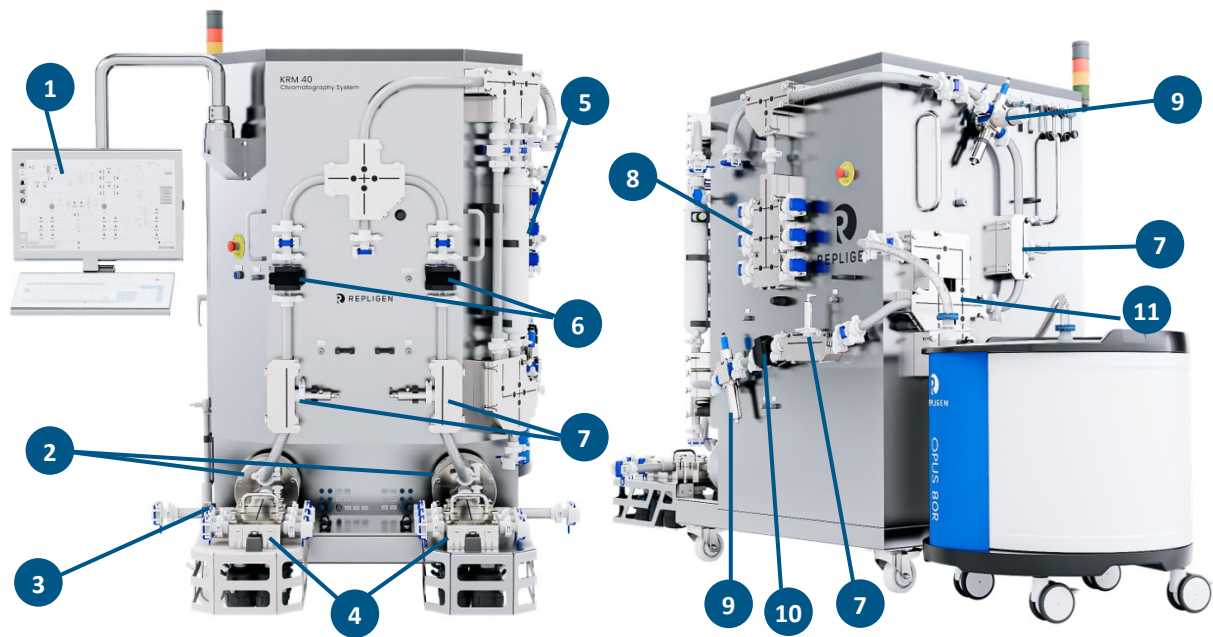
Process Valves

Number of automated valves	42 ON/OFF valves (standard) or 42 ON/OFF valves, 1 control valve (option on the post-column)
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Operating Parameters (Flow Kit)

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

Figure 1. KRM 40 Chromatography System Components



Components

1.

HMI, touch screen and glass keyboard
2.

2X 4-chamber diaphragm pumps
3.

Inlet air sensor
4.

2X Inlet valve blocks
5.

Filter and level sensor assembly
6.

2X Ultrasonic flow meters
7.

4X Pressure sensors
8.

Outlet valve block
9.

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

Pre-column bubble detector
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	
KRM30 with bubble trap filter bypass	≤5.1 L
KRM30 with bubble trap filter inline	≤7.7 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, as well as any external connections.

Automation

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

Power	Instrument power: 120 – 240 VAC, single-phase, 50/60 Hz, 15 A Main power: 380 – 480 VAC, three-phase, 50/60 Hz, 20 A
Compressed air	Instrument air: 5.8 – 8 barg, Festo 12 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

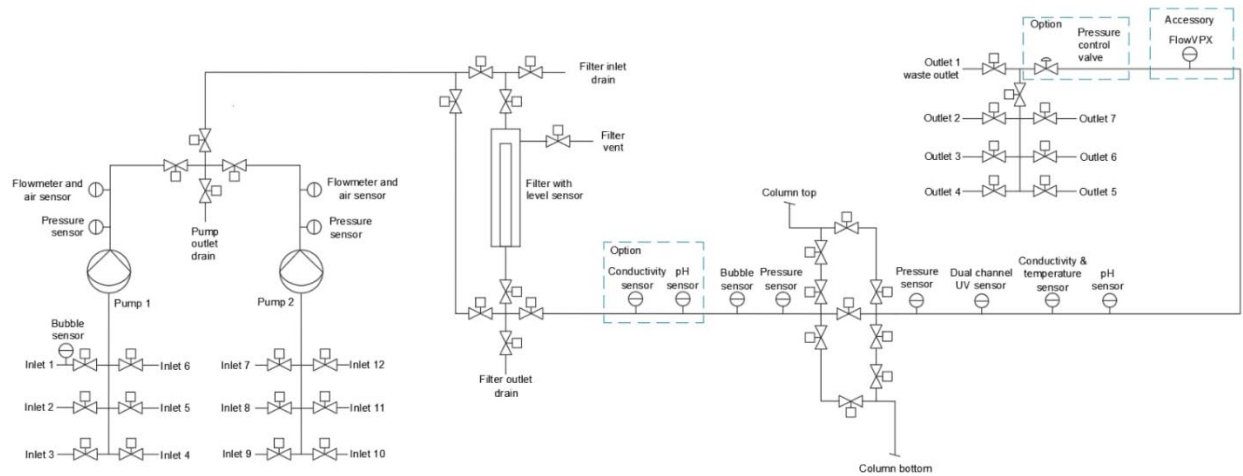
Outlet Connections

Pump Outlet Line	Bubble Trap Filter Line	Post Column Line
• Pump outlet drain	• Filter inlet drain • Filter vent • Filter outlet drain	• Outlet 1 waste outlet • Outlet 2 • Outlet 3 • Outlet 4 • Outlet 5 • Outlet 6 • Outlet 7

Compliance

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

Figure 2. Process Flow Diagram

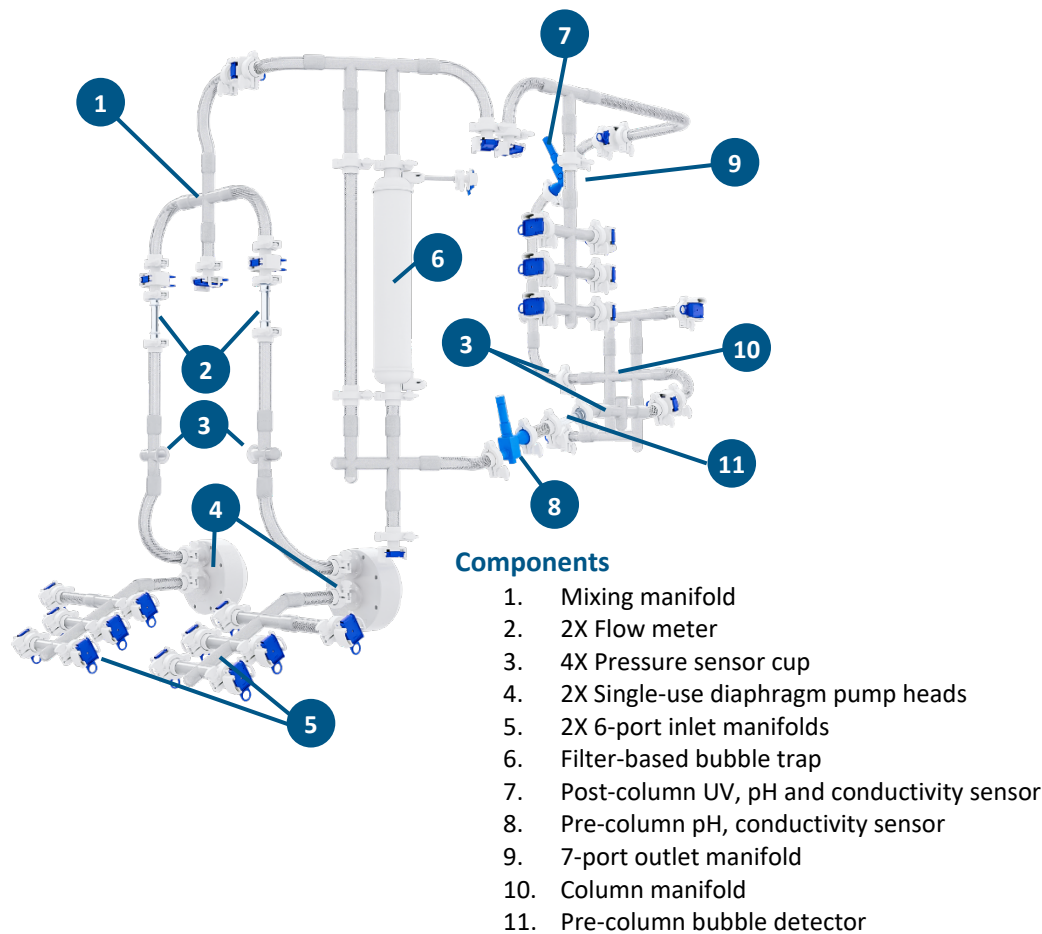


KRM 40 Chromatography System - System Configurations & Options

Hardware PN#	Description
KRM30	SINGLE-USE CHROMATOGRAPHY SYSTEM (0.75-INCH ID)
KRM30BASE	CHROM075 base assembly ☒ System main unit module with linear, step gradient capability ☒ Two (2) 4-chamber diaphragm pumps (line 1, line 2) ☒ Two (2) Repligen valve manifold with six (6) inlets each (12 inlets per the system) ☒ Two (2) non-product-contact ultrasonic flow meters (line 1, line 2) ☒ Four (4) non-product-contact pressure sensors (line 1, line 2, pre & post-column) ☒ Bubble trap filter assembly with liquid level detector ☒ Two (2) non-product-contact ultrasonic bubble detectors (product load inlet, pre-column) ☒ Repligen chromatography valve manifold ☒ Conductivity/temperature sensor (post-column) ☒ pH sensor (post-column) ☒ Repligen valve manifold with seven (7) outlets (post-column) ☒ HMI touchscreen, swingarm & glass keyboard ☒ 21 CFR Part 11 and ALCOA+ compliant system software ☒ System CE and UL certifications
KRM30HW01	Isocratic hardware configuration (single pump and 6 inlets only)
KRM30HW02	Post-column pressure control valve (pneumatic)
KRM30HW03*	Post-column UV sensor wavelength 280/300 nm
KRM30HW04*	Post-column UV sensor wavelength 254/280 nm
KRM30HW06	Pre-column conductivity and pH sensor assembly
KRM30HW07	Alarm beacon
KRM30HW09	Power configuration US
KRM30HW10	Power configuration EU
KRM30HW11	Power configuration UK
ACC-VPX-02-A	Integrated PATsmart™ FlowVPX® for KRM40: US
ACC-VPX-02-F	Integrated PATsmart FlowVPX for KRM40: EU
ACC-VPX-02-G	Integrated PATsmart FlowVPX for KRM40: UK

*Either KRM40HW03 or KRM40HW04 should be selected. Both options cannot be chosen together.

Figure 3. Single-Use System Flow Path Kit



Single-Use Flow Path Kit	
Overview	• The complete single-use flow path kit consists of all required 1" ID molded silicone tubing valve liner sub-assemblies, 1" 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)	• 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 – 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" TC, 1" ID as a standard or CPC AseptiQuik® L as an option ¹
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¹ Other connector types are available upon request. Please reach out to the 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 (i.e., 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 will conform 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
Sequencing	The system will be delivered with a series of standard recipes that demonstrate typical process steps for your application. These recipes are fully configurable and may be adjusted by the end-user to suit their specific needs once the system is delivered. 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 process control options for 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 pre-configured electronic batch and recipe reports as well as 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	System provides Acronis to allow for routine machine level backups.
Safety	System automatically implements 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 Maxicaps® (Size: 20")
Type	Single-use sterilizing -grade filter
Materials of Construction (product contact)	- Membrane: polyethersulfone (PES) - Capsule: polypropylene (PP) - O-rings: silicone - Support fleece: polyester
Filtration area	1.2 m ²
Maximum differential pressure	5 bar @ 20°C in direction of flow
Retention Rating	0.2 µm
Connections	1½" TC ASME BPE

Flow Cell (Post-Column) Single-Use

Manufacturer	Optek
Model	SUC27
Type	Single-use flow cell
Materials of Construction (product contact)	- Windows: Quartz, UV transparent - Gasket: ethylene propylene diene monomer (EPDM, FDA, USP Class VI) - Sensor body: polyphenylsulfone (PPSU) - Electrode pins: stainless steel 316L
Connections	1" TC, 1" 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°C – 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 & Pump 2

Manufacturer	Quattroflow
Model	QF5KSU
Type	Diaphragm pump with ring drive unit, pressure plate, 5° shaft
Materials of Construction (product contact)	• Pump chamber: PP • Valve plate: PP • Diaphragms: thermoplastic elastomer (TPE) • Valves: EPDM • O-rings: EPDM
Connection	1.5" TC ASME BPE
Flow range	Manufacturer specified: max. 100 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	Endress+Hauser
Model	Cerabar® PMP23 Series
Type	Pressure transmitter
Material of Construction	316L SS (mounting body and diaphragm)
Pressure range	Installed/configured: 0 – 4.14 barg
Accuracy	Installed/configured: ±0.06 barg
Multi-use	Yes
Product contact	No

Flow (Pump 1 & Pump 2)	
Manufacturer	Levitronix
Model	Leviflow® LFSC-i20X.1
Type	Stainless steel clamp-on ultrasonic flow sensor and transmitter with rigid single use tubing insert
Size	1" TC, ¾" ID
Materials of Construction	- Converter: Polyphenylene sulfide/polytetrafluoroethylene-like coating (PPS/PTFE-like coating)/PP - Flow pipe: PP
Flow range	Manufacturer: 0 – 80 LPM
Accuracy	- Installed/configured for 0 – 8 LPM: ±0.16 LPM - Installed/configured for 8 – 80 LPM: ±2% of reading (Applies when the process fluid has physical properties similar to water.)
Multi-use	Converter: Yes
Product contact	Flow pipe: No
Bubble Detector (Product Load Inlet)	
Manufacturer	Sonotec
Model	SONOCHECK ABD06 Series
Type	Bubble detector and transmitter
Materials of Construction	- Housing and Cover: Plastic/POM - Measuring Cell: Plastic/PMMA
Multi-use	Yes (sensor only)
Product contact	No
Bubble Detector (Pre-Column)	
Manufacturer	Levitronix
Model	LFSC Series
Type	Bubble detector and transmitter
Connections	1" TC, ¾" ID
Materials of Construction	- Converter: PPS/PTFE-like coating/PP - Flow pipe: PP
Multi-use	Converter: Yes
Product contact	Flow pipe: Yes

Conductivity and Temperature (Post-Column)	
Manufacturer	Optek
Model	ACF60-SU-35 conductivity sensor with temperature
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 - Conductivity: 10 – 150 mS/cm accuracy is $\pm 5\%$ of the actual reading - Temperature: Installed/configured: $\pm 1^\circ\text{C}$
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	SS316L
Wavelength	Standard dual wavelength: 254/280 nm or 280/300 nm
Optical path length	Standard: 2.5 mm
UV range	Manufacturer specified: 0 – 2 AU
Accuracy	Linearity within $\pm 1\%$ of respective measuring range (specific to application)
Multi-Use	Yes
Product Contact	No. Installed on single-use flow cell (SUC27) with quartz window

pH (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: Ø 12 mm x 120 mm
Multi-use	No
Product contact	Yes

Pressure Regulator and Transmitter (Instrument Air Line)

Manufacturer	Festo
Model	MS6-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 bar
Grade of filtration	5 µm
Multi-use	Yes
Product contact	No

Level Switch for bubble trap

Manufacturer	Turck
Model	BC10 Series
Type	Capacitive Sensor
Materials of Construction	Plastic
Range	Manufacturer specified: - Rated switching distance (flush): 10 mm - Rated switching distance (non-flush) 15 mm
Accuracy	Manufacturer specified: ≤2% of full scale (fs)
Multi-use	Yes
Product contact	No

Optional: Equipment, Critical Components and Instruments Details

Equipment & Components	
Flow Cell (Pre-Column) Single-Use	
Manufacturer	Optek
Model	SUC23
Type	Single-use flow cell
Materials of Construction (product contact)	- Gasket: EPDM (FDA, USP class VI) - Sensor body: PPSU - Electrode pins: stainless steel 316 L
Connections	1" TC, 1" ID
Instruments: conductivity	See Conductivity (Pre-Column) in the Instruments table.
Instruments: pH	See pH (Pre-Column) in the Instruments table.
Process pressure	0 – 6 barg; May be reduced in combination with pH probe.
Process temperature	2°C – 50°C; May be reduced in combination with pH probe.
Pneumatic Pressure Control Valve (Post column)	
Manufacturer	Repligen
Type	Repligen Pneumatic 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)	- 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)	
Manufacturer	Optek
Model	ACF60-SU-35 conductivity sensor
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

Optional Accessories: Equipment and Instrument Details

Instrument	
Product Concentration (Post-Column)	
Manufacturer	Repligen
Model	PATsmart™ FlowVPX® System
Type	In-line measurements using Variable Pathlength
Note	For further details, please refer to the FlowVPX Technical Specification document.



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