

СИСТЕМЫ БИОХРОМАТОГРАФИИ COPRIME



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CoPrime® Biochromatography Process-Scale Systems

Fully automated, configurable systems for biopharmaceutical manufacturing and cGMP process scale applications

The CoPrime® biochromatography systems are designed to achieve optimum separation and purification of monoclonal antibodies, vaccines, plasma, and therapeutic proteins. The systems support rapid scale-up and are ideally suited for pilot and process scale.

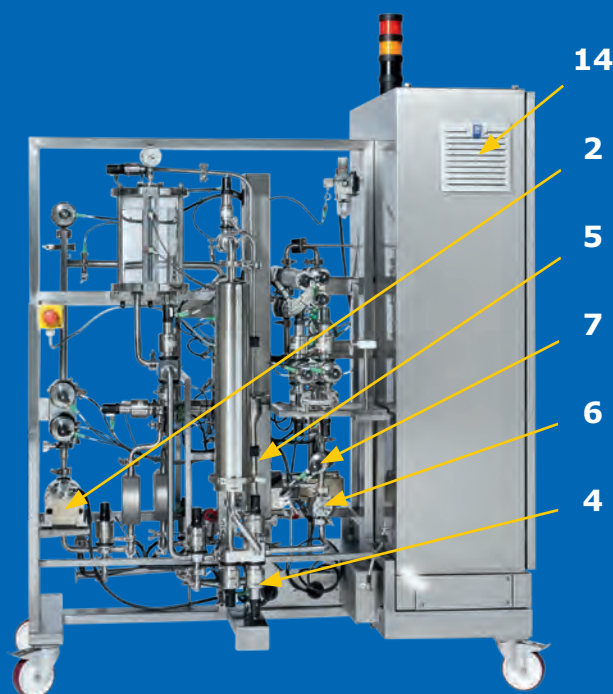
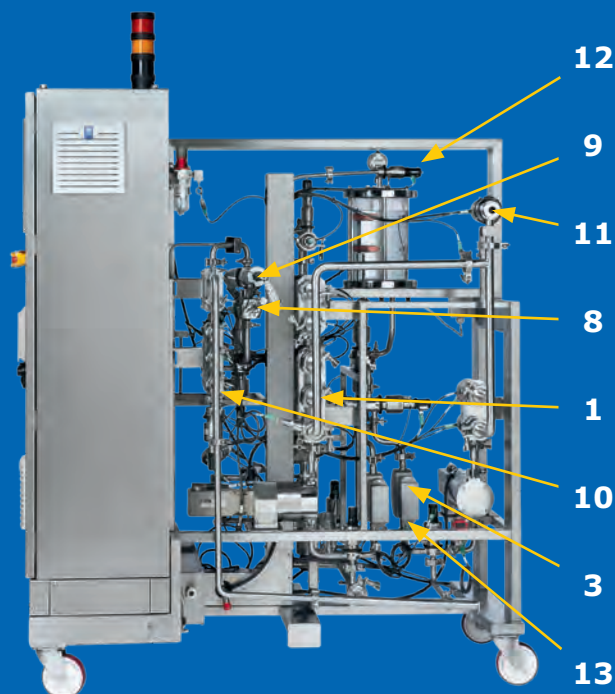
The CoPrime® systems are designed based on 50 years of process knowledge and engineering expertise to provide a configurable, intuitive process-scale purification solution. CoPrime® B and C sizes have an extended flow rate span and optimized performance for greater gradient accuracy and purification reproduction. The CoPrime® 40 L covers higher scales and allows to scale-up directly from CoPrime® 20 L.

Benefits

- Scalability with 2 flow rate ranges: CoPrime® 20 L up to 1200 L/h and CoPrime® 40 L up to 2500 L/h
- Optimized design for very low hold-up volume
- Gradient precision across an extended flow rate window
- Consistent purified fractions over multiple cycles for optimum performance, reliability, and robustness
- Intuitive and simplified HMI enhances operator experience and interaction, and easy access to components and instrumentation simplifies maintenance
- Improved operational efficiency when combined with our Cogent® Process-scale Tangential Flow Filtration System



Configure to meet your purification requirements...



Select from the options below to add to the CoPrime® base platform to best meet your unique chromatography processing requirements. Some of the options have been included in the CoPrime® size C base system, see table 1 for details.

The CoPrime® size B base platform includes: air sensor on product inlet line, two inlets ports, one Quattroflow® inlet pump, pressure transmitter and pressure switch on pump outlet, bubble trap with vent valve and air break, pre-column air sensor, pre-column pressure sensor and transmitter, column flow path valve block (forward, reverse or bypass), post column pressure transmitter sensor & transmitter, two outlets and drain ports, system drain line, electrical enclosure, and pressurized air supply block.

The CoPrime® base platform must be purchased with a flowmeter option (option 3 or 13) and the post-column instrumentation (options 8 and 9).

Option 1: 5 inlet manifold on 1 pump for multiple buffer processing

Option 2: Second pump with 2 inlets enabling:

- Mixing of two products with a regulated flow rate ratio (2% accuracy of the measured value from 180 L/h to 1200 L/h)
- Linear gradient, from 10% to 90%, according to a rated slope based on flow rate or conductivity (closed control loop: 2% accuracy of the measured value on volume or 2% accuracy of the full scale on conductivity)
- Step gradient, from 10% to 90%, according to set points on flow rate or conductivity (closed control loop: 2% accuracy of the measured value on flow or 2% accuracy of the full scale on conductivity)

Option 3: Mass flowmeter

One mass flowmeter is set up between the pump and the bubble trap for monitoring and regulation of the flow fed to the column.

Note: This option includes only one flowmeter. If option 2 (second pump) is selected, the flowmeter option is to be selected twice. The mass flowmeter option excludes the mag flowmeter option.

Option 4: Valve block of pre-column filter either disposable or in a housing

Note: Filter and housing not included.

Option 5: Valve block and pre-column filter housing

Note: Series 3000™ housing 20 in. I/O TC ¾ in.
– Type 226 Code 7, Recessed Base

Option 6: Pre-column pH and conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the filter and the column.

Option 7: HETP inlet block valve

This option enables injection of the HETP sample as close as possible to the column inlet, through a NovAseptic® divert valve.

Note: It is possible to perform an HETP sequence using an inlet port instead of the dedicated divert valve.

Option 8: Post-column pH conductivity

A conductivity sensor (with temperature compensation) and a pH sensor are fitted in the same flow cell, which is integrated in line between the column and outlet ports. Two ranges of conductivity are defined, one for the process and another for cleaning.

Option 9: Post-column UV dual wavelength

With this option, a mono-wavelength UV absorption sensor, Optek® AF45 sensor, or a dual-wavelength with an Optek® AF46 sensor is proposed.

Option 10: Five outlets

Three additional ¾ in. outlet ports with NovAseptic® valves are added downstream of the column to separate different fractions.

Option 11: CIP manifold for cleaning the entire system (excluding the column) in CIP, from one single inlet to one single outlet

Option 12: Feedback switches on NovAseptic® valve

With this option, every valve is mounted with an integrated position feedback switch. Closed position is physically detected.

Option 13: Electromagnetic flowmeter

The performance of the flowmeter is dependent on the conductivity of the product. Product conductivity must be greater than 5 µS/cm for liquids, in general, and greater than 10 µS/cm for demineralized water.

Option 14: Filter hoods

The addition of stainless steel filter hoods on the enclosure filters and fan allows an IP rating of IPx5.

CoPrime® size	CoPrime® Size B – Biochromatography System 20 L	CoPrime® Size C – Biochromatography System 40 L
Total options	14 options	8 options
Option 1: 5 inlet ports	Yes	Included in base system
Option 2: 2 nd feed pump	Yes	
Option 3: mass flow meter	Yes	
Option 4: valve block for pre-column filter	Yes	
Option 5: valve block and pre-column filter	Yes	Yes
Option 6: pre-column pH and conductivity sensor	Yes	Yes
Option 7: HETP	Yes	Not available
Option 8: post-column pH and conductivity sensor	Yes	Yes
Option 9: post-column UV absorption sensor	Yes	Yes
Option 10: 5 outlet ports	Yes	Yes
Option 11: CIP manifolds	Yes	Yes
Option 12: valve position feedback-switch	Yes	Yes
Option 13: magnetic flowmeter	Yes	Not available
Option 14: system IPx5 rated	Yes	Included in base system

Table 1: Options for CoPrime® size B and size C systems.

Designed for Easy, Reliable Processing

Embedded NovAseptic® Valves

With 20 years of proven performance, these “Aseptic by Design” valves deliver optimal performance, reliability, durability, and ease of maintenance. Our NovAseptic® connectors have no dead legs for maximum product recovery with zero hold-up volume, and are in compliance with the most stringent cleanability requirements.

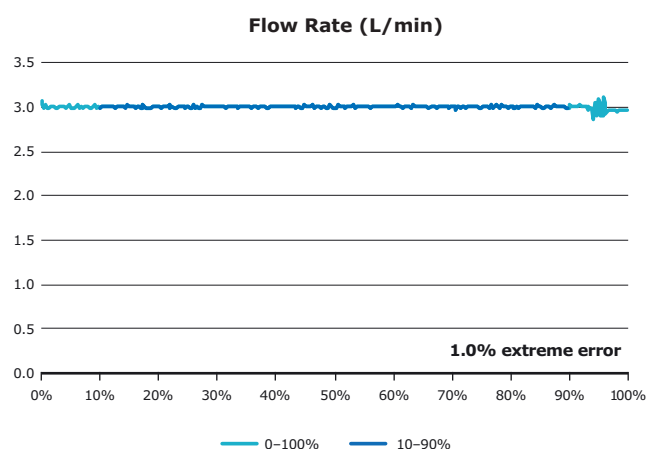
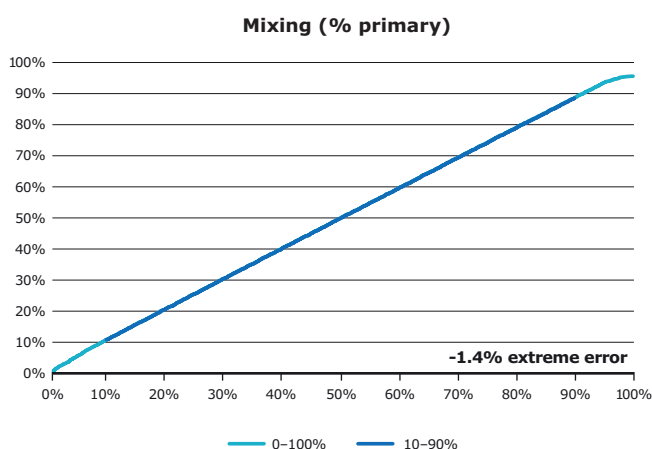
CoPrime® size B System Robust Chromatography Performance

Gradient accuracy over extended window of operation

The system is designed to deliver gradients using optional pump-based mixing at an accuracy of $\pm 2\%$ over a 10–90% gradient mix range.

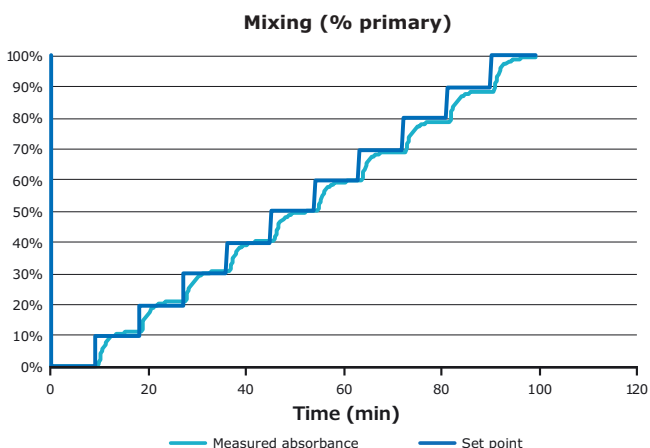
Linear Gradient per Percentage at 3 L/min

The extreme errors at 3 L/min measured on the range 10–90% are **-1.4%** on mixing and **1.0%** on total flow rate.



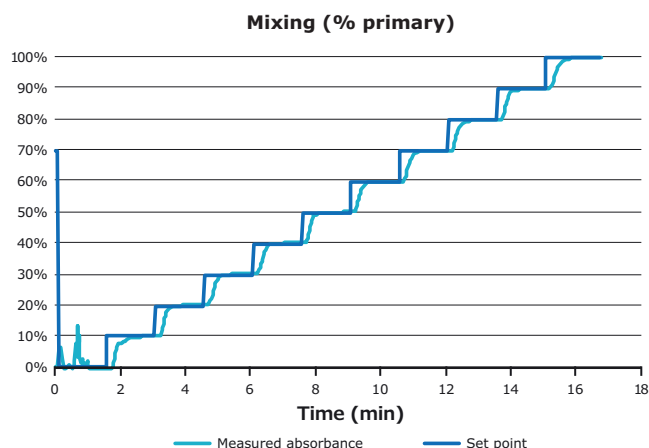
Step Gradient per Percentage at 3 L/min

The extreme errors measured on the range 10–90% are **-1.3%** on mixing and **0.0%** on total flow rate.



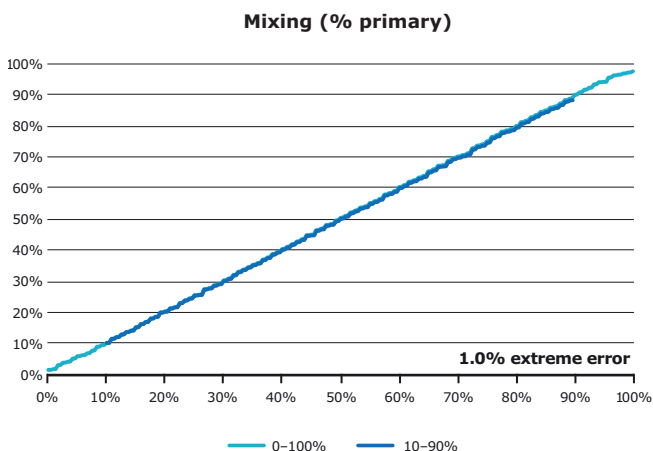
Step Gradient per Percentage at 20 L/min

The extreme errors measured on the range 10–90% are **-0.2%** on mixing and **-0.1%** on total flow rate.



Linear Gradient per Percentage at 20 L/min

The extreme errors measured on the range 10–90% are **1.0%** on mixing and **0.4%** on total flow rate.

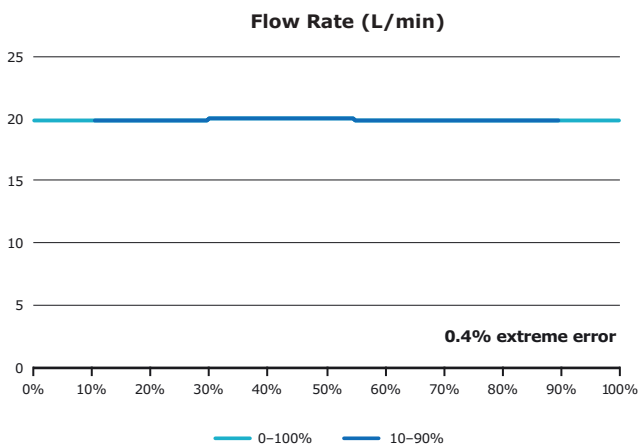


Proven Sanitary Design with Automatic CIP Cycle and Manifold

During cleanability studies, a bovine serum solution was pumped through the system and then flushed with NaOH and WFI or RO water. The results showed a TOC less than 3 ppm.

Extensive Process Monitoring

Each flow cell is specially designed to ensure complete passage of all process fluids, resulting in rapid sensor response and precise system operation. Pre-column sensors monitor the presence of air, flow, pressure, pH, conductivity, and temperature. Post-column sensors monitor UV, pH, conductivity, and temperature. All sensing elements are constructed of materials that conform to FDA guidelines and are contained within distinct flow cells for easy access and maintenance.

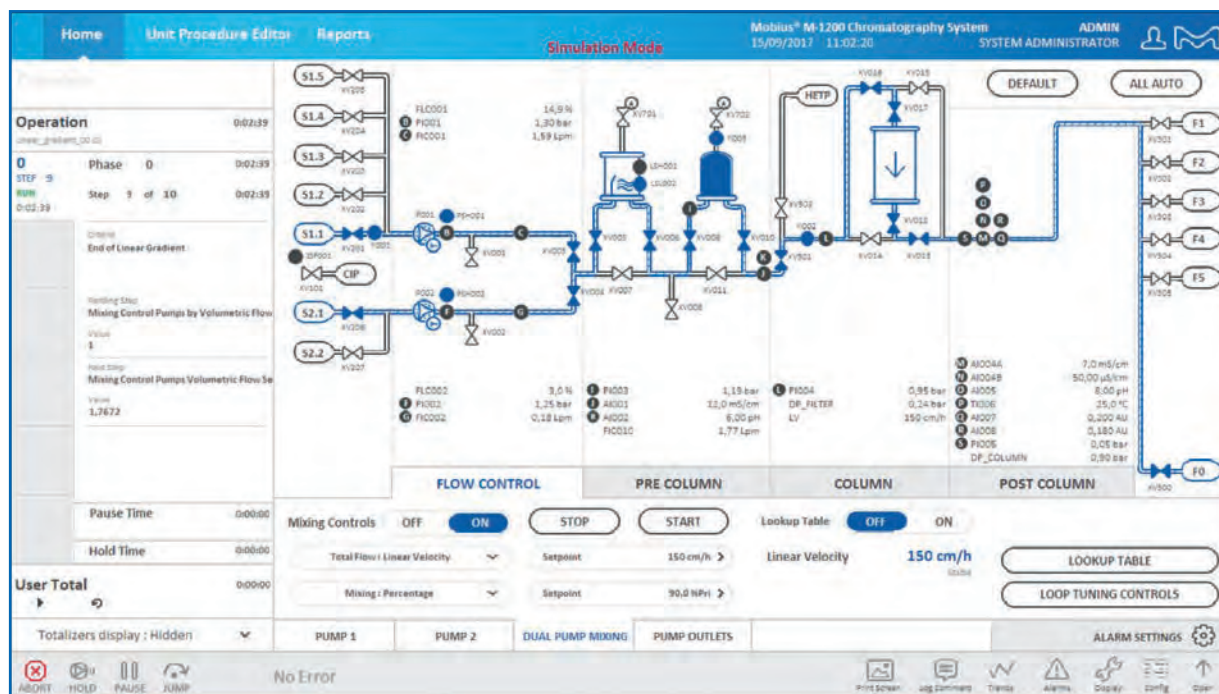


Total Process Control and Connectivity

Common Control Platform® Software (CCP®) for Multiple Unit Operations

From Mobius® bioreactors to clarification, chromatography, tangential flow filtration, and virus filtration systems, our CCP® software can provide you with one familiar interface that simplifies software management and reduces the

learning curve for new operators. This software package is available to support all application sizes, accelerating tech transfer and process scale-up.



Monitors Processes and Enables Batch Reporting

The latest version of CCP® software is powerful, intuitive and graphical; providing real-time monitoring and total in-depth control of your biochromatography platform. Create process operations using the recipe editor, monitor the process from the home screen, and create reports for the batch using the configurable report generator.

Comprehensive and Secure Data Acquisition

CCP® software was designed to support compliance to 21 CFR part 11 and was developed under GAMP5 guidelines. The software includes an accessible audit trail and electronic signatures for verification. CCP® software is suited for manufacturing equipment from development to large-scale, using industrial computers and controllers for reliability.

Network Integration

Data transfer to the plant control system enables data collected by CCP® software to be centrally stored and managed.

Powerful Recipe Editor Simplifies Generation of Process Specific Separation Protocols

CCP® software monitors and adjusts all process parameters to ensure execution of a preprogrammed method or "recipe" using the Recipe Editor. You can quickly and efficiently configure, modify, test, and ultimately, lock these recipes for initial evaluation, repetitive process investigation, or transfer to production operations. Complex operations are easily constructed without prior programming experience.

Backup and Restoration

Backup and restoration of data can be managed via network integration.

Security Synchronization

Security synchronization allows user accounts to automatically coordinate with the networked plant control system for faster and simpler user account control and editing.

Comprehensive Range of Value-added Services and Support

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, lower costs, and support regulatory compliance. 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)
- Site acceptance test (SAT) (*combined with IQ/OQ*)
- Installation qualification/operational qualification (IQ/OQ) (*combined with SAT*)
- Performance qualification support (PQ)

Training

Appropriate training for users is not only cGMP requirements, it also ensures 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.

- Interacting with the Human Machine Interface
- Manual and automatic system operation
- Troubleshooting issues
- Creating and managing your own recipes
- Process recommendations

CCP® Recipe Creation Service

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.

Preventive Maintenance


Regular maintenance of your system is critical to avoid unnecessary downtime for repairs, minimize the risk of process deviations, and maintain optimum performance and compliance.

Services catalogue numbers

Please contact your local sales specialist	CoPrime® System – FAT execution incl. protocol
SSVQUACPB1	CoPrime® System – SAT & IQ/OQ execution incl. protocol & travel
SSVQUACPB2	CoPrime® System dummy skid configuration – SAT execution incl. protocol & travel
SSVQUADOC	CoPrime® System documentation verification
SSVRPCCPB	CCP® recipe design qty 3
PTRCPBOP	CoPrime® System operator training, 1 day
PTRCPBCCP1	CoPrime® System – CCP® V.6 recipe writing, 1.5 day
PTRCPBCCP2	CoPrime® System use, troubleshooting and CCP® V.6 recipe writing, 3 days
PTRCPBCCP3	CoPrime® System – system use, process design, troubleshooting and CCP® V.6, recipe writing
SSVPRMCPB	CoPrime® Preventive Maintenance execution incl. protocol & travel

Specifications

	CoPrime® Size B – Biochromatography System 20 L	CoPrime® Size C – Biochromatography System 40 L
Mechanical specifications		
System dimension L × W × H, in mm (Inches)	1,680 × 926 ¹ × 1,814 ² (66.2" × 36.4" × 72.9") ¹ with option 14, instead 851 ² without top flashlight	1,990 × 926 ¹ × 2,024 ² (78.4" × 36.4" × 79.5") ¹ with option 14, instead 851 ² without top flashlight
Net Weight	410 kg (full options)	800 kg (full options)
Materials of Construction	Piping: Stainless steel 316 L Elastomer: EPDM in compliance with 21 CFR 177.2600	Piping: Stainless steel 316 L Elastomer: EPDM in compliance with 21 CFR 177.2600
Connections		
Main line pre-pump	TC 1"1/2 OD 1"	TC 1"1/2 OD 1"1/2
Main line post-pump	TC 3/4" OD 3/4"	TC 1"1/2 OD 1"
Fractions lines	TC 3/4" OD 3/4"	TC 1"1/2 OD 1"
CIP inlet line	TC 1"1/2 OD 1"	TC 1"1/2 OD 1"1/2
Drain	TC 1"1/2 OD 1"	TC 1"1/2 OD 1"1/2
Operating specifications		
Max Fluid viscosity	2 cP	2 cP
Product Temperature Range	+4 to +30 °C	+4 to +30 °C
Maximum Pressure	4 barg	6 barg
System operating Pressure	+4 to +30 °C	+4 to +30 °C
Operating Humidity	15–60% (non-condensing)	15–60% (non-condensing)
Instrument specification and Performances		
Pumps		
Feed Pump P001	Quattroflow® Quaternary diaphragm pump Flow rate: 0.3–20 L/min	Quattroflow® Quaternary diaphragm pump Flow rate: 0.83 to 40 L/min
Feed Pump P002	Same pump, optional	Same pump, included
UV		
UV sensor	Optek® Measurement range: 0 to 2 AU +/-0.04	Optek® Measurement range: 0 to 2 AU +/-0.04
OPL options	2.5 mm 5 mm 10 mm	2.5 mm 5 mm 10 mm
Wavelengths options	Single wavelength: 254 nm 280 nm 300 nm 313 nm Dual wavelength: 254 nm, 280 nm 254 nm, 313 nm 254 nm, 300 nm 280 nm, 300 nm 280 nm, 313 nm 300 nm, 313 nm	Single wavelength: 254 nm 280 nm 300 nm 313 nm Dual wavelength: 254 nm, 280 nm 254 nm, 313 nm 254 nm, 300 nm 280 nm, 300 nm 280 nm, 313 nm 300 nm, 313 nm
Probes		
Flowmeters	Endress+hauser Range: 1–25 L/min +/-1% MV	Endress+hauser Range: 4–50 L/min +/-1% MV
Conductivity sensors	Optek® Pre-column process range: 0–200 mS/cm +/-4 mS/cm Post-column process range: 0.1–200 mS/cm +/-4 mS/cm Cleaning range: 0.1–50 µS/cm +/-1 µS/cm	Optek® Pre-column process range: 0–200 mS/cm +/-4 mS/cm Post-column process range: 0.1–200 mS/cm +/-4 mS/cm Cleaning range: 0.1–50 µS/cm +/-1 µS/cm
pH sensor	Mettler-Toledo Range: 0–14 pH +/-0.1	Mettler-Toledo Range: 0–14 pH +/-0.1



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