

BioProcess Modular System

PROCESS CHROMATOGRAPHY

The BioProcess™ Modular System is an automated liquid chromatography system built for process scale-up and large-scale biopharmaceutical manufacturing (Fig 1 and 2). The system can be configured to meet specific process demands and has the accuracy and documentation required for the use in GMP-regulated environments. The design is based on the ÄKTAprocess™ chromatography system, facilitating technology transfer and process scale-up. The system is also compatible with the AxiChrom™ chromatography column family.

Part of a scalable chromatography platform

- Versatile configuration for different process needs
- Suitable for GMP-regulated manufacturing
- Compatible with AxiChrom chromatography columns and BioProcess Resin Mixer for efficient unit operations

Flexibility to configure to manufacturing needs

The BioProcess Modular System is available in three flow-rate ranges from 1 to 12 000 L/h. The BioProcess Modular System 1/4 inch is suitable for small-scale GMP production, while the larger 1 1/2- and 2-inch systems are suitable for large-scale commercial production (Fig 3 and 4).

The compact design with a built-in computer, allows the system to fit neatly into a plant with minimum floor-space utilization. A range of configurations provides flexibility to adjust to specific process needs (Fig 5 and 6). Configurations include the choice of extra inlets and outlets, the type and quantity of selected sensors, and isocratic versus gradient functionality. All component options are part of the validated and tested hardware design space to ensure compliance and reliability in GMP-regulated environments. The built-in industrial computer with UNICORN™ software allows standalone operation or integration into any plant-wide control system. The system has built-in functionality to be connected to an OPC client to enable the use of a uniform interface between UNICORN and other software systems such as DeltaV™, Siemens™, and Rockwell™. For more OPC information, see the UNICORN Administration and Technical Manual and the UNICORN OPC manual.



Fig 1. The BioProcess Modular System 1/4 inch is suitable for small-scale GMP production.



Fig 2. The 1 1/2- and 2-inch BioProcess Modular Systems are suitable for large-scale commercial production.

Clinical manufacturing

Full-scale manufacturing



Fig 3. BioProcess Modular Systems are part of a scalable solution based on the ÄKTAprocess system design.

As an option a PROFIBUS™ gateway can be selected, enabling field bus communication to other software systems. The signal list is predefined, please refer to the communication list available when configuring the product.

Post-installation modification to increase usability and lifespan

Owing to the flexibility of the design, post-installation changes such as the addition of valves, filters, and pumps are possible. This allows a system to be reassigned to another process with different requirements, thereby increasing the versatility and working life. Upgrades can also be installed to increase the lifespan of the system, which also protects the investment value of the system.

Sanitary design

The BioProcess Modular System has several features that make sanitization with 1 M sodium hydroxide simple and effective. UNICORN software allows automation of cleaning in place (CIP) and a patented air trap design makes CIP more efficient. The wetted parts can be changed to prevent cross-contamination when the system is used for campaigning.

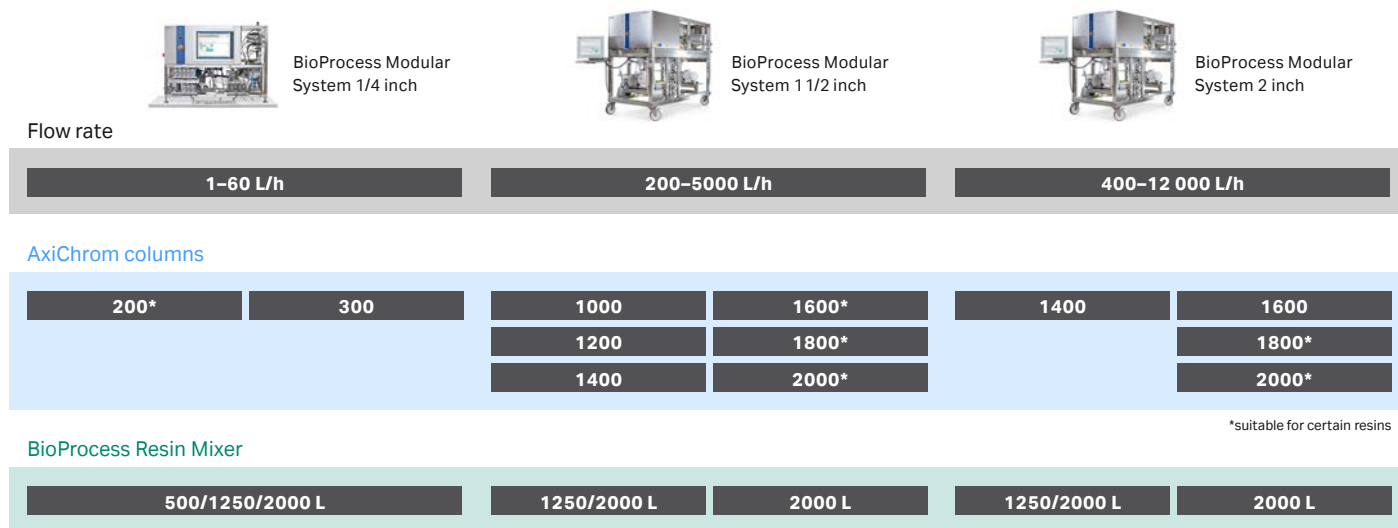


Fig 4. Overview of compatibility with AxiChrom columns and BioProcess Resin Mixer.

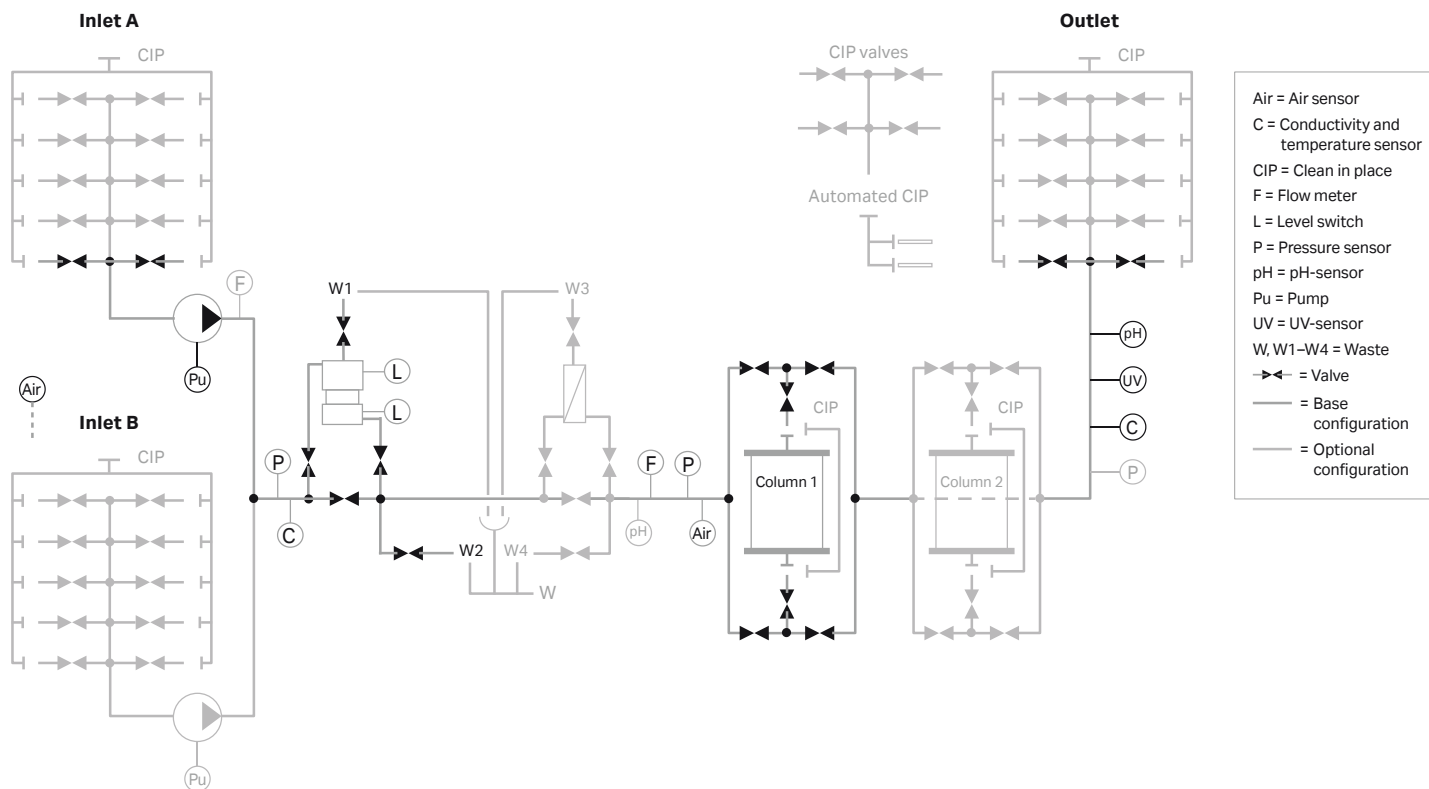


Fig 5. Piping and instrumentation diagram for BioProcess Modular System 1/4 inch.

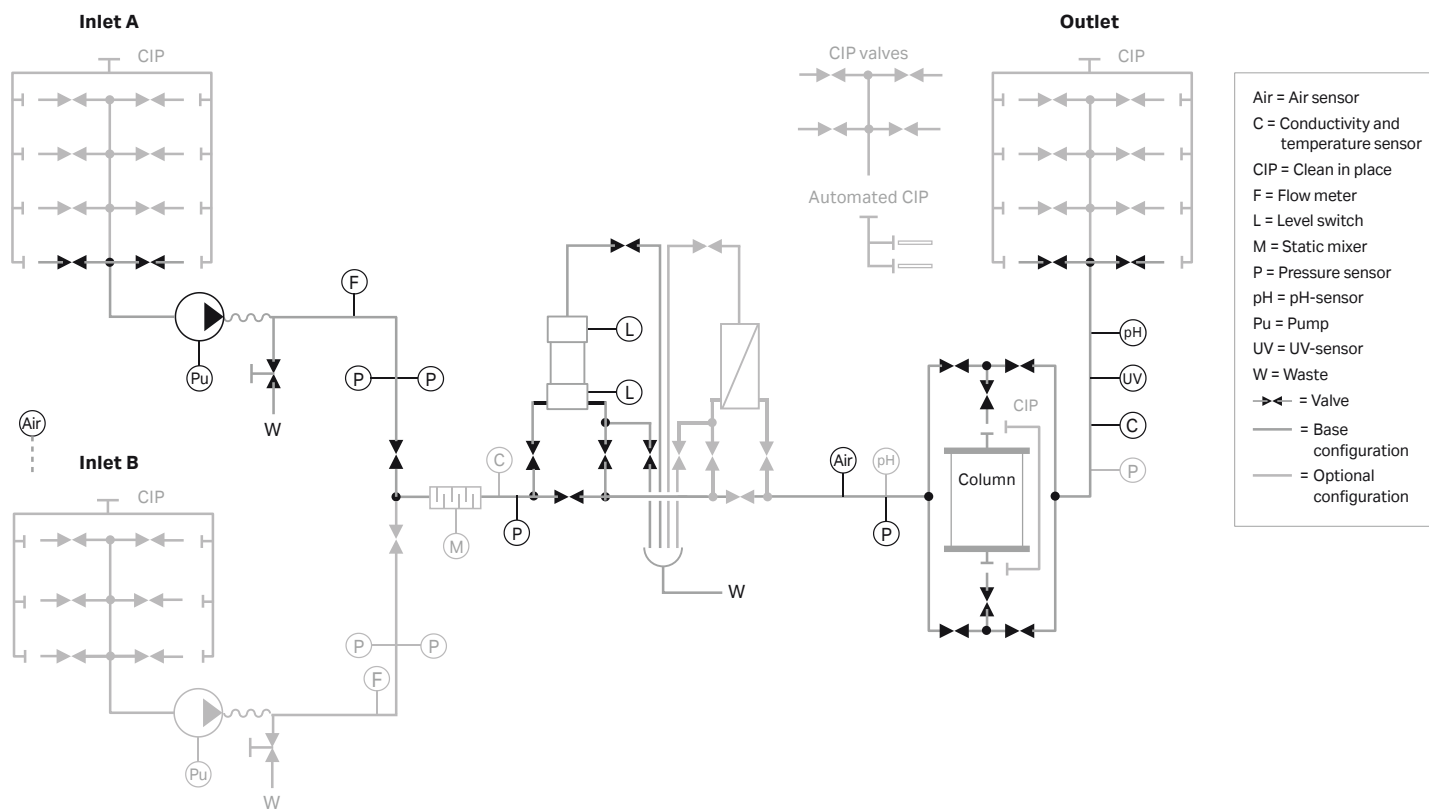


Fig 6. Piping and instrumentation diagram for BioProcess Modular Systems 1 1/2 inch and 2 inch.

Offering robust and reliable purification at large scale

Robust column packing is key to achieving a reliable chromatographic process. Reproducibility is essential as a process moves from process development to full-scale manufacturing. AxiChrom columns use Intelligent packing to ensure consistent and reproducible results across different scales and column sizes. The BioProcess Modular System is compatible with Intelligent packing using AxiChrom columns.

The system can be configured to develop gradients with feedback loop technology. This ensures thorough mixing of liquids/solvents without air bubbles, so that even challenging gradients can be created with high accuracy (Fig 7).

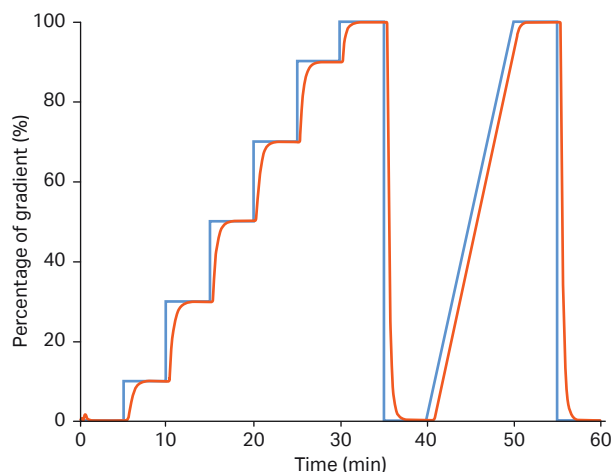


Fig 7. Chromatogram from a BioProcess Modular System, showing programmed (blue) and actual (orange) step gradient with 98% accuracy.

Chromatography unit operation involves many steps that can be individually optimized for a simplified workflow. Apart from being compatible with AxiChrom columns, the BioProcess Modular System can also be integrated with the BioProcess Resin Mixer to enable an automated solution for resin transfer and column packing and unpacking that helps facilitate effective chromatography unit operations.

Process control at all levels

The Bioprocess Modular System is delivered with the UNICORN control system preinstalled and configured on the built-in industrial computer. No specific actions are required with respect to the control system and the system can be used directly after power-up.

The system is prepared to handle other control solutions, such as DeltaV, Siemens, and Rockwell. As these solutions need to be tailored to fit the environment, they are offered as customization projects.

UNICORN software is a proven and familiar interface for both chromatography and membrane separations that provides efficient control of processes, flexible method programming, extensive data evaluation, and powerful reporting functionality. Scouting for method development and peak comparison provides a high degree of efficiency in pharmaceutical production, as well as process scale-up and scale-down work.

The UNICORN software is designed according to GAMP™ 5 guidelines (ISPE) and can be used in a manner that follows 21 CFR Part 11, US FDA's regulation on electronic records and signatures. The software supports full data integrity and consistency throughout the process, enabling digitized and validated manufacturing. Process data is reliably stored in a database repository located on the system hardware. For access control, the software is secured by password-protected user login. Systems can also be connected to a server set up by the user for any additional database management.

User activities are logged in audit trails for usage history. The UNICORN software is dedicated to chromatography operations and provides the ability to set up runs, tools to evaluate and analyze data, generate reports, and more.

Full regulatory documentation and services

The system is delivered with comprehensive operating instructions and extensive system documentation including assembly drawings, piping and instrumentation diagram, and system specifications. Installation and operation qualification (IQ/OQ) protocols are available. IQ/OQ can be performed either by the user or by a certified specialist.

System specifications

	BioProcess Modular System 1/4 inch	BioProcess Modular System 1 1/2 inch	BioProcess Modular System 2 inch
Piping material	Stainless steel (SS) or Polypropylene (PP)	SS	SS
Flow rate range			
Range	1–60 L/h	200–5000 L/h	400–12 000 L/h
Accuracy	± 2% or 0.5 L/h	± 2%	± 2%
Dimensions (W × D × H)	1250 × 960 × 1000 mm	1154 × 2378 × 2037 mm	1105 × 2378 × 2200 mm
Dimensions (W × D × H) with floor stand	1250 × 1060 × 1900 mm	-	-
Operating max. pressure	PP: 4 bar g, SS: 6 bar g	4 bar g	4 bar g
Pressure sensor			
Range	PP: 0.1–4, SS: 0.1–6 bar g	0.1–4 bar g	0.1–4 bar g
Accuracy	± 0.12 bar g	± 0.12 bar g	± 0.12 bar g
Conductivity sensor			
Range	0.1–200 mS/cm	0.1–200 mS/cm	0.1–200 mS/cm
Accuracy	< 100 mS/cm: ± 2 % or 0.5 mS/cm 100–200 mS/cm: ± 4%	± 2% or 0.5 mS/cm	± 2% or 0.5 mS/cm
Temperature sensor			
Range	2°C to 80°C	2°C to 80°C	2°C to 80°C
Accuracy	± 2°C	± 1°C	± 1°C
pH sensor			
Range	2–12	2–12	2–12
Accuracy	± 0.15 pH	± 0.15 pH	± 0.15 pH
UV sensor: fixed or variable/multiple wavelength			
Range	0–2	0–2	0–2
Accuracy	Linearity ± 5 % (± 2 % for variable/multiple wavelength)	Linearity ± 5 % (± 2 % for variable/multiple wavelength)	Linearity ± 5 % (± 2 % for variable/multiple wavelength)
Wetted parts	BioProcess Modular System 1/4 inch	BioProcess Modular System 1 1/2 inch	BioProcess Modular System 2 inch
Main piping size	SS: 1/4 inch PP: ID 4.75 mm	1 1/2 inch	2 inch
Flange type	Hygienic tube clamp connection (TC)	Hygienic tube clamp connection (TC)	Hygienic tube clamp connection (TC)
Gaskets and O-rings	Ethylene propylene diene monomer rubber (EPDM), fluorinated propylene monomer (FPM/FKM)	EPDM, FPM/FKM	EPDM, FPM/FKM
Flow meter	EN 1.4404 (316L), EN 1.4539 (904L)	EN 1.4404 (316L), EN 1.4539 (904L)	EN 1.4404 (316L), EN 1.4539 (904L)
Air trap	SS: EN 1.4404 (316L), Glass PP: PP, Glass	EN 1.4404 (316L), Glass	EN 1.4404 (316L), Glass
Air sensor	Polyetheretherketone (PEEK)	EN 1.4404 (316L)	EN 1.4404 (316L)
pH sensor	Glass, polytetrafluoroethylene (PTFE)	Glass, PTFE	Glass, PTFE
Conductivity/temperature sensor	PP, titanium grade 2	PEEK	PEEK
UV sensor	PEEK, titanium grade 2, glass	EN 1.4404 (316L), titanium grade 2, glass	EN 1.4404 (316L), titanium grade 2, glass
Pressure sensor	EN 2.4602 (UNS N06022)	EN 2.4602 (UNS N06022)	EN 2.4602 (UNS N06022)

Wetted parts (continuing)	BioProcess Modular System 1/4 inch	BioProcess Modular System 1 1/2 inch	BioProcess Modular System 2 inch
Pump chamber	PP: PP, Thermoplastic SS: EN 1.4435 (316L), Thermoplastic	EN 1.4435 (316L), Thermoplastic	EN 1.4435 (316L), Thermoplastic
Filter housing	SS housing: EN 1.4404 (316L) Capsule: PP+customer supplied filter	EN 1.4404 (316L)	EN 1.4404 (316L)
Material requirements for wetted parts	USP class VI, 21 CFR 177, animal origin free or in compliance with EMA/410/01		
Material traceability for process wetted and pressure retaining non-metallic materials, minimum	EN 10204 2.1		
Material traceability for process wetted and pressure retaining metals	EN 10204 3.1		
AxiChrom column compatibility	BioProcess Modular System 1/4 inch	BioProcess Modular System 1 1/2 inch	BioProcess Modular System 2 inch
AxiChrom column range (mm)	200*, 300	1000, 1200, 1400, 1600*, 1800*, 2000*	1400, 1600, 1800*, 2000*
System control			
Software	UNICORN 6.3.2 or later		

* Dependent on resin characteristics

Ordering information

To order the BioProcess Modular System, please contact your local sales representative.

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