

Software specifications

BioStream is software developed in compliance with 21 CFR Part 11, cGMP, GAMP and CSV.

- **Electronic recording** : A closed system is assumed and is compliant with 21 CFR Part 11, Subpart B(a) ~ (e).
- **Electronic signature** : ID and password are employed and comply with 21 CFR Part 11 Subpart C. Complies with identification constituent element of CSV guidelines.
- **System validation** : Lifecycle model of development and validation is constructed and verified at each step of planning, designing, implementation, and testing. Documents are prepared in compliance with CSV guidelines.

Operational function	Information	Contents
Operation control function	Automatic operation (Auto)	If flow path composition, pump setting and various operations are set by hour units, a wide range of operations becomes possible.
	Manual operation (Manual)	Pump, valves, and the flow path can be operated by visually in an easy-to-understand manner - clicking on the icon.
Monitor display function	Operating state	States of various equipment, the fluid passing line, and the sensor display are displayed and renewed in real time.
	Chart	Detector data, instrument data, and the fraction are shown in the chart in real time.
	Alarm state	At alarm occurrence, each type of trouble can be checked.
Operational program preparation function	Operational program preparation	Items necessary for automatic operation can be set and stored in a file. A maximum 10 files can be interlinked for operation.
Data management function (Management of electronic recording)	Collection of operational data (Run data)	Detector data and instrument data are collected and recorded.
	Preparation of operation report (Report)	Reports including information necessary for operation records are automatically generated.
	Backup	Various data are automatically backed up at storing.
	Encryption	All stored files are encrypted to maintain security.
	Recording of history (System log)	Log-in information, operating state, alarm occurrence, and data storage are automatically recorded together with user information.
	Printing	All management data can be printed.
Security function	User information (Management of electronic signature)	Management of user information and log-in information is possible by the combination of the ID and password. User information necessary for log-in can be registered in four steps at the operation level.
	Alarm setting	Arbitrary setting of alarms is possible for various equipment and instruments.
System setting function	Security setting	Setting of log-in security is possible.
	Others	Setting of all related systems is possible.
	Sensor calibration	Correction of equipment is possible.
Maintenance setting function	Maintenance and inspection	Confirmation of running hours and the number of times of running of equipment is possible.
Measures for failures	power failure	Uninterruptible power supply system is used for back-up of PLC, PC and instruments. Even if instantaneous power failure occurred, operations can be continued.
	communication failures	When communication failure occurs during operation, the operation is stopped, but data are stored.



YMC Pilot Column for Bioprocess Chromatography

Pilot scales glass columns made by YMC Europe GmbH (Germany) are available. YMC offers comprehensive support.

Specifications

- Inner Diameter : ϕ 300mm or larger columns are available upon requests.
- Bed Length : 80-455mm, 450-750mm (Adjustable range)
- Wetted Materials : Glass, Acrylic

For more information, please visit <http://www.ymc.co.jp/en/chromato/glass/scale.html>



YMC-BioPro Ion Exchange Media

Ion exchange media with superior binding capacity and recovery are available.

Specifications

	YMC-BioPro Q30	YMC-BioPro Q75	YMC-BioPro S30	YMC-BioPro S75
Matrix	Hydrophilic porous polymer			
Particle size	30 μ m	75 μ m	30 μ m	75 μ m
Charged group	-CH ₂ N ⁺ (CH ₃) ₃		-CH ₂ CH ₂ CH ₂ CH ₂ SO ₃ ⁻	
Usable pH range	2 - 12		2 - 12	

For more information, please visit http://www.ymc.co.jp/en/columns/ymc_gel/ymc_biopro.html

Worldwide Availability

YMC America, Inc.
www.ymcamerica.com

YMC Europe GmbH
www.ymc-europe.com

YMC India Pvt.Ltd.
www.ymcindia.com

YMC Korea Co., Ltd.
www.ymckorea.com

YMC Shanghai Rep. Office
www.ymcchina.com

YMC Singapore Tradelinks Pte. Ltd.
www.ymc.sg

YMC Taiwan Co.,Ltd.
www.ymctaiwan.com



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Distributor

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YMC LF-0014P-R00E

Bioprocess Chromatography System

BioStream



YMC CO., LTD.
<http://www.ymc.co.jp>

BioStream

BioStream is a bioprocess chromatography system which has been newly developed with YMC's intellectual assets and know-how cultivated from 30 years of experience. With its superior in operability, performance and quality, BioStream achieves sanitation, speed and high-grade purification required by separation and purification processes of biotechnology-based medicines etc.

YMC continues to offer prompt support when the need arises after installation.



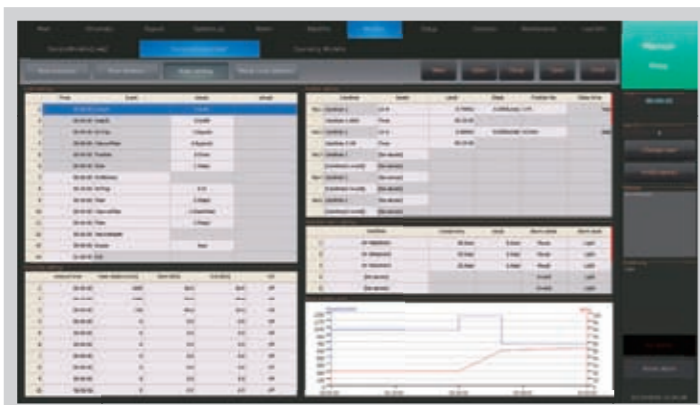
Features



Touch Panel / Chromatography Operation

21.5" large-screen touch panel display enables a high level of visibility and operability at a manufacturing site. The screen is designed to operate visually and sensuously.

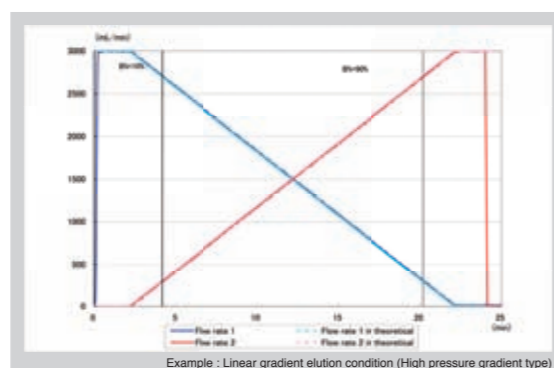
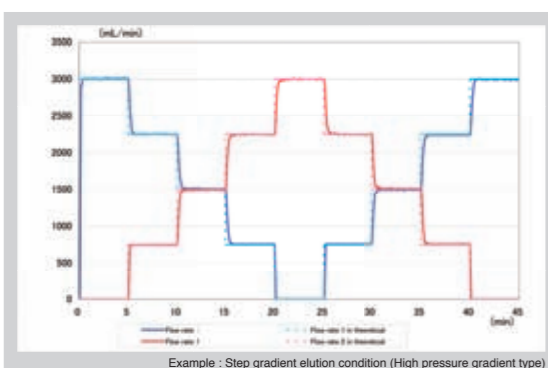
Operating status or monitoring information of each sensor can be checked at a glance on the main control screen.



Operating Program

"Event", "Fraction Condition", "Solvent Condition", "Warning Condition" can be checked on the same screen. This allows creating flexible programs intuitively and easily.

A gradient chart also helps you to program just as you imagined.



Pump / Advanced Flow Control

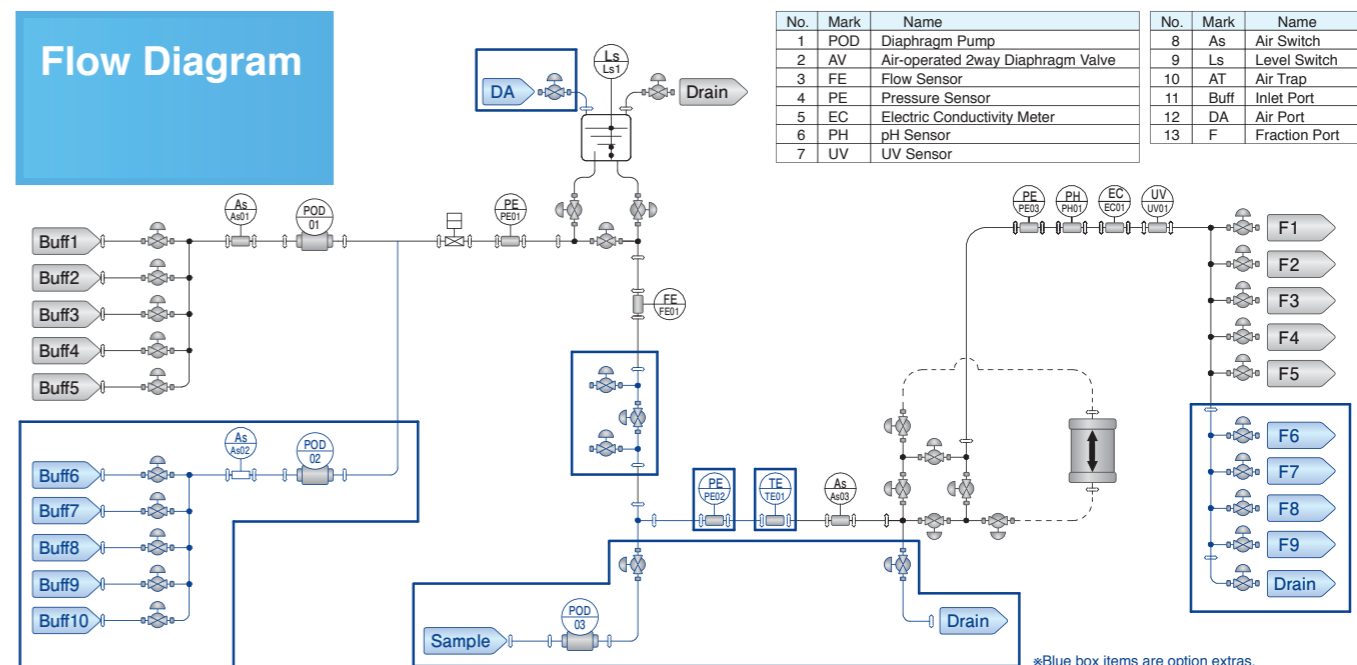
BioStream is equipped with quintuplex diaphragm pumps and can pump at a low flow rate. The pumps are composed of oil-free materials. It is safe to use BioStream at production lines. A high-accuracy servo motor and a flowmeter feedback system are combined to achieve extremely high flow-rate precision.



Variable 3-Wavelength UV Detector

Variable 3-Wavelength UV Detector with diode array is developed completely in-house. Not only targeted peptides but also viruses and impurities can be detected.

Flow Diagram



Standard Specifications

Name	BioStream				
Product number	BSTP-800	BSTP-03K	BSTS-03K	BSTS-10K	BSTS-30K
Maximum flow rate	800 mL/min	3000 mL/min	3000 mL/min	10 L/min	30 L/min
Tubing material	PFA		SUS		
Connection joint	3A 1/4" ferrule joint	ISO 8A ferrule joint	ISO 8A ferrule joint	ISO 10A, 15A ferrule joint	ISO 1S ferrule joint
Valve drive	Air operated				
Pump	Diaphragm (Oil free diaphragm)				
Operating pressure	0.5 MPa (Max. 0.6 MPa)				
Operating temperature	5-30°C				
Wetted materials	PFA, PTFE, Quartz, Glass, EPDM		SUS316, PTFE, Quartz, Glass, EPDM		
Inlet	5 ch				
Outlet	5 ch				
Accuracy of flow rate controller	± 2%F.S.				
Equipped sensor	pH sensor 2-12 (Accuracy 2%F.S.)				
	Conductivity sensor 0-200 mS/cm (Accuracy 2%F.S.)				
	Pressure sensor 0-1.0 MPa (Accuracy 2%F.S., 2 sensors loaded in front and back of the column)				
	Flow sensor (Accuracy 1%F.S.)				
Other standard function	UV sensor Any 3-wavelength within the range of 200 to 400 nm (Accuracy 2%F.S.)				
	Air trap				
	Air sensor				
	Column bypass and column switching				
Dimension (W×D×H)	800×850×1300mm	900×1100×1800mm	900×1100×1800mm	1300×1200×1800mm	2000×1500×1800mm
Weight	200 kg	250 kg	300 kg	400 kg	600 kg
Utility	Single-phase 100 V (10A)	Three-phase 200 V (10A)		Three-phase 200 V (20A)	Three-phase 200 V (30A)
	Instrument air 0.5 MPa				

Optional Extras

A wide range of optional extras meet your requirements.

- **High pressure gradient function** : Achieves highly accurate gradient in feedback operation. Another pump to be mounted.
- **Pressure sensor** : Monitors residual pressure in flow paths. To be mounted at the "OUT" side of a column.
- **Thermometer** : Monitors temperature inside the lines. To be mounted at the IN-side of a column.
- **External port** : Enables filters to be set in the lines. To be mounted at the IN-side of a column.
- **Sample pump** : Delivers at precise rate even for small amounts. To be mounted at the IN-side of a column.
- **Fraction channel** : Can be mounted. Max. 10 channels including a drain channel.