



PROCESS-SCALE CHROMATOGRAPHY

Bio-Rad® Process Chromatography Skid

- Systems are available for pilot to production scale
- Multiple options enable a wide range of configurations
- Entire system is designed for easy cleaning and maintenance
- Unit is configured for simultaneous inline dilution and gradient operation for high performance and reduced cost
- Skid conforms to ASME BPE requirements
- User-friendly software meets U.S. FDA 21 CFR Part 11 requirements
- Skid includes documentation for regulatory submission
- Steam-in-place capability available

Isocratic System, Gradient Capability, and Inline Dilution — Included in a Proven Platform Designed for your Purification Process

The versatile Bio-Rad process chromatography skid can be tailored to different applications using the proven platform approach; different options can be integrated into the core platform.

Each system is optimized to the column diameter and process requirements.

Independent System

The Bio-Rad process chromatography skid is self-contained and incorporates all the necessary components (pumps, valves, and instruments), control cabinets (pneumatic and electric), and the touch screen interface used to run the chromatography process.

The components of the skid are housed within a protective frame. The frame, made of stainless steel with a closed construction design, is also used to lift the skid.

The electrical cabinet work surface is sloped for convenience and visibility of the system while the user is working on the touchscreen.



BIO-RAD

Modular Concept

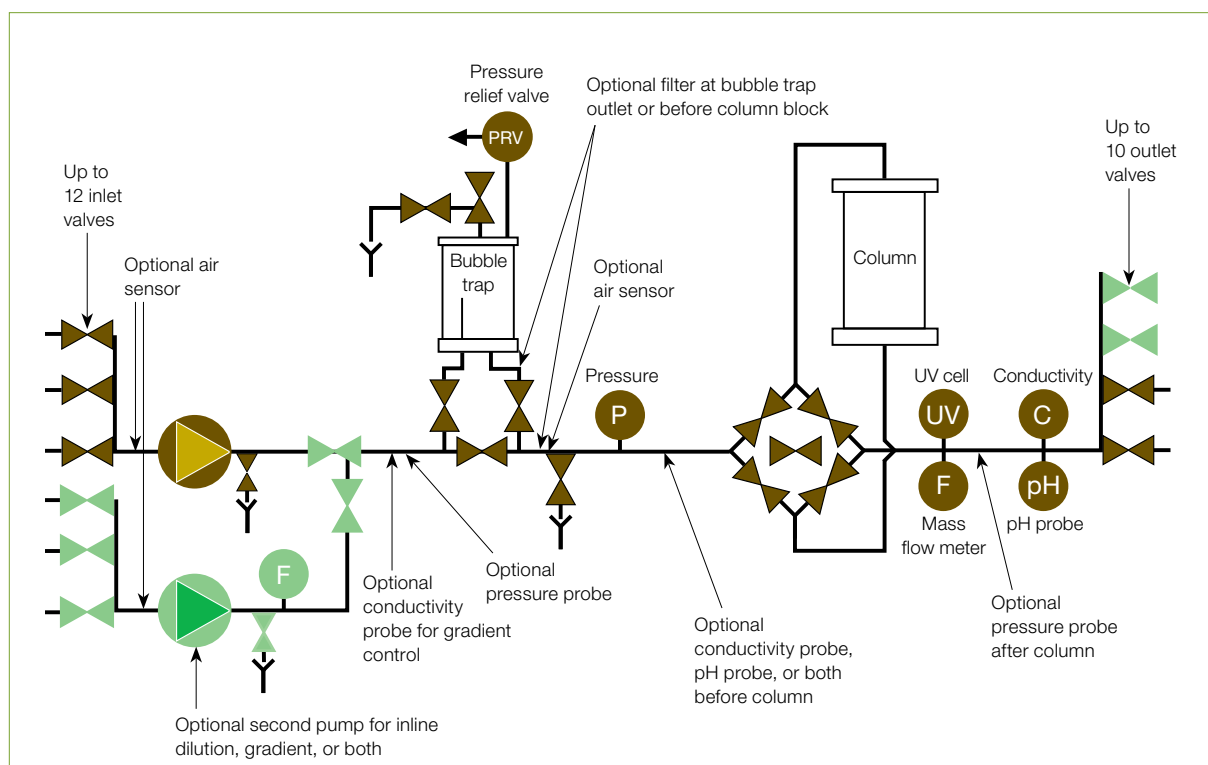
The platform design allows easy customization of the process chromatography skid. One or more systems that meet your precise process requirements can be produced by choosing from the required options. You may specify combinations of sensors and the number of valves and ports.

Options include:

- Multihead pumps
- Gradient function (controlled either by flow rate only or by flow rate and conductivity)
- Additional inlet and outlet valves
- Pressure sensor (before filter or after column)

- Inline filter housing
- Air sensor (after bubble trap, before pump, or both)
- Additional conductivity and temperature sensors (before column)
- Additional pH sensor (before column)
- Sampling valve (after column)
- Software for calculation of HETP, asymmetry, number of theoretical plates, and other parameters
- Position detectors for valves
- Steam-in-place (SIP)

Each option includes the required combination of hardware and software modules. All standard features and options have been validated on the Bio-Rad platform.



Many options exist for customization of the Bio-Rad process chromatography skid.

System Specifications

Pressure rating		Up to 6 bar
Temperature range		Ambient 4–30°C Process fluids 4–60°C
Inline dilution capabilities		1:2 to 1:10
Gradient capabilities		10–90%
Material	Process tube	Stainless steel 316L ASME
	Frame	Stainless steel 304L
	Bubble trap	Glass or acrylic
	Gaskets	EPDM or GYLON

Precise Inline Dilution and Gradient

The system can be equipped with a second pump and flow meter adapted to the dilution ratio required for the application. A conductivity probe can also be installed after the pumps to perform gradient or inline dilution with conductivity compensation. Careful matching of instruments and pumps leads to a maximum flow rate error of 1% at the skid nominal flow rate.

User-Friendly Software

The system controller employs a simple, user-friendly interface via the touchscreen for data input and programming commands.

The process skid is password-protected (four access levels), and all events and actions (alarms, process steps, manual commands, and so on) are recorded in accordance with cGMP guidelines.

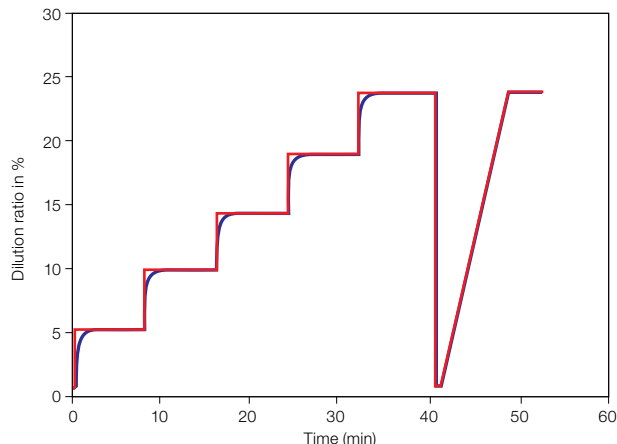
The software allows the system to be operated in manual or automatic modes.

The automatic mode has:

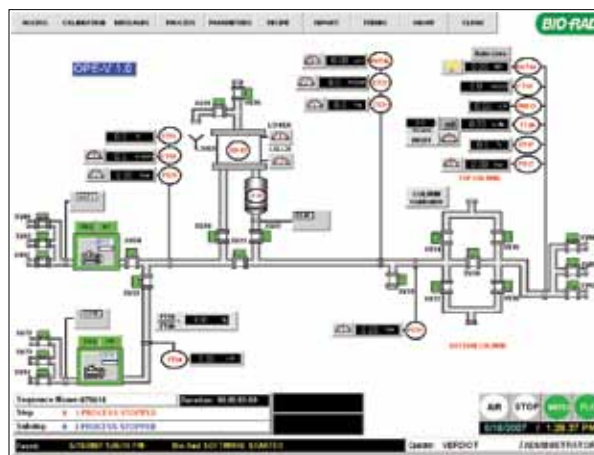
- Multiple steps
- Configurable fluid paths
- Control of valves and column valve
- Multiple end-of-step conditions
- Pausing and halting alarms
- Interactive pausing steps

Full trend review, manipulation, and printing from the system are all standard. Data export and configurable interfacing to external software is included also.

The software meets U.S. FDA 21 CFR Part 11 requirements.



Step and linear gradient on process chromatography skid size 3 at 1,000 l/h.



Overview of column operation as seen on the system controller screen.

Technical Specifications for Process Skids

Process Skid Category	Flow Range, L/h		Process Pipe (ASME BPE)	Maximum Dimensions (L x W x H), mm	Surface Finish, μm	Bubble Trap Volume, L
	Rotary Diaphragm Pump	Multihead Diaphragm Pump				
00*	5–120	N/A	N/A	1,060 x 750 x 610	$R_a \leq 0.4$	0.2
01	5–250	15–165	3/8"	1,500 x 1,000 x 1,700	$R_a \leq 0.4$	0.4
02	25–600	54–540	1/2"	1,500 x 1,000 x 1,700	$R_a \leq 0.4$	1.0
03	40–1,200	105–1,050	3/4"	1,500 x 1,000 x 1,700	$R_a \leq 0.4$	2.7
04	300–3,150	315–3,150	1"	upon request	$R_a \leq 0.4$	4.6
05	300–4,500	450–5,400**	1.5"	upon request	$R_a \leq 0.4$	4.6

* For further information please request bulletin 5997.

** With lobe pump.

Hygienic Design

All process piping and valves are made from 316L stainless steel to conform to ASME BPE requirements.

Only membrane valves are used for the process flow path. Valve blocks and compact instruments are utilized to minimize the holdup volumes.

The cables and pneumatic lines are run in closed stainless steel conduits and carefully arranged to optimize the visibility of and access to the process components for cleaning.

The system can be cleaned in place with NaOH. The option for automated cleaning in place includes a specialized program and an adapted design to enable the system to be reproducibly sterilized.

Enhanced Flexibility

Each Bio-Rad chromatography skid will perform over a predefined range of column diameters and process flow rates. It is easy to select the appropriate skid category from the tables (shown at right) for gradient or isocratic systems. The application ranges of the skid categories overlap, and therefore it is possible that one or more skids can handle specific requirements, as shown in the tables.

You can choose a Bio-Rad process chromatography skid for your current application or process conditions while knowing that the equipment has been designed to be flexible. It can be used for multiple flow rates and other column diameter ranges, and therefore it will remain useful for different processes and process conditions and for future applications.

Compatibility of process skid category and column diameter; gradient system (flow rate, L/h).

		Column diameter, mm										
		100	200	300	350	400	450	600	800	1,000	1,200	1,400
Linear speed, cm/h	50		15,7	35,3	48	63	80	141	251	393	565	770
	75		23,6	53,0	72	94	119	212	377	589	848	1,155
	100		31,4	70,7	96	126	159	283	503	785	1,131	1,539
	125	9,8	39,3	88,4	120	157	199	353	628	982	1,414	1,924
	150	11,8	47,1	106,0	144	188	239	424	754	1,178	1,696	2,309
	175	13,7	55,0	123,7	168	220	278	495	880	1,374	1,979	2,694
	200	15,7	62,8	141,4	192	251	318	565	1,005	1,571	2,262	3,079
	225	17,7	70,7	159,0	216	283	358	636	1,131	1,767	2,545	3,464
	250	19,6	78,5	176,7	241	314	398	707	1,257	1,963	2,827	3,848
	275	21,6	88,4	194,4	265	346	347	778	1,382	2,160	3,110	4,233
	300	23,6	94,2	212,1	289	377	477	848	1,508	2,356	3,393	4,618
	325	25,5	102,1	229,7	313	408	517	919	1,634	2,553	3,676	5,003
	350	27,5	110,0	247,4	337	440	557	990	1,759	2,749	3,958	5,388
	400	31,4	125,7	282,7	385	503	636	1,131	2,011	3,142	4,524	
	450	35,3	141,4	318,1	433	565	716	1,272	2,262	3,534	5,089	
	500	39,3	157,1	353,4	481	628	795	1,414	2,513	3,927		
600	47,1	188,5	424,1	577	754	954	1,696	3,016	4,712			
700	55,0	219,9	494,8	672	880	1,113	1,979	3,519				

Compatibility of process skid category and column diameter; isocratic system (flow rate, L/h).

		Column diameter, mm										
		100	200	300	350	400	450	600	800	1,000	1,200	1,400
Linear speed, cm/h	50		15,7	35,3	48	63	80	141	251	393	565	770
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	Process skid category 00*
	Process skid category 01
	Process skid category 02
	Process skid category 03
	Process skid category 04
	Process skid category 05

GYLON is a trademark of Garlock Sealing Technologies.

* For more information, request bulletin 5997.



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