



PROCESS-SCALE CHROMATOGRAPHY

Bio-Rad® Process Chromatography Skid

- Available for small scale production
- Designed for easy cleaning and maintenance
- Configured for simultaneous in-line dilution and gradient operation for high performance and reduced cost
- User-friendly software meets U.S. FDA 21 CFR Part 11 requirements
- Includes documentation for regulatory submission

Bio-Rad Introduces the Process Chromatography Skid 00

The versatile Bio-Rad process chromatography skid 00 is a benchtop system for small scale manufacturing processes. Possessing the dimensions of a pilot system, skid 00 has a flow rate from 5–120 L/hr and is recommended for columns in the range of 70–296 mm in diameter.

Independent System

The Bio-Rad process chromatography skid 00 is a self-contained system that integrates all necessary hardware components. A wireless tablet PC with SCADA software is used to run the chromatography process and to communicate with the PLC.

The housing is made of stainless steel with a closed construction design. This allows the skid to be moved easily.

Enhanced Flexibility

The equipment has been designed with the flexibility to be used for multiple flow rates and column diameters, as shown in Table 1. Ideal column diameters range from 70–296 mm with linear flow rates starting at 7 cm/hr and going up to more than 3,000 cm/hr. Skid 00 is the ideal counterpart of high performance media.

Table 1. Skid 00 column diameters and linear flow rates.

Column Diameter, mm	Linear Flow Rate, cm/hr
70	129–3,120
100	64–1,528
140	32–780
180	20–472
200	16–382
250	10–244
296	7–174

Modular Concept

The platform design offers the flexibility to adapt the process chromatography skid 00 to multiple processes. In addition to the standard components shown in Figure 1, the following options are available:

- 4 additional outlet valves
- Pressure sensor (after column)
- Additional pump for sample injection
- Air sensor (after bubble trap)
- Additional pH probe (before column)
- Additional conductivity and temperature sensors (before column)

Each option includes the required combination of hardware and software modules.

All standard optional components have been validated on the Bio-Rad platform.



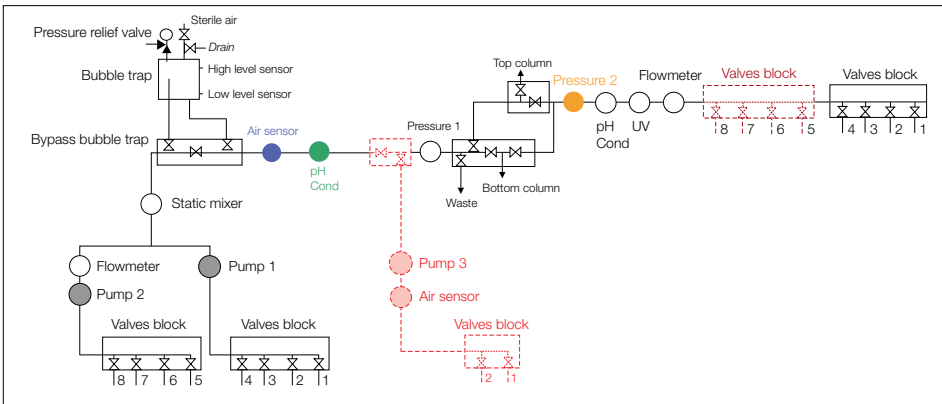
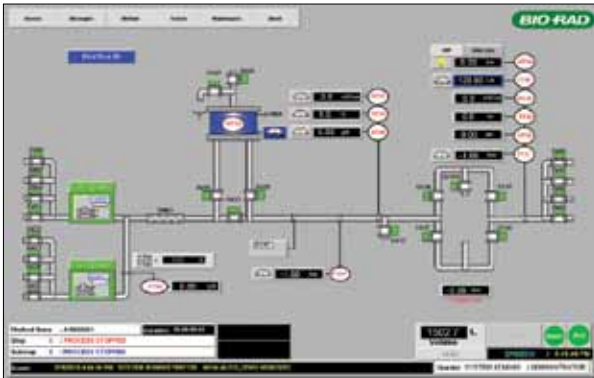


Fig. 1. PID of Skid 00. (Available options are marked in color.)

System Controller Screen



User-Friendly Software

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

The process skid is password protected (four customizable access levels), and all events and actions are recorded in accordance with cGMP guidelines.

The software allows the system to be operated in manual or automatic mode. The automatic mode includes:

- 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 are included.

Specifications

Flow rate	5–120 L/hr
Operating pressure	Up to 6 bar at column inlet
Flowmeter accuracy	Max error 0.35% of the measured value
Dilution accuracy	Max error 3% of the measured value
Tubing dimensions	ID 4.8 mm after the pump ID 6.35 mm before the pump
Temperature range	2°C–30°C (60°C for CIP)
Pump	Membrane pump technology
UV wavelength range	190–740 nm (one wavelength at a time)
Conductivity range	0–500 mS/cm
pH range	0–14
Bubble trap	0.2 L acrylic/glass tube equipped with: – 2 level sensors (ultrasonic technology) – 1 drain valve – 1 sterile air injection valve (0.4 bar)
Valves	Pneumatic membrane valves
Mixer	Stainless steel static mixer
Air sensor	Optical fiber technology, noninvasive
Pressure sensor	Equipped with stainless steel membrane
Material and certificates for wetted parts	Cells and valves body: PEEK Flowmeters: PFA Valves membrane: EPDM Tubing: FEP Stainless steel: 316 L, 1.4404 for wetted parts Bubble trap: Acrylic or glass All wetted parts in compliance with FDA requirements 3.1b certificates delivered with stainless steel parts
Surface finish	Ra<0.4 μm
Back pressure (without column, with water)	At 50 L/H: 0.4 bar At 80 L/H: 1.2 bar At 120 L/H: 1.8 bar
Degree protection	IP55
Weight	135 kg
Fitting	Sanitary fittings with plastic nuts
Dimensions (H x W x D)	1,060 x 750 x 610 mm (without control PC)
Power supply	220 V 1p 50/60 Hz (or 115 V 1p 50/60 Hz)
Air supply	6 bar
Control	PLC: OMRON SCADA: iFix 5.0 PC: Laptop Dell E6400 Intel Core 2 2.4 Ghz HD: 80 GB Screen: 14.1"
Support	4 feet, installation on a lab desk

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

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