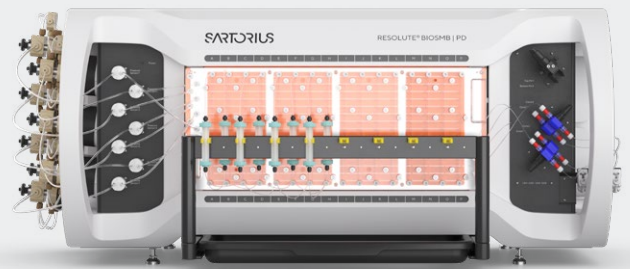


Resolute® BioSMB PD System

Continuous Single-Use,
Multicolumn
Chromatography



Benefits

- Reduces resin costs by up to 80% without impacting critical process conditions like separation media or buffer types.
- Proven to achieve equal or better purification performance of traditional chromatography processes within 1 week of experimentation.
- Connect up to 16 columns, membranes, or monoliths to increase flexibility, efficiency, throughput, or productivity.
- Less than 1 mL of valve hold-up volume reduces need for pump washes.

Product Information

The Resolute® BioSMB platform is the first disposable flow path, continuous multicolumn chromatography solution that is fully scalable from the Process Development (PD) laboratory to GMP manufacturing. The Resolute® BioSMB PD system is specifically designed to allow users to convert an existing batch process into a continuous chromatography step without impacting the purification performance. Processes can be transferred to the Resolute® BioSMB PD system without modifications to chromatographic media, buffers, or product critical quality attributes. Resolute® BioSMB technology provides process consistency across all scales – development, clinical and full production – and is also practical to implement in flexible, multi-product facilities.

Applications

Resolute® BioSMB PD technology is the ideal solution for biopharmaceutical production applications ranging from early-stage process development through clinical manufacture and beyond. This integrated system contains the hardware and software components to fully automate and drive efficiency to all chromatography processes, especially those where chromatography media costs are most influential.

Standard use cases include bind | elute chromatography (Protein A affinity, ion exchange, mixed mode, hydrophobic interaction) and flow-through such as size exclusion or ion exchange polishing. It provides an open platform for downstream processing that enables the use of any separation technology, including packed-bed chromatography, membrane chromatography, monoliths and expanded bed adsorption (EBA) chromatography.

Key System Features

Batch chromatographic processing typically utilizes only 50% to 70% of the chromatographic column's total binding capacity. The Resolute® BioSMB PD, on the other hand, uses a series of substantially smaller, interconnected columns. The first column in the load zone is allowed to reach breakthrough and the product breakthrough is captured on a second column. The binding capacity of the first column can thus be exploited well beyond its batch dynamic binding capacity. In many cases, such processes can be operated close to the equilibrium or static binding capacity of the chromatographic media, thus leading to a significant reduction in chromatographic media use.

The Resolute® BioSMB PD use of continuous counter current loading means that the load zone must accommodate only the mass transfer zone, which generally represents a small percentage of a batch column. This allows the entire process to be conducted in a much smaller system carrying only a fraction of the chromatography media used in a standard batch process. When used in larger scale applications, the Resolute® BioSMB technology can cycle chromatography media more frequently, resulting in higher resin utilization, and ultimately the elimination of packing skids, large stainless steel columns and other support infrastructure required for typical batch chromatography processing. This results in a smaller overall footprint and a more scalable configuration.

While competitive systems use a complex set of valves, the Resolute® BioSMB technology uses an integrated valve cassette specially designed and patented as a single-use component. The new valve system eliminates the need for a difficult cleaning validation process.

The ability to use up to 16 columns with the Resolute® BioSMB enables the Resolute® BioSMB PD to support the broader application base of capture and polishing steps such as in hydrophobic interaction chromatography (HIC), size exclusion chromatography (SEC), mixed mode chromatography, as well as combinations of these technologies. The availability of a greater number of columns provides a particular benefit to applications with feeds that have been concentrated and those with production titers greater than 5 g/L.

Compared with competing systems, the Resolute® BioSMB PD is designed to offer far greater capabilities than those that can be provided by simple chromatographic media utilization optimization. As an example, the position of the buffer selection valves in the Resolute® BioSMB PD is very different from other systems and contributes directly to process optimization in multiple ways. Because each column used with the Resolute® BioSMB PD is assigned a series of valves arranged in a single-use array, the result is that every pump is delivering one buffer throughout the entire process and will never undergo composition gradients and | or wash steps. In addition, the system volume that actually is subject to composition changes in the Resolute® BioSMB PD is minimized well beyond that of other system designs. This eliminates many of the uncertainties associated with scale-up | scale-down, validation and process control.



Technical Data

General Specifications

Dimensions (W × D × H)	155 × 81 × 61 cm (61 × 32 × 24 in.)
Access or Bench Capacity	Min. 10 ft. (3.048 m) linear bench space for system and fluid vessels
Weight	172 kg (380 lbs)
Electrical Requirements	115 V or 230 V
Required Air Supply	At least 2 barg (29.0 psig) above process pressure
Recommended Air Supply	Dry, oil-free and particle-free air. Pressure range: 6 to 10 bar (87 - 145 psig)

System and Valve Cassette Specifications

Flow Rate Range	1 mm cassette: Up to 50 mL/min 3 mm cassette: Up to 100 mL/min
Inlets	Maximum 8 (including loopback)
Outlets	Maximum 6 (including loopback)
Columns	Up to 16
Maximum Operating Pressure	10 barg (145 psig)

Sensor Specifications

Pressure	Linear up to 10.3 bar (150 psi)
Ultraviolet-Visible (UV)	4 dual wavelength UV sensors each with 260/280 nm
pH	Range of 0–14, accuracy is depending on actual calibration range
Conductivity	Range: 1 µS/cm – 200 mS/cm Accuracy: 0.25 mS/cm (range 10–200 mS/cm) 3.0 µS/cm (range 0–100 µS/cm)

Pump Specifications

7 pumps, stepper motor belt drive dual piston pumps, PEEK fluid path, automated piston seal wash, double capsule check valve with additional anti-siphoning valve

Accuracy	0.5–50 mL/min ±5% (with 1 mm cassette) 0.5–100 mL/min ±5% (with 3 mm cassette)
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Ordering Information


Part Number	Description
BIOSMB-PD-LD100B	Resolute® BioSMB PD 1 mm process development system
BIOSMB-VC-1	Resolute® BioSMB PD 1 mm process development valve cassette only
BIOSMB-VC-3	Resolute® BioSMB PD 3 mm process development valve cassette only
BIOSMB-TK-1A	1 mm tubing kit only for 1 mm cassette
BIOSMB-TK-3A	3 mm tubing kit only for 3 mm cassette
BIOSMB-PH	Resolute® BioSMB pH probe for both sizes of housing
BIOSMB-PH-1	Resolute® BioSMB pH housing for 1 mm setup
BIOSMB-PT-1	Resolute® BioSMB pressure transducer
BIOSMB-COND	Resolute® BioSMB conductivity sensor
BIOSMB-UV-02	Resolute® BioSMB UV flow cell, 2 mm optical path
BIOSMB-PD-CH	Pack of column holders

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