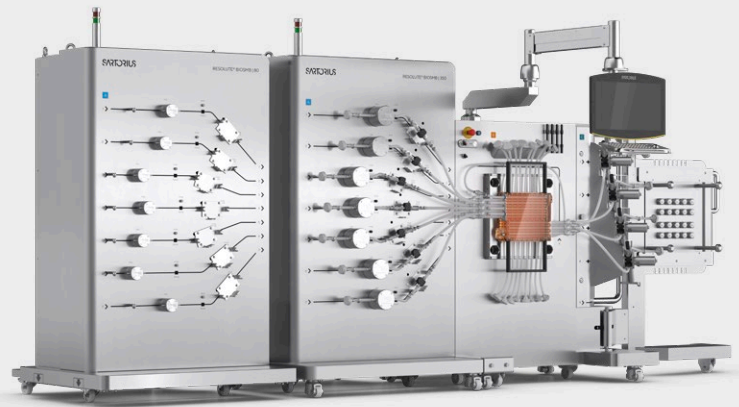


# Resolute® BioSMB 80 and BioSMB 350

Single-Use Continuous  
Chromatography Systems  
for Perfusion and Batch  
Bioreactor Processes



## Product Information

The Resolute® BioSMB 80 and BioSMB 350 multi-column chromatography systems are designed for clinical and commercial manufacture of biologics. Compared to traditional chromatographic processes, the Resolute® BioSMB 80 and 350 deliver a 3 to 6-fold increase in throughput while requiring up to 30% less chromatography media. This is achieved through a unique single-use valve system which enables multi-column processing and flexible flow configurations.

## Features and Benefits

- Highly efficient resin utilization
- 3–5× increase in productivity
- Flexibility to reduce production line equipment
- Easy-to-install flow kits (less than 30 minutes)

# Introduction

## System Concept

The Resolute® BioSMB 80 and 350 systems enable full scale up from process development (via the Resolute® BioSMB PD) up to 4,000 L fed-batch and perfusion clinical and commercial processes. Chromatographic processes developed using batch methodology can be readily transferred to the Resolute® BioSMB without changing resin, buffers, or product quality assays.

Two operators can install the disposable flow kit on the Resolute® BioSMB 80 and 350 in less than 30 minutes. By using up to eight smaller pre-packed columns, the need for column packing skids, large columns, and other column support infrastructure is eliminated.

## Resolute® BioSMB Continuous Chromatography Systems

### 1. Process Flexibility

The flexibility of the valve cassette to support multiple columns and the modular design of the Resolute® BioSMB 80 and 350 enable a downstream production line to hold a wide range of processing volumes. The Resolute® BioSMB can be used to increase the efficiency of chromatography steps in a process by reducing resin requirements, increasing throughput, and offering the flexibility equivalent to multiple batch chromatography systems.

The Resolute® BioSMB 80 and 350 are designed with a pump module that can be exchanged to support a wide flow rate range without requiring a separate chromatography system (see next page, Resolute® BioSMB pump modules).

### 2. Resin Utilization

Batch chromatographic processing typically utilizes only 50% to 70% of the available binding capacity in the column. The Resolute® BioSMB platform can simultaneously load product onto multiple columns, maximizing the available binding capacity. This enables better utilization and requires less total buffer consumption. Additionally, the Resolute® BioSMB 80 and 350 can achieve a higher binding capacity at lower residence times, offering throughput advantages over batch chromatography.

The resin utilization benefits can be leveraged to optimize the throughput of a purification strategy by running processes at shorter residence times and thus increasing productivity.

### 3. Achieving Higher Throughput

Essential to the process economics of the Resolute® BioSMB platform is the availability of multiple columns for continuous loading. In high-titer chromatography applications, the non-loading steps of the process are typically longer than the loading steps. With single and two-column system designs, loading cannot be repeated until the non-load steps are completed. With the Resolute® BioSMB, the process can be configured with more columns such that the loading steps are continuous; there is always a column ready to be loaded.

The Resolute® BioSMB 80 and 380 have the ability to process on up to eight columns and are capable of achieving up to 6-fold increase in throughput over batch, even at titers greater than 10 g/L.

### 4. Valve Cassette and Flow Kit

The core of the Resolute® BioSMB technology is a valve array arranged in a compact disposable valve cassette. This is specifically designed and patented as a disposable flow kit component and eliminates the need for difficult cleaning validation processes. All Resolute® BioSMB 80 and 350 flow kits are supplied gamma-irradiated and meet the standards set by the Sartorius quality team for clinical and commercial manufacturing.

Each column used with the Resolute® BioSMB system is assigned a series of valves arranged in a dedicated array, resulting in each pump delivering a single fluid through the entire process and eliminating the need for pump washes between steps.

Additionally, throughout the Resolute® BioSMB product range, the system hold-up volume is minimized, eliminating many of the uncertainties associated with scaling, validation, and process control.

### 5. Scale Up and Scale Down

To complement the Resolute® BioSMB 80 and 350, a bench scale version is available: the Resolute® BioSMB PD. The Resolute® BioSMB PD uses the same valve technology, flow kit configuration, and recipe creation and handling to ensure simple scale-down or scale-up. This system is available for flow rates ranging from 1-100 mL/min.

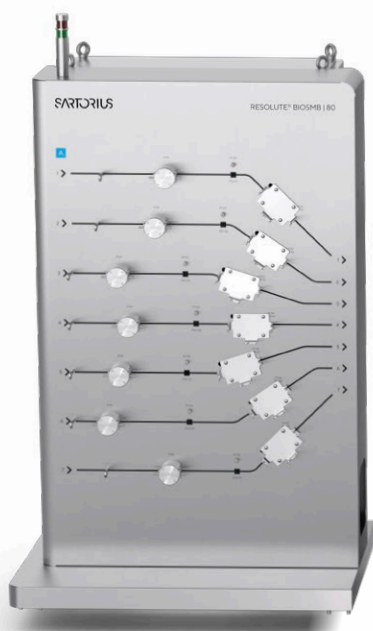
# Applications

## Resolute® BioSMB Pump Modules

If a complete Resolute® BioSMB 80 or 350 system is purchased, it is possible to buy a Resolute® BioSMB 350 or 80 pump module, respectively, to increase the flexibility of the main system.

The pump module can be exchanged easily, requiring a mechanical changeout of the module and a switch in the software. The mechanical swap of the two pump modules typically takes less than an hour. This modularity allows the system to run either from 5 L/h–80 L/h (Resolute® BioSMB 80 pump module) or 30 L/h–350 L/h (Resolute® BioSMB 350 pump module).

With the Resolute® BioSMB 80 and 350 systems, the pump module aligns with the applicable flow kit. The rest of the Resolute® BioSMB 80 and 350 system can support either a Resolute® BioSMB 80 or Resolute® BioSMB 350 flow kit.



**Figure 1:** Resolute® BioSMB 80 Pump Module

The Resolute® BioSMB 80 and 350 are the ideal solution for manufacturing-scale chromatography processes and can offer efficiency, throughput, and flexibility benefits for all modes of chromatography.

## Resolute® BioSMB 80 for Perfusion Bioreactor Processes

The Resolute® BioSMB 80, when coupled with the aseptic connector Resolute® BioSMB 80 flow kit, is ideal for extended continuous processes where bioburden contamination may become a higher risk to product quality. The Resolute® BioSMB 80 aseptic connector flow kit is supplied gamma-irradiated and closed with aseptic connections to minimize any bioburden risk from manufacture or installation.

## Resolute® BioSMB 350 for Batch Bioreactor Processes

The Resolute® BioSMB 350 is targeted for batch bioreactor-based processes upwards of 4,000 L. The flow rate capability, wider single-use tubing, and larger bore cassette manifold meet the requirements for high throughput continuous processing in a flexible facility.

## Software

The software is designed to provide the operator with a clear and easy-to-use interface. It has been developed in accordance with usability and user interface standards for GMP systems for the most efficient and accessible experience.

# Technical Data

## Resolute® BioSMB 80 | 350 System and Resolute® Flow Kits

### System Specifications

Dimension (w × d × h)	2.7 × 1.4 × 2.2 m (106 × 55 × 87 inch)   Height without alarm tower: 1.9 m (75 inch)	
Weight	1,000 kg	
Flow rate range Resolute® BioSMB 80	5 – 80 L/h	
Flow rate range Resolute® BioSMB 350	18 – 350 L/h	
Inlets number	8 (7 usable + 1 for system use as second pass)	
Outlets number	6 (5 usable + 1 for system use as second pass)	
Number of column positions	8	
Number of pumps	7	
Maximum operating pressure	4 bar (58 psi)	
Air supply	6 bar (87 psi) with integrated pressure regulator	
Electricity supply (other voltages available)	<b>CE version</b> 400 VAC 50/60 Hz 32 A – 15 kW	<b>UL version</b> 208 VAC 50/60 Hz 32 A – 15 kW

### Flow Kit Specifications

Item	Description
Hose and connectors Resolute® BioSMB 80	<ul style="list-style-type: none"> <li>▪ Silicone braided tubing ID: ¼ inch</li> <li>▪ Kleenpak®</li> <li>▪ Presto sterile connector for external connections. HFC39 connectors for internal connections</li> </ul> <p>(Note: The process 80 flow kit is available with sanitary connection connections in place of the Kleenpak® connectors. Contact us for more details.)</p>
Hose and connectors Resolute® BioSMB 350	<ul style="list-style-type: none"> <li>▪ Silicone braided tubing ID: ¾ inch with HFC39 connectors for internal connections and sanitary connection clamp ¾ inch for upstream and downstream connections</li> </ul>
Pressure sensor	<ul style="list-style-type: none"> <li>▪ 7 pressure transmitters (1 after each pump with integrated pressure switch)</li> <li>▪ 0.0 – 4.0 bar</li> </ul> <p>(Note: Maximum operating pressure for system is 4 barg   58 psig)</p>
Flow sensor	<ul style="list-style-type: none"> <li>▪ 7 ultrasonic non-invasive flowmeters (1 after each pump)</li> <li>▪ Resolute® BioSMB 350: 3% or 5.4 L/hr whichever is higher</li> <li>▪ Resolute® BioSMB 80: 5% or 3.6 L/hr whichever is higher</li> </ul> <p>(Note: Accuracy is confirmed using water. Other fluidic properties may have an impact on accuracy)</p>
Air sensor	<ul style="list-style-type: none"> <li>▪ 7 integrated with flowmeters</li> </ul>
Conductivity sensor	<ul style="list-style-type: none"> <li>▪ 4 sensors (on outlets 1 – 4)</li> <li>▪ Range: 0.0 µS/cm – 150.0 mS/cm, accuracy*: ± 5% with two point calibration at 1.332 12.154 mS/cm**</li> <li>▪ Calibration standards at 22 °C values will be different at other temperatures.</li> </ul>
pH sensor	<ul style="list-style-type: none"> <li>▪ 4 sensors (on outlets 3 – 10)</li> <li>▪ Range: 0.0 – 14.0, accuracy: ± 0.2</li> </ul>
UV sensor	<ul style="list-style-type: none"> <li>▪ 4 UV-VIS sensors each with wavelengths in 280 nm as standard ± 0.03 AU</li> </ul>
Process pump	<ul style="list-style-type: none"> <li>▪ 4 piston diaphragm single-use</li> <li>▪ The single-use pump heads are Quattroflow™ sanitary diaphragm pumps, 4 pistons with polypropylene (PP), ethylene propylene diene monomer (EPDM)   PP compound diaphragm and EPDM valves</li> </ul>
Gamma irradiation dose	<ul style="list-style-type: none"> <li>▪ 25 kGy</li> </ul>

\* Accuracy from supplier documentation

### Process Wetted Components Materials of Construction

Description	Materials
Tubes	Platinum cured silicone
Fittings	Polycarbonate, polypropylene, polyphenylsulfone
Valve diaphragm	Fluoroelastomer (FKM)
pH sensor	Glass
Pump head	Polypropylene, EPDM/PP compound
Pressure sensor	Polysulfone
UV-VIS sensor windows	Quartz
Conductivity sensor	Polysulfone
BioPAT® Flow Pipe	Polybutylene terephthalate (PBT)

# Ordering Information

For quotation, please contact your local Sales Representative.

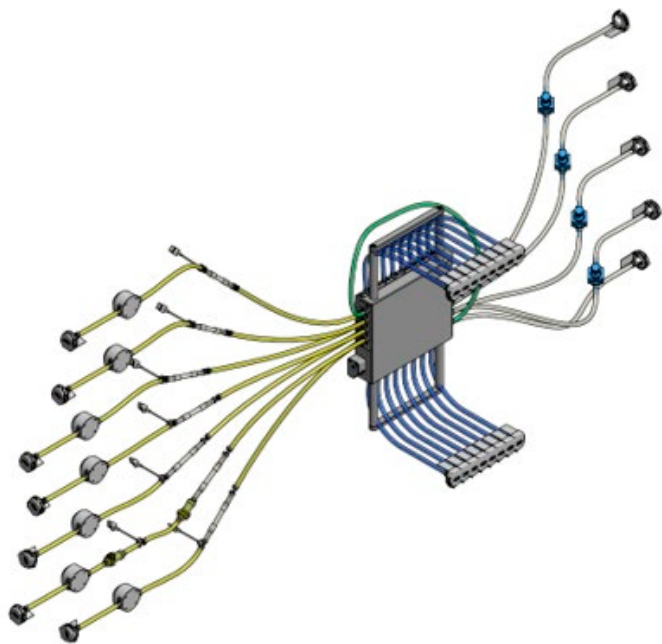
## Resolute® BioSMB 80 System

Part Number	Description
BIOSMB-PRO-080-CE	Resolute® BioSMB 80 system (Electrical rating: CE)
BIOSMB-PRO-080-UL	Resolute® BioSMB 80 system (Electrical rating: UL)
BIOSMB-PRO-080-PUM	Resolute® BioSMB 80 with pump module

## Resolute® BioSMB 80 Flow Kits

Part Number	Description
BIOSMB PF-5-BPF	Resolute® BioSMB 80 aseptic flow kit with BioPAT® flow
BIOSMB-PF-TC-BPF	Resolute® BioSMB 80 TC flow kit with BioPAT® flow

The Resolute® BioSMB 80 system is comprised of one single flow kit. The system is supplied double-bagged and gamma-irradiated.



**Figure 2:** Resolute® BioSMB 80 Flow Kit

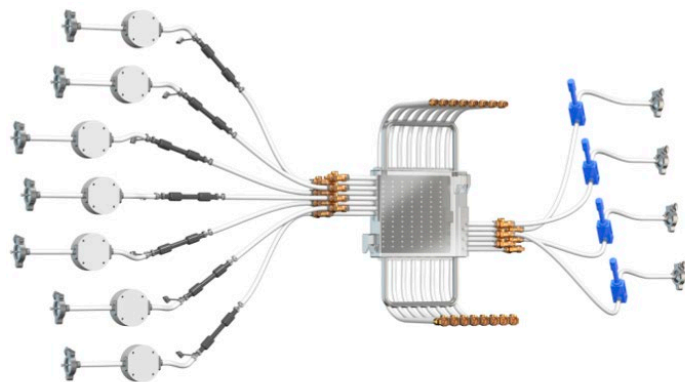
## Resolute® BioSMB 350 System

Part Number	Description
BIOSMB-PRO-350-CE	Resolute® BioSMB 350 system (Electrical rating: CE)
BIOSMB-PRO-350-UL	Resolute® BioSMB 350 system (Electrical rating: UL)
BIOSMB-PRO-350-PUM	Resolute® BioSMB 350 with pump module

## Resolute® BioSMB 350 Flow Kits

Part Number	Description
BIOSMB-IT-8-BPF	Resolute® BioSMB 350 inlet lines with BioPAT® flow
BIOSMB-OT-8	Resolute® BioSMB 350 outlet tubing set
BIOSMB-CT-8	Resolute® BioSMB 350 column tubing set
BIOSMB-VB-8	Resolute® BioSMB 350 valve cassette assembly

The Resolute® BioSMB 350 system is comprised of four separate flow kits; inlet flow kit, valve cassette flow kit, column flow kit and outlet flow kit. These can be purchased individually. The flow kits are supplied individually double-bagged and gamma-irradiated.



**Figure 3:** Resolute® BioSMB 350 Flow Kit  
(Second Pass and Column Tubing Not Shown.)

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