SARTORIUS

Product Datasheet

Resolute® BioSC Pilot

Moving From a Chromatography Skid to Connected Downstream Processing

Executive Summary

Resolute® BioSC Pilot is a connected chromatography system capable of performing an entire downstream process. The technology can simultaneously and continuously operate three chromatography separations, either in batch or multi-column mode, including viral inactivation and in-line buffer preparation. The chaining of multiple unit operations together creates a compact and intensified process.

Features and Benefits

- Simple orchestration of multiple unit operations by one system
- Footprint reduction by combining up to three chromatography steps in addition to virus inactivation and in-line buffer dilution | preparation
- Minimized downtime, lower COGs, and reduced risk of contamination enabled by limiting liquid handling

Relevant Applications

- Process intensification
- Monoclonal antibodies (mAbs), biosimilars, and other proteins
- Recombinant proteins and peptides
- Traditional and viral vector vaccines
- Plasmid mRNA
- AAL, LV...

Process Intensification

Process intensification is a holistic framework to maximize the overall productivity of the unit operation(s), the manufacturing process, and/or the facility output for biomanufacturing.

- Enables faster drug development
- Increases the efficiency and productivity of GMP manufacturing
- Applicable to any process irrespective of molecule
- Can be step-wise (per unit operation) or end-to-end for maximum impact
- Other terms used in the same context include "continuous," "connected," and "integrated"

Lower COGS
>30%

Flexible Smaller Footprint
50%–70%

Faster Buildout Time
<2 Years

Higher Productivity
2–3× with PI

Different Molecules Can Be Manufactured in the Same Facility

Resolute® BioSC Pilot Chromatography System

Next Generation Multi-Use Chromatography System

Resolute® BioSC represents a new generation of multi-use chromatography systems designed to simplify your purification journey. The technology is engineered with a modular approach, offering multiple configurations to which facilities can quickly adapt as requirements change.
The systems cover all process strategies, from traditional batch to intensified processes, and all scales, from process development to commercial manufacturing.

From Batch to Connected Process

- Resolute® BioSC process modules are available in batch or multi-column configuration
- Up to three chromatography steps can be managed by one control module (up to six columns)
- The modules can be combined to provide multi-step unit operations, e.g., capture. virus inactivation, and ion exchange

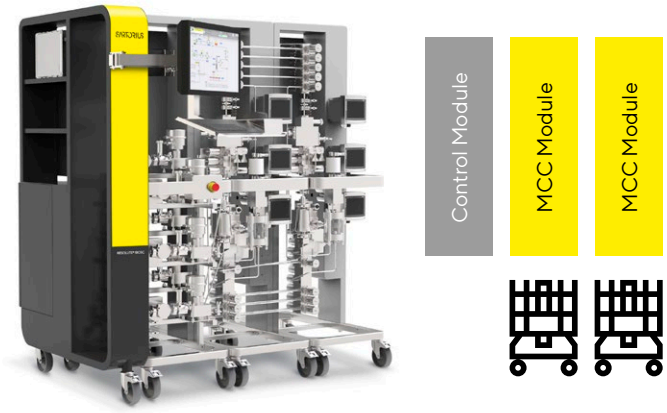
Typical System Configuration

Figure 1: *Resolute® BioSC in Batch Mode.*

The batch process shown in Figure 1 enables the performance of:

- One chromatography step
- Buffer preparation

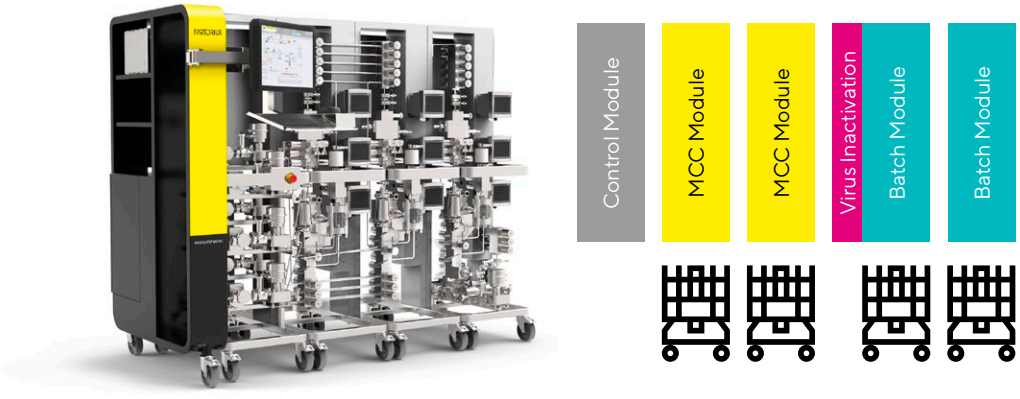
Figure 2: *Resolute® BioSC Configured for Multi-Column Chromatography.*



The multi-column chromatography process shown in Figure 2 enables the performance of:

- Parallel batch processes
- MCC capture
- Buffer preparation
- Virus inactivation
- 2 – 6 columns

Figure 3: *Resolute® BioSC Configured for Multi-Step*



The multi-step process shown in Figure 3 enables the performance of:

- Parallel batch processes
- MCC capture
- Batch steps
- Buffer preparation
- Virus inactivation
- Up to six columns

Switch to a Single Downstream Process System

Operate Three Chromatography Separations Simultaneously and Continuously

This new generation of connected chromatography systems can simultaneously and continuously operate three chromatography separations, either in batch or multi-column chromatography mode, including viral inactivation and in-line buffer preparation.

Employing a single skid capable of performing the entire downstream process - from capture to polishing – represents a drastic footprint reduction and significant cost savings. Linking multiple unit operations together creates a compact and intensified process.

- Productivity gains through the removal of non-added value activities, integration of process steps, and usage
- Enhanced quality through closed processing and continuous monitoring
- Flexibility through configurable and stackable modules

Virus Inactivation

When working in batch mode, virus inactivation is often performed in a dedicated tank where the acidification and neutralization steps are operated by another system, independent of the chromatography skid.

The patented Resolute® BioSC VI integrated feature enables full automation and integration of virus inactivation and chromatography process management within a single skid.

Resolute® BioSC can work:
- in static mode with a 100% tank-based and fully automated process
- in dynamic and faster mode with in-line acidification (with pH acidification occurring during the liquid transfer)

All parameters are monitored and controlled by the same software.

In-line Buffer Preparation

Buffer preparation often causes bottlenecks in biopharmaceutical manufacturing operations as it requires significant space, time, and resources. Chromatography processes have a high buffer requirement.

To make this stage more efficient, we included an exclusive in-line buffer preparation feature (dedicated to up to 8 inlets) that automatically prepares solutions with the correct pH, conductivity, and concentration from source solutions. These parameters are continuously monitored and controlled by a dedicated algorithm which enables rapid feedback and promotes accuracy in processing. This feature also helps to minimize buffer tank footprint, CAPEX, and downtime.

Main functions
- Gradient
- Buffer preparation capacities
- Inter module in-line buffer adjustments

A Unique Controller Automates Your Fully Connected DSP

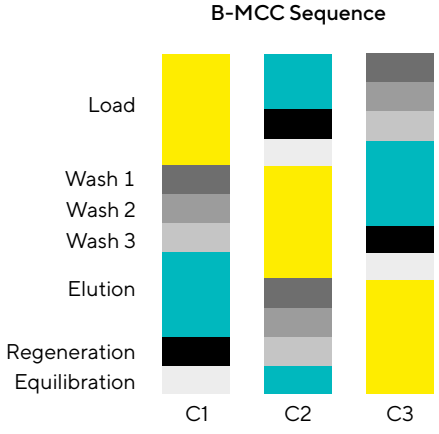
Resolute® BioSC software enables the orchestration of multiple chromatography steps on the different modules. Our team of experts will lead you through the conversion of your batch recipe to an integrated BioSC recipe.

Resolute® BioSC Multi-Column Processes

This technology can manage both batch and multi-column processes:

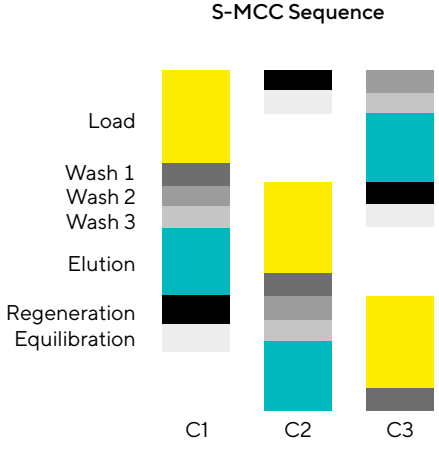
Batch Multi-Column, Process Intensification by Scaling-Out

- Fast and easy way to increase production efficiency
- Simple switch from batch to MCC
- Footprint savings compared to having multiple unit operations



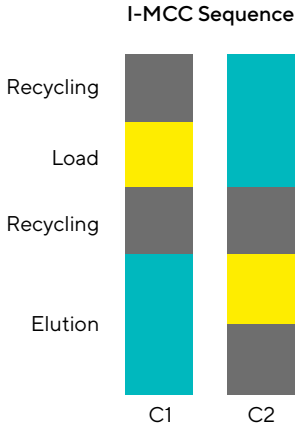
Sequential Multi-Column, Semi-Continuous Capture

- Decreased footprint and volumes
- Reduced of COGs



Isocratic Multi-Column, Process Intensification for Size Exclusion Chromatography

- Suited for size-exclusion chromatography and vaccines
- Minimized resin volumes and footprint
- Reduced buffer consumption
- Optimized process time
- Maximized product recovery and process yield



Simulate and Design Your Transition From Batch to Intensified Process

A deep process understanding is becoming increasingly important to design a chromatographic separation method that consistently delivers high-quality products.

For this reason, Resolute® BioSC is supported by exclusive simulation and optimization software for the development of intensified chromatography processes. This process development accelerator enables scientists to develop their own multi-column processes, even without expert knowledge. Regardless of the application of the Resolute® BioSC system, the process simulation tool delivers quick, simple, and successful implementation.

Technical Specifications

General Information	
Flow rates range	5 – 150 L/hr
Max. operating pressure	5 bars
Temperature	4 – 50 °C
Number of column module	Configurable from 1 to 6
Type of Process	Batch, multi-column (parallel, sequential, and isocratic), and connected processes
Buffer preparation	Up to 1 : 10 (<2% error from 10 to 150 LPH)
Linear gradient capability	5 – 95% (<2% error from 10 to 150 LPH)
GMP manufacturing	Stainless steel 316L (material 3.1B) All gaskets are FDA USP Class VI Surface roughness <0.6µm EP Sanitary design; fully cleanable 3D rule on valves Polypropylene piping
Automation	SCADA interface on WINDOWS 10 Programmable Logic Controller (PLC) GAMP guidelines and FDA CFR 21 Part 11 regulations
Electrical	100 to 240 VAC 1 phase
Footprint (W × D × H)	700 × 1000 × 1830 mm
Standard and norms	EC Machine Directive EC Low Voltage Directive EC Electro Magnetic Compatibility Directive UL508A (for US version)

Functional Information	
Number of inlets for batch module	Configurable from 2 to 16
Number of inlets for multi-column module	Configurable from 2 to 8 Segregated lines (One pump per inlet)
Number of outlets	Configurable from 2 to 10
Air sensors	Yes, on each column
Bubble trap and filter	Yes, on each column
By-pass/up-flow	Yes, on each column
UV	Three simultaneous wavelength measurements per column UV/VIS variable wavelength (200 to 600 nm)
pH/Conductivity	pH and conductivity before and after each column
Process Simulation Software	Included

Spare Parts

Item	Description
Valve maintenance kit	Spare parts used for valve maintenance (EPDM membrane for valves)
Instrument maintenance kit (pH, UV)	Spare parts used for instrument maintenance ▪ UV: 1* Deuterium lamp for UV detector ▪ pH: 1* pH Electrode 0 – 14 pH units
Filter maintenance kit	Spare parts used for filter maintenance (Bubble trap vent filter)
Pump maintenance kit	Spare parts used for pump maintenance (Pump service kit)

Ordering Information

The Resolute® BioSC Pilot system can be configured to meet your process needs through a modular design concept. Reach out to a Sartorius sales representative or application specialist for more information.

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