Simplifying Progress

Continuous Downstream Process Orchestration in Pionic® Platform

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1. Introduction

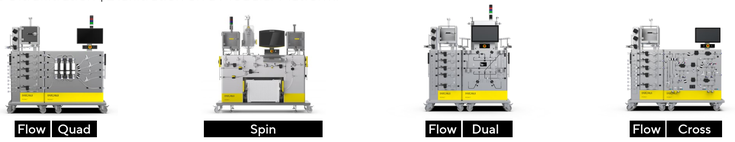
Biopharmaceutical companies are under constant pressure to reduce costs, time, footprint, and resource use while improving yield, quality, and productivity. However, regulatory constraints, risk aversion, and legacy infrastructure often slow the adoption of new technologies. Pionic® breaks through these barriers with a modular, ready-for-use platform for chromatography, filtration, viral inactivation, and ultrafiltration (UF) | diafiltration (DF). This poster demonstrates how Pionic® modules can be orchestrated using Sartorius software.

2. Introducing Pionic®

Bridging the Gap in Downstream Process Intensification

Process intensification is widely recognized as an important strategy for enhancing efficiency in biomanufacturing. While upstream processes have seen significant advancements through strategies like intensified seed trains and dynamic perfusion, downstream adoption has faced challenges due to:
- Risk aversion and resistance to change
- Resource-intensive modification of existing infrastructures
- Product quality concerns

Figure 1: *Illustration of Pionic® Modules Capable of Performing Chromatography, Filtration, Viral Inactivation, and Ultrafiltration | Diafiltration on a Modular Platform.*



Flow
- Modular (3 or 5 pumps)
- Connected to Dual, Quad, and Cross
- In-line dilution capability
- Product conditioning in surge tank

Dual
- Dual filters or dual chromatography
- Dynamic loading
- Aseptic venting

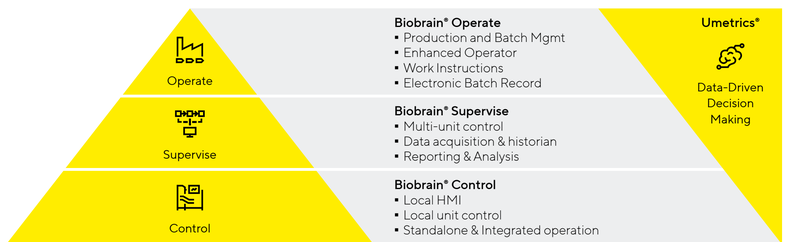
Quad
- 4 chromatography devices
- In parallel or sequential process
- Ease installation with valve cassette

Cross
- Single-pass UF and DF
- Combines both UF and DF steps
- Up to 3 steps in one system (UF1 | DF | UF2)

Spin
- Low-pH viral inactivation
- Unique incubation chamber
- Acidification, incubation, and neutralization

2.1 Biobrain® Automation Software

Figure 2: *Sartorius Software Structure*

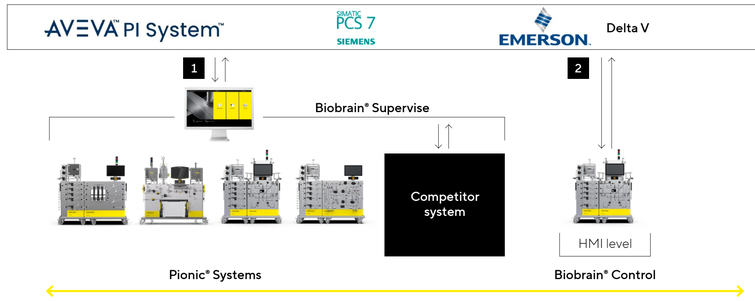


2.2 Integration Infrastructure

Traditional downstream platforms are often large, fixed, and difficult to adapt for connected or continuous operations. As a result, many biomanufacturers perceive that the effort, cost, and disruption required to reconfigure existing infrastructure may outweigh the benefits of intensification.

Pionic® is designed to overcome these barriers with a modular, ready-for-use platform that fits both new and existing facilities. It enables manufacturers to adopt intensification strategies step by step—connecting selected unit operations to ease bottlenecks, improve productivity, and build toward a fully continuous downstream process. In the examples below, several unit operations are connected (physically and digitally) to increase productivity and remove bottlenecks in existing facilities. The orchestration layer transfers data bi-directionally across equipment "islands" and can send process commands at the equipment phase level, enabling true integration and automated coordination without custom engineering.

Figure 3: *Illustration of Pionic® Modules With an Example of Two Types of Automation Integration.*
(1) *SCADA-Level Integration — Benefit from all Sartorius-provided content including process recipes | logic*
(2) *HMI-Level Integration — Benefit from all Sartorius-provided content including unit recipe*



3. Orchestration Concept

3.1 Concept

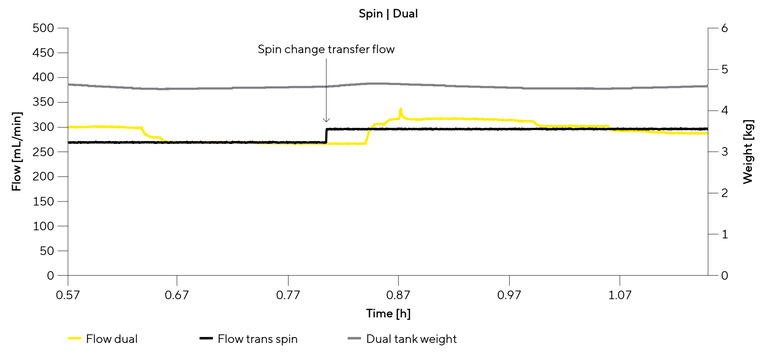
Pionic® modules, built on Biobrain® Control, are designed for modular flexibility — each unit operates autonomously using integrated surge tank level control. This ensures process stability and allows independent module operation in a decoupled, flexible setup.

However, when multiple modules are orchestrated using Biobrain® Supervise, the platform enables advanced control strategies to coordinate operations between upstream and downstream units.
- Dynamic flow setpoint control: Based on real-time surge tank levels, Biobrain® Supervise automatically adjusts the flow setpoints of connected modules. This ensures optimal operation and protects consumables (e.g., columns, filters, and incubation chambers) by dynamically applying upper and lower limits.
- Exception management and interlock logic: The orchestration engine allows the definition of exception handling scenarios. For example:
  - If a surge tank reaches its maximum level, downstream filtration modules are automatically paused.
  - If a chromatography column requires strict stability, the process can be halted before entering the loading phase when certain conditions are unmet.
- Resumption can be automatic (once safe levels are restored) or manual (requiring operator validation).
- Cross-module calculations: Biobrain® Supervise can also calculate and display derived parameters in real time using data from multiple modules. Examples include mass flow integration and surge tank residence time estimation.

This orchestration logic enables truly modular, yet coordinated bioprocesses that adapt dynamically to conditions, protect sensitive materials, and reduce operator workload — while paving the way for continuous downstream intensification.

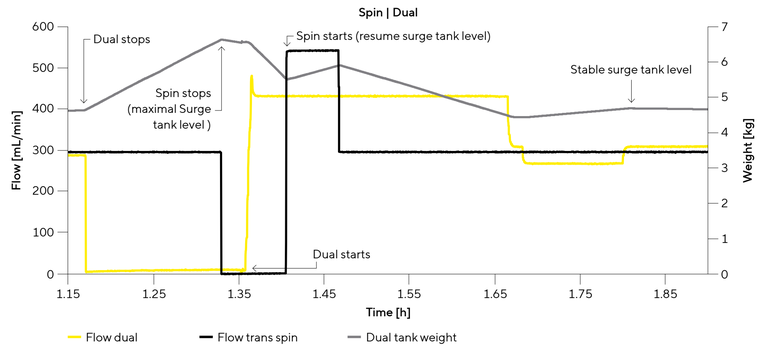
3.2 Flow Control Test

Figure 4: *Graphic Illustrating How Flow Control Works in Pionic® Dual Connected After Pionic® Spin*



3.3 Exception Case Test

Figure 5: *Graphic Illustrating the Behavior of Pionic® Dual When the Homogenization Tank Reached a Defined Value*



4. Summary and Conclusion

Pionic® platform is an innovative solution designed to support process intensification across multiple maturity levels:
- Level 1: Standalone intensified units
- Level 2: Connected unit operations
- Level 3: Fully continuous, end-to-end biomanufacturing

With the support of Biobrain® Software, all Pionic® modules can be seamlessly integrated, rearranged, and orchestrated to operate as a coordinated and stable continuous process. This includes:
- Dynamic adaptation of setpoints based on flow conditions or product concentration
- Customizable exception handling, allowing users to define and preview system responses to deviations or events — tailored to their specific process needs

This modular, scalable approach empowers biopharmaceutical manufacturers to transition at their own pace — paving the way for the future of connected and intensified downstream processing.

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