SARTORIUS

Product Datasheet

Pionic® Spin

Low-pH Flow-Through Virus Inactivation for Integrated Continuous Biomanufacturing

Product Information

Pionic® Spin represents a groundbreaking advancement in downstream bioprocessing. Comprised of an incubator, versatile recirculation loop | 3D biocontainers, and the innovative flowkit, this autonomous aseptic closed-unit operation is designed to revolutionize low-pH virus inactivation process workflows, offering unparalleled flexibility and control from clinical to commercial production.

Features and Benefits

- Universal integration into existing infrastructures.
- Scalable results with an adjustable incubation flow rate of 1 – 22 L/h.
- 28-day duration with automated in-flow pH titration.
- In-flow inactivation of > 5 $\log_{10}$ enveloped virus.
- Consistent outflow from variable inlet flow with flexible biocontainers.

Overview

Relevant Applications

Integrated continuous biomanufacturing of monoclonal antibodies (mAbs) at clinical and commercial scales.

Relevant Process Steps

Low-pH Virus Inactivation

- Elute peak blending
- Acidification via spin mixing
- Flow-through incubation
- Surge tank neutralization
- Transfer out

Description

Pionic® Spin: Revolutionizing Low pH Virus Inactivation
Ensuring the safety and purity of biopharmaceuticals is paramount in today's biopharmaceutical landscape. Viral contamination poses a significant threat, and low pH inactivation is a critical step in many purification processes. However, traditional low-pH inactivation methods can be inefficient, time-consuming, and potentially detrimental to product quality.

Pionic® Spin is a breakthrough in continuous bioprocessing, redefining low-pH virus inactivation. It features a proprietary spin incubator design (plug flow reactor), along with unique pH control, and innovative mixing, flow, and level control to achieve rapid, efficient, and robust virus inactivation at low pH.

Product Highlights

- **Enhanced Inactivation Efficiency:** Pionic® Spin is a high-performance virus inactivation system designed to ensure process efficiency and reduce risks.
- **Long Duration Processing:** Enables continuous processing, increasing efficiency, which translates to higher throughput and reduced manufacturing costs.
- **Improved Product Quality:** Pionic® Spin's gentle yet time-effective approach minimizes the risk of protein aggregation and other product degradation often associated with traditional batch low pH methods. The tight residence time distribution and absence of static product hold time ensure minimal overexposure while achieving effective viral log reduction.

Pionic® Spin: The First Step in an Innovative Downstream Intensification Platform
Pionic® Spin is the initial module of our Pionic® platform, a downstream process intensification solution. This ready-for-use platform for chromatography, filtration, viral inactivation, and ultrafiltration | diafiltration integrates into both new and existing facilities, minimizing disruptions and supporting diverse intensification strategies. Developed in collaboration with leading CDMOs and biomanufacturers, our Pionic® platform meets industry standards and offers a proven solution that reduces uncertainties.

Each Pionic® system offers flexibility for integrated and continuous downstream processes intensification, either by intensifying a single unit operation or linking multiple units together.

For more information on Pionic®, visit
sartorius.com/pionic

Technical Specifications

Components Overview

Figure 1: *Key Components of Pionic® Spin*

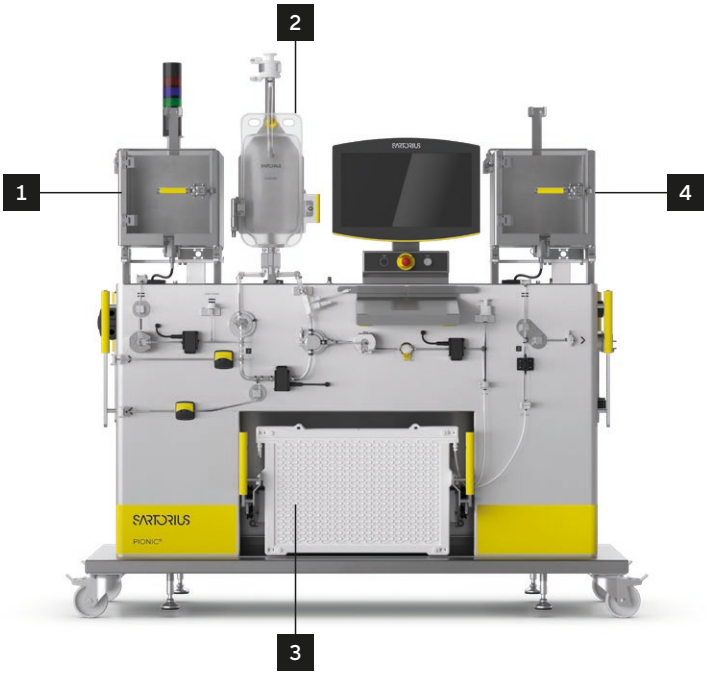

Figure 1 shows Pionic® Spin and its four key components:

[1] 20 L mixing bag for homogenizing elution peaks
[2] 3 L recirculation bag for precise acidification using a novel pH control strategy
[3] Pionic® Spin Incubator for consistent incubation and virus inactivation
[4] 20 L mixing bag for neutralization before transfer to the polishing unit

System and Automation

Specification	Details
Vendor | manufacturer	Sartorius
System name	Pionic® Spin
System dimensions (W × H × D)	1,950 × 2,098 × 1,005 mm
Mobility	4 castor rollers
Weight	450 kg
Protection rating	IP44
Power needs	One phase + N + PE
Operating voltage	100 – 240 V
Frequency	50 – 60 Hz
Max. current at lowest voltage	2.63 A
Instrument air pressure	7 bar
Materials of construction (frame and hardware)	Stainless steel

Automation Monitoring

All data can be acquired and historized by a DCS* via an OPC** UA interface.

Automation Control

Able to accept control commands from industrial DCS. Available connectivity options include: connecting to SCADA or DCS systems via OPC UA, connecting to an MES system via OPC UA, and a system integration package available for user automation team support.

* DCS = Distributed Control System
** OPC = Open Platform Communications

Pionic® Spin Incubator

The incubator's curved fluid path is optimized for high Dean numbers at different flow rates, ensuring radial mixing and a narrow residence time distribution for continuous incubation. Operators can adjust flow rates to achieve minimum residence time or adapt chamber volume for a set flow rate.

The flow rate range can be expanded by increasing volume or path length with additional plate modules or altering the plate module's inner dimensions.

Specification	Details
Basis of product flow path design	20 L mix tank for eluate homogenization, recirculation loop for acidification, modular plug flow chamber (serpentine channels), transfer to second 20 L mixing tank for neutralization
Incubator technology	Plug flow reactor based on serpentine flow path
Materials of construction (product contact surfaces)	ABS

The incubator is offered in a range of flow path sizes, featuring the following technical specifications:

Material Description	Approx. Inner Diameter [mm]	Approx. Volume per Plate [mL]	Plates in Serial [n]	Approx. Volume for Device [mL]	Anticipated Process Range @ 1mPas and RT > 30 min [L/h]
Pionic® Spin Incubator 0.75	2.2	187	4	748	1.0 – 1.2
Pionic® Spin Incubator 1.5	2.2	187	8	1,496	2.0 – 2.6
Pionic® Spin Incubator 1.0	3.8	495	2	990	1.4 – 1.8
Pionic® Spin Incubator 2.0	3.8	495	4	1,980	2.8 – 3.6
Pionic® Spin Incubator 3.0	3.8	495	6	2,970	4.2 – 5.4
Pionic® Spin Incubator 1.4	6.5	700	2	1,400	2.0 – 2.4
Pionic® Spin Incubator 2.8	6.5	700	4	2,800	3.8 – 5.0
Pionic® Spin Incubator 4.2	6.5	700	6	4,200	5.8 – 7.4
Pionic® Spin Incubator 5.6	6.5	700	8	5,600	7.6 – 10.0
Pionic® Spin Incubator 7.0	6.5	700	10	7,000	9.4 – 12.4
Pionic® Spin Incubator 3.2	9.0	1,580	2	3,160	4.2 – 5.6
Pionic® Spin Incubator 6.4	9.0	1,580	4	6,320	8.4 – 11.2
Pionic® Spin Incubator 9.5	9.0	1,580	6	9,480	12.6 – 16.8
Pionic® Spin Incubator 12.5	9.0	1,580	8	12,640	17.0 – 22.2

Ready-for-Use Flowkits

Specification	Details
Flowkit and tubing connections	Closed processing, genderless sterile connectors
Process pumps, makes and models	3 × Quattroflow — QF30SU, 3 × Watson Marlow — WM114DVP, 1 × Watson Marlow WM520R, 1 × Levitronix — Puralev i30SU
Valves, make and model	GEMÜ — Sumondo "zero dead leg" T-Valve, Carten — Pinch valve
Mixing technology	2D 3 L low hold-up volume fast recirculation flow mixing loop, 3D 20 L mixing bags — active bottom impeller driven
Pressure sensors, make and model, locations	Sartorius — BioPAT® Pressure, inlet line to incubator | transfer line (outlet)
Flow sensors, make and model, location	Sartorius — BioPAT® Low Flow Sensor, feedline | recirculation loop | incubation line | transfer line
Conductivity sensors, make and model, location	Sartorius — BioPAT® flow-through pH | conductivity sensor, recirculation loop | transfer line (outlet)
pH sensors, locations, makes and models	Recirculation loop: Sartorius — BioPAT® flow-through pH | conductivity sensor 20 L mixing bag probes: Sartorius — SU pH electrode for Biostat STR®
pH sensors (calibration)	1 pt reference calibration to offline sample
UV sensors, make and model, location	Sartorius — BioPAT® Spectro UV, outlet line of incubator

	[1] Buffer	[2] Recirculation	[3] UV	[4] Base	[5] Transfer
Tube Types (ID × OD)	Pharmed® BPT | ⅛" × ¼"	Pharmed® BPT | ⅛"' × ¼" Liveo™ Pharma 80 Tubing | ⅛" × ¼" Tuflux®SIL | ⅜" × ⅝"	Liveo™ Pharma 80 Tubing | ⅛" × ¼"	Pharmed® BPT | ⅛" × ¼"	Pharmed® BPT | ⅛" × ¼" Liveo™ Pharma 80 Tubing | ⅛" × ¼"
Connectors		Sterile connector (AseptiQuik® S)			
Airfilter	—	Sartopore® Air size 4	—	—	—
Pressure sensor	—	▪	—	—	▪
Flow sensor	—	▪	—	—	▪
Control valve (pneumatically operated single-use diaphragm valve for flow | pressure control. Membrane material: TPE)	—	▪	—	—	—
Pinch Valve (not part of FK but uses tubes of FK* to control flow)	—	▪	—	—	▪
Peristaltic Pumps (not part of FK but uses tubes of FK to control flow)	▪	▪	—	▪	—
SU pump head	—	Feed and incubation pump (TPE, EPDM, PP): 5-piston single-use diaphragm pump Recirculation pump (PP): magnetic levitating pump	—	—	Transfer pump (TPE, EPDM, PP): 5-piston single-use diaphragm pump
UV sensor	—	—	▪	—	—
Bags	—	2D Flexsafe® 3 L incl. Sartopore® Air Size 7 and sampling port	—	—	—

* FK = Flowkit

3D Bags

The 20 L homogenization and neutralization bags feature an identical design, supporting simple integration.
The homogenization bag expertly mixes added eluates, ensuring uniformity, while the neutralization bag efficiently balances the feed medium during virus inactivation, enhancing product safety and quality.

Specification	Details
Minimum volume	2 L
Maximum volume	20 L

Ordering Information

For quotation, please contact your local sales representative.

Item	Description	Unit | Box	Article No.
Hardware (EMA)	Pionic® Spin 30 System	1	ETO-CVI-SY-101-02L
Flowkit (EMA)	Pionic® Spin Base Flowkit	5	FBT318635
	Pionic® Spin Buffer Flowkit	5	FBT318632
	Pionic® Spin UV Flowkit	5	FBT318634
	Pionic® Spin Transfer Flowkit	5	FBT318636
	Pionic® Spin Recirculation Flowkit	1	FBT318633
3D Bags (EMA)	Pionic® Spin 20 L Mixing Bag	1	FMS319340
Incubation Chamber (EMA)*	Pionic Spin® Incubator 1.4	1	CVI-IC-6MM-02LH

* Further Pionic® Spin incubator sizes are available upon request.

Peripherals and Accessories

Additional Product	Article No.
Interface Consulting Service Basic (integration into customer network e.g., domain)	ICSM_BB_Basic_Small
Interface Consultant Service Advanced (integration into MES | DCS System)	ICSM_BB_Advanced_Small
Biobrain® Supervise	No fixed material number (configurable product as part of MFCS4).
Customized Recipe for Biobrain®	BPS0052
Biobrain® GMP Expert Option	BPS0059

Services

Service	Description	Article No.
Pionic® Spin Installation	Reliable system installation ensures robust performance.	S876TINST
Pionic® Spin Installation Pack (incl. travel exp.)		S876TINSTP
Pionic® Spin Qualification — SAT	Ensures compliance and quality.	S876TSAT
Pionic® Spin Qualification — SAT Pack (incl. travel exp.)		S876TSATP
Pionic® Spin Calibration	Calibration according to standards.	S876TCALOS
Single Maintenance	Provides reliability and productivity.	S876TSM
Service Level Agreement, Essential	Protects equipment stability annually.	S876TSLAE
Service Level Agreement, Advanced	Protects equipment stability annually with extended coverage and control.	S876TSLAA
Service Level Agreement, Comprehensive	Protects equipment stability annually with maximal protection and support.	S876TSLAC

Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
sartorius.com

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