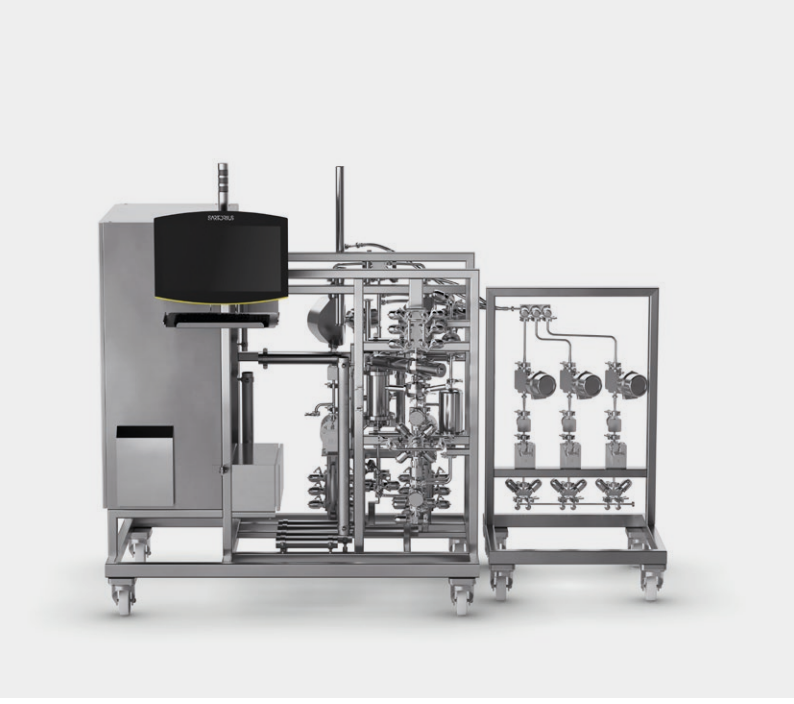
SARTORIUS

Product Datasheet

Resolute® Flowdrive Inline Conditioning Systems

A standalone and integrated buffer preparation solutions for downstream processing



Product Information

Resolute® Flowdrive In-Line Conditioning (ILC) systems formulate buffers for delivery direct to a chromatography column or membrane. Standalone ILC buffer preparation systems (without chromatography liquid handling) can be provided on request. Typically, these systems will use four or five pumps to supply water, salt, acid, and base, often with the option to add additional components such as detergent, EDTA, or polysorbate. In APAC markets, the systems are known as BPCS (buffer preparation chromatography systems).

Features and Benefits

- No empirical data required for system programming
- First-principles approach ensures correct formulation across diverse buffers
- Calculates pump control loop (PID) values for quick setpoint acquisition
- Control algorithms aligned with hardware to maximize efficiency
- Complementary tools available to define correct setpoints

Overview

Compared to a traditional chromatography system, Resolute® Flowdrive ILC systems are characterized by the following additional features:

- Static mixer
- Different-sized pumps, typically larger pumps connected to water and product streams, and smaller pumps connected to salt, acid, and base stock solutions
- Software to direct out-of-specification buffers to waste and return the system online only once specifications are met

The combination of flow path and control system design enables precise conductivity gradient control with ≤3% accuracy while simultaneously maintaining steady-state pH.

Resolute® Flowdrive ILC skids are also capable of performing in-line dilution (ILD), which is the mixing of a binary mixture (commonly water and a concentrate) to deliver a solution at the correct concentration. All two-pump chromatography skids supplied by Sartorius are capable of ILD without modification.

Relevant applications

- Chromatography processes requiring point-of-use buffer formulation
- Processes requiring standalone buffer preparation

Relevant process steps

- General buffer supply for downstream processing
- Capture and polishing chromatography



Control philosophy

The key to successful ILC is the combination of robust PID controllers to reach and maintain set points (pH, conductivity, and flow rate) and the correct determination of controller set points.

Setpoints can be determined by one of three methods, depending on the buffers required:

- Using our sizing tool to perform a Debye-Hückel calculation eliminates the need for bench experiments. This thermodynamic method determines the required acid-base ratio while accounting for pH shifts caused by the salt.
  This algorithm is applicable up to a maximum of 0.4M NaCl.
- When using an acid-base stock solution of the same molarity and species, the acid-base ratio is independent of pKA. In this case, the setpoint is governed only by the required dilution ratio from stock to 1 × concentration, while the other pump is required only to regulate the pH setpoint.
- Offline testing

For the majority of buffers, the sizing tool can be used. Given the desired formulation flow rate, the chosen pump sizes, and the available stock solutions, the tool will output the necessary setpoints for both composition and PID setpoint control.

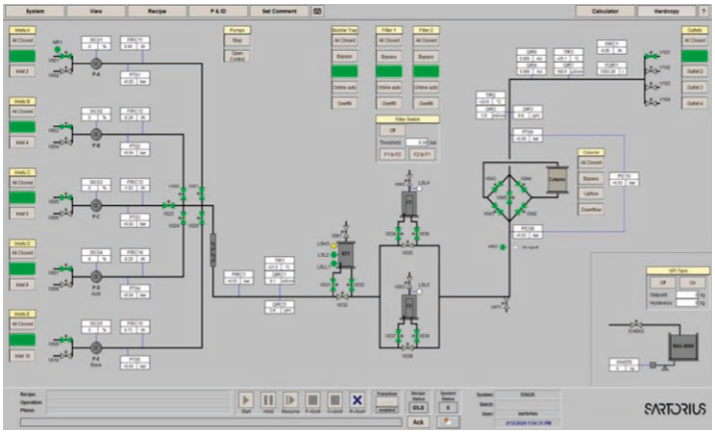
These setpoints can then be transferred into the recipe.

Where appropriate, our experts can support end users by reviewing buffer requirements and assisting with setpoint determination.

Automation

Figure 1 shows the system interface supporting automation.

Figure 1: Typical Resolute® Flowdrive ILC system user interface



The automation concept is based on Recipe and Operation Editors, which allow the user to easily configure automated process sequences and transitions:

Recipe → Operation → Phase

With the required setpoints defined, the intuitive control system enables seamless programming of combined ILC and chromatography operations, ensuring transparency and ease of troubleshooting.

The column bypass function can divert fluids to drain if they fall outside pH and | or conductivity specifications.

Performance Data

Gradient capability
The following examples are from a 0.5" system. The gradient accuracy shown in Table 1 is based on the error of reading in any 80% region of the gradient compared to the time-adjusted setpoint.

Figures 2 – 5 show the gradient capabilities of the Resolute® Flowdrive ILC.

Table 1: Gradient accuracy

L/hr	Gradient accuracy whilst maintaining 1:5 salt dilution
<200	≥ 3% higher total flow givers better mixing
200	2%
400	1%

Figure 2: Conductivity gradient formation at 400 L/hr output flow rate with gradient from 5 – 50 mS/cm while controlling to pH to 7.0 using 20 mM Na_2HPO_4 and 20 mM NaH_2PO_4. The acid and base stock solutions were diluted 5×.

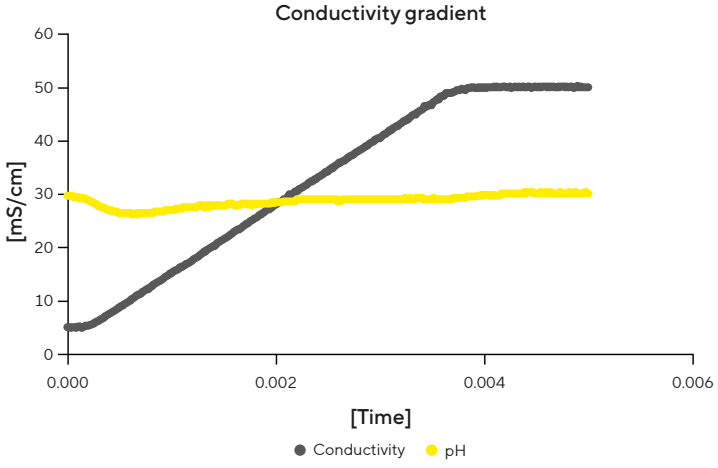


Figure 3: The Resolute® Flowdrive ILC can simultaneously perform conductivity and pH gradients, as shown here with a conductivity gradient from 5 to 50 mS/cm and a pH gradient from 5.5 to 7.

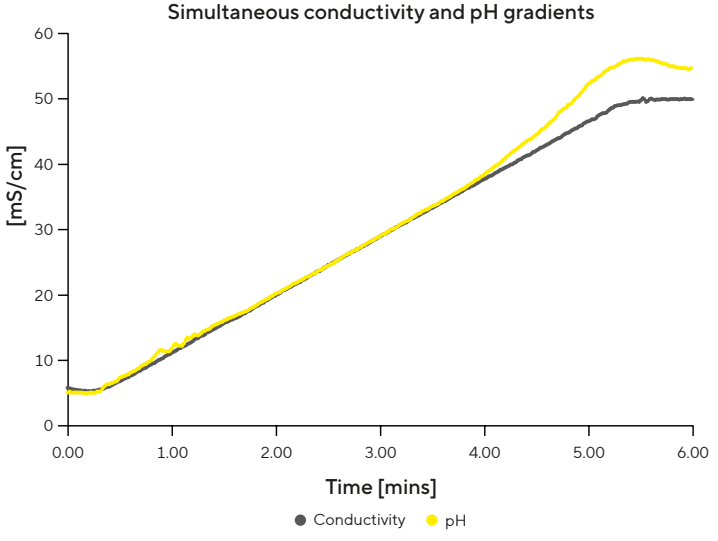


Figure 4: Pump P-B and P-D can be used alone in a traditional two-pump gradient format. These two QF150 pumps allow a 5 - 95% gradient above 60 L/hr. A 1:50 dilution ratio is possible.

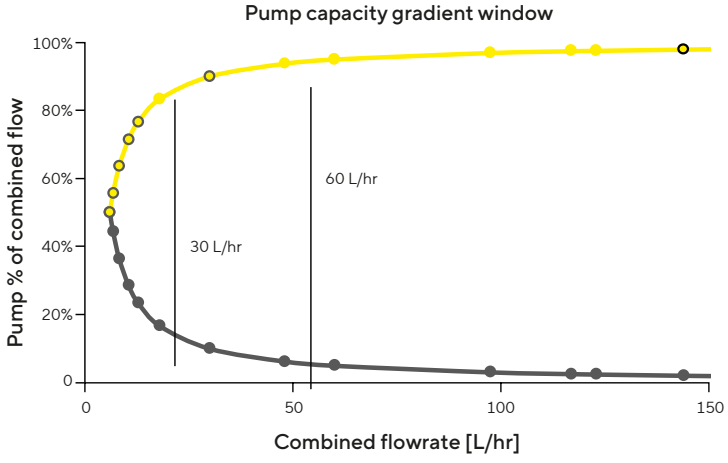
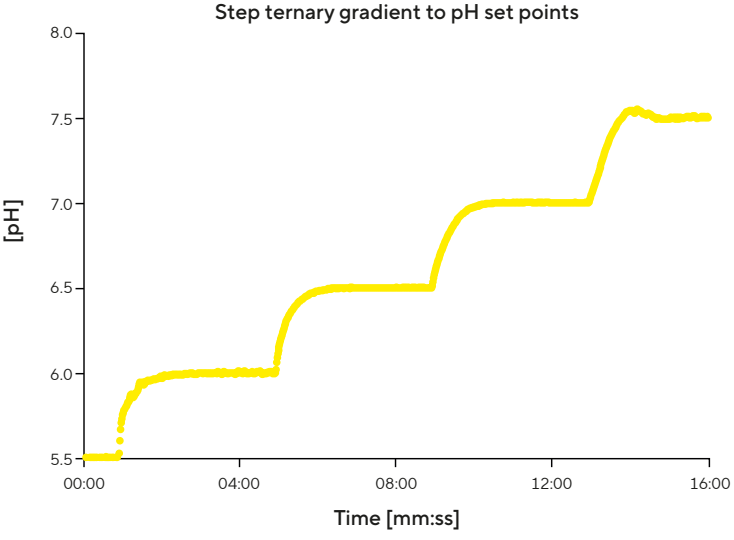


Figure 5: Various steady-state pH setpoints with a 20 mM $NaPO_4$ acid and base stock solution at 400 L/hr outflow



Technical Specifications

Sizing

Size	M	L	XL	XXL
Pipe ID (")	0.50	0.75	1.00	1.50
System flow rate (L/hr)	20 – 500	30 – 1,200	60 – 2,500	150 – 5,000

Technical details

Type	Description
Pump control	Profinet
Overpressure protection	No switches. Overpressure via software. Interior valves are N.O. Proximity feedback on all valves.
Maximum pressure	4 - 6 barg dependent on size
Pipe work	Sized to pumps
Process fluid operating temperature range	60 to 80 °C at < 1 bar (for CIP) 30 to 60 °C at < 3 barg (for CIP)
Valve proximity feedback	Yes
Material of construction — piping (all wetted parts)	SS316 L (1.4404) Hastelloy on request
Piping surface (internal surface finish)	≤ 0.6 Ra EP
Piping surface (external surface finish)	≤ 1.2 Ra EP
Material of construction — gasket	EPDM
System frame and cabinet materials of construction	304 stainless steel
Pneumatic supply	6 bar | 90 psi
External UPS power supply	Yes
Internal UPS battery	No
Process fluid filter	(× 2) Includes an auto filter switch function upon pressure ceiling criteria. Includes a liquid detector.
Bubbletrap	Borosilicate glass (× 3 liquid detectors)
Online auto fill for filter and bubbletrap	Yes
Static mixer	Yes, 5 elements post converge. Includes a separate cleaning spool.
Conductivity sensors × 3	0 - 150 mS | pre-column 0 - 150 mS | post-column 0 - 100 µS | post-column
pH	0 - 14 pre-column 0 - 14 post-column
UV	0 - 3AU 280 nm 5 mm OPL 0 - 3AU 254 nm 5 mm OPL
Flow	× 5 coriolis flow meters with ProfiNet communication
Inlet and outlet valves	× 2 inlets per pump, × 4 outlets, × 1 drain valve

Software Specifications

Key software functions and capabilities are given below.

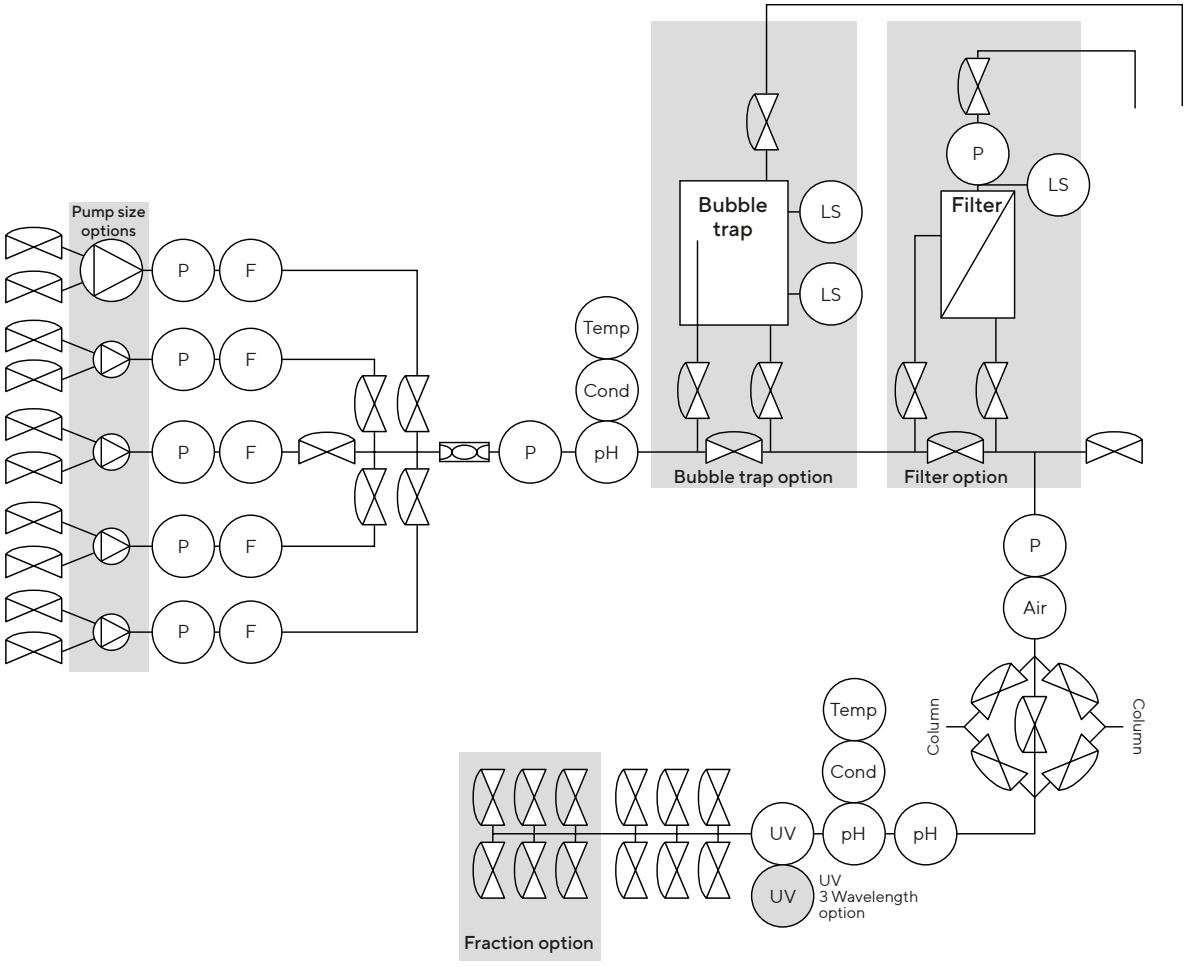
Type	Description
Water dispense function	Yes, signal to external WFI dispense valve to control vessel volume between high and low weight setpoints.
Filter switch function	Yes, automatic switching between filters upon reaching pressure threshold (where multiple filters are specified)
Conductivity gradient	Yes, 3% accuracy (typically 1%)
pH gradient	Yes, 3% accuracy (typically 2%)
Gradient mix ratio	Yes, 3% accuracy (typically 1%)
× 2 gradients simultaneously	Yes, 3% accuracy
Gradient on pumps B and D only	Yes, Note. This is needed to replicate traditional batch mode gradients where both pumps B and D are the same size, and therefore no dilution is required.
Steady-state mix ratio	Yes, A:B, A:C, B:C, or A:B:C (based on percentage, not flow)
P-D or P-E can control to FIRC14+FIRC15	Yes This mode can be used if the acid and base are the same molarity.
FIRC14+FIRC15 = acid (P-D) and base (P-E)	**Example Buffer** P-A controls the total flow rate 400 L/hr P-B controls the conductivity gradient 10 - 20 mS/cm P-C controls the flow rate 50 L/hr P-D controls the combined flow rate 100 L/hr P-E control to pH 7.4
Pressure ceiling	The flow control can also have a pressure ceiling function. If the column inlet or column differential pressure exceeds × bar, then all pumps decrease by a defined percentage, preventing the ceiling from being exceeded. This function can be used for column flow packing or for membrane adsorbers.
Valve pulse	All valves have a pulse on | off and overlap to allow CIP

The system is equipped with the following closed-loop feedback controllers to support optimal ILC performance across a range of buffers and flow rates.

Pump	Fluid	Available controller
Pump 1	WFI | product	Pump 1 flow rate Total flow rate Precolumn pressure Column differential pressure
Pump 2	Salt	Pre-column conductivity Pump 2 flow rate
Pump 3	Salt	Pre-column conductivity Pump 3 flow rate
Pump 4	Acid | flow	Pre-column pH Pump 4 flow rate
Pump 5	Base	Pre-column pH Pump 5 flow rate

A typical system is shown in Figure 6.

Figure 6: Typical system schematic



Ordering Information

We recommend organizing a technical discussion between our process engineers and the customer after reviewing this sheet and the system's capabilities.

Sartorius offers the possibility to design and engineer automated ILC systems customized to specific customer requirements as a customized or engineered-to-order project. Custom projects include a full review of the user requirement specifications and subsequent accommodation of any necessary changes. The system will be made to order and will have a Process Technology Engineer and Project Manager collaborating closely with the customer throughout the project execution. Several design reviews will ensure a complete solution for hardware and software.

All systems are supplied on a customized basis; the specifications outlined here represent a mature and proven platform from which our designs are developed, greatly minimizing the effort and risk involved in supplying these systems.

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