

Flexact® TFI System

A flexible, fully automated system for liquid transfer and filtration



Product Information

The Flexact® TFI provides a highly adaptable solution for transfer and filtration (TFI) of media and buffers across upstream and downstream processes. Unlike systems with fixed, predefined operational sequences, the Flexact® TFI enables operators to develop and execute process-specific recipes that align precisely with their manufacturing requirements.

Its configurable architecture supports a broad range of applications and process variations, offering users the flexibility needed to efficiently accommodate new molecules, process changes, or scale-up activities. This adaptability ensures seamless integration into evolving manufacturing environments while maintaining operational robustness and control.

Features and Benefits

- User-friendly recipe editor: Modular phase sequencing simplifies customization
- Compact design: Small footprint enables seamless integration
- Versatile setup options: Compatible with Palletank® and remote input | output (RIO)-Connect units
- Designed for single-use flow kits and filter transfer sets: Supports flexible configurations

Overview

Relevant applications

- Monoclonal antibodies
- Vaccines
- pDNA
- mRNA
- Recombinant proteins
- Viral vectors

Relevant process steps

- Virus filtration
- Virus inactivation
- Cell clarification
- Media and buffer preparation
- Product and buffer transfer

Introduction

Flexact® TFI is designed for operational excellence across the most common dead-end filtration applications for upstream and downstream processes in cGMP and cleanroom environments. Unlike traditional systems, it operates without predefined constraints, supporting customized workflows and optimized operational performance, with flexible recipe creation tailored to specific processes and applications.

Key system features

- Flexible recipe-based automation for multiple unit operations
- Advanced process control with integrated process analytical technologies (PAT; pressure | flow and event-based transitions via RIO-Connect for Palletank®)
- Broad application coverage across upstream and downstream workflows

System Concept

Flexact® TFI

Flexact® TFI features a work platform that incorporates the process hardware and automation software. The LCD touch screen can be freely repositioned to ensure it is easily accessible, enabling operators to control process operations efficiently.

The automation system provides visualization of all relevant process values, statuses, and alarms. There are various options for controlling the process, either manually or automatically, using the integrated phase and recipe system. All data and user interactions are stored locally on the system, and historical data can be shown for further analysis. The integrated batch and reporting system enables 21 CFR Part 11-compliant documentation of the process.

For secure fluid level management, a weight signal can be connected to the Flexact® TFI, either by load cells that are an integrated part of a Sartorius Palletank® or by external floor scales. The operator can connect one weighing signal (either the load cell of a Palletank® or any other scale) directly to the Flexact® TFI control cabinet; more weighing signals can be connected using the optional RIO-Connect unit. A flow totalizer can be used to determine the amount of transferred liquid, as an alternative to the weight measurement.

RIO-Connect for Palletank®

The combination of the Flexact® TFI and RIO-Connect for Palletank® enables the following functionalities:

- Monitoring and data acquisition of all process values of the measurements in a Palletank® (temperature, pH, conductivity and weight) including visualization, trending, and reporting
- Remote control of the mixing drive unit
- Use of Palletank® weight for automatic termination of a filtration or transfer process on Flexact® TFI in case more than one weighing signal is needed

The RIO-Connect unit can be mounted on the Palletank®, a separate trolley, or a wall, and supports seamless integration of temperature, pH, conductivity, and weight signals, along with remote control for the mixing drive unit, into the Flexact® TFI or facility-wide DCS system.

With RIO-Connect for Palletank®, all local measurements are efficiently gathered and transmitted via a single Ethernet-based connection (Profinet, EtherNet | IP, Modbus TCP | IP, or OPC UA) to the supervisory system. Integration efforts are significantly reduced by leveraging established industrial communication protocols.

The RIO-Connect unit is designed without local visualization or operation, allowing all functionalities to be accessed through the supervisory system. This means operators can continue using a familiar user interface, minimizing qualification efforts. Flexact® TFI supports the simultaneous connection of up to five RIO-Connect units, which can be exchanged between process runs.

Standards and Guidelines

The Flexact® TFI concept is designed and manufactured according to the following standards, guidelines, and legal requirements.

Quality management system

- ISO 9001:2015 Quality management systems

Directives

- 2006/42/EC (Machinery Directive)
- 2014/30/EC (Electromagnetic Compatibility Directive)
- 2011/65/EU (RoHS Directive)

Standards

- EN ISO 12100:2010 Safety of machinery – General principles for design – Risk assessment and risk reduction
- EN 55011 (1 B) Industrial, scientific and medical equipment. Radio frequency disturbance characteristics. Limits and methods of measurement
- EN 60204-1 Safety of machinery. Electrical equipment of machines – General requirements
- UL508A Standard for Industrial Control Panels (USA only)

Automation System

General approach

The Flexact® TFI automation system is built on a Siemens S7 PLC and WinCC V7 platform, utilizing the Sartorius Biotech Control (SBC) library to deliver core process control functionality. It is a fully integrated package unit that includes the HMI, process control, and data storage capabilities. No external computer system is required for operation (Figure 1).

The software is designed as a standalone application that can be combined with the following field devices:

- Peristaltic or diaphragm pumps
- Up to three pressure sensors
- Feed flow measurement
- Up to three inlet and | or two outlet RIO-Connect units
- One external balance via RS232 communication
- Up to five pinch valves (three inlet, two outlet)

The automation approach for the Flexact® TFI is based on segregation of the system into five different areas (Table 1). Each area can be configured independently from others, i.e., the type or number of inlets is not relevant for the way the pump control works.

Table 1: Basic automation functionalities

	Standard	With RIO-connect
Pump control		
Pressure control	Yes	Yes
Flow control	Yes	Yes
Pump speed control	Yes	Yes
Pump termination		
Weight	Yes	Yes
Flow totalizer	Yes	Yes
Time	Yes	Yes
Empty tube	Yes	Yes
Manual	Yes	Yes
Min. flow	Yes	Yes
Max. pressure	Yes	Yes
Pinch valves		
Inlet valves	Yes	Yes
Outlet valves	Yes	Yes
Mixing		
Mixing control	No	Yes
Weight		
Weight input	1	1 – 6
Sensor control		
pH adjustment	No	Yes

By combining the functionalities of the different areas, the Flexact® TFI provides the flexibility to perform specific processes or filtrations. This can be done manually or with the help of prequalified phases and the internal recipe system.

The following process phases are available:

- Control pump
- Select balance (if applicable)
- 5 control valves (if applicable)
- 5 control agitators (if applicable and RIO-Connect for Palletank® is connected)

Software architecture

Sartorius develops application software for the PLC and SCADA system and provides all necessary documentation to support qualification. The application software is made with Siemens WinCC V7 and Siemens STEP7 (TIA-Portal), and based on a standard Sartorius module library, structured according to the ISA-S88 standard into the following modules:

- Control modules
- Equipment modules
- Phases
- Recipe editor for sequencing phases

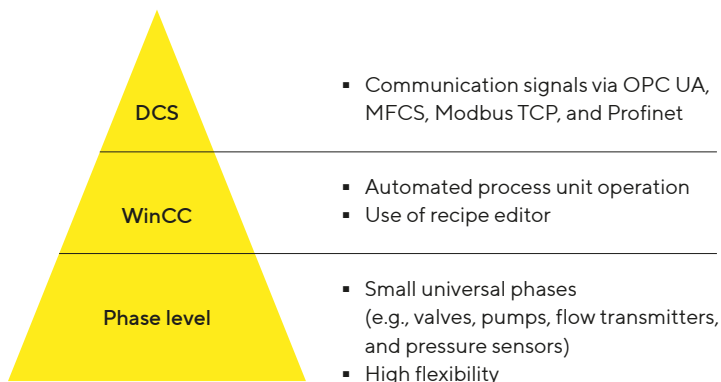
In case of power failure, the system transitions into a safe operating mode (shutdown of all operations) and raises an alarm. Operation can be resumed without interruption until a pre-defined time (normally 5 minutes). After exhaustion of internal UPS (approximately 5 minutes), the system shuts down automatically and user interaction is required to restart. All process data and settings are saved. Besides the HMI functionality used for visualization and operation of the plant, the system provides additional capabilities, including for example:

- Management of user permissions (Windows user management and SIMATIC logon)
- Storage of process data
- Generation of reports
- Alarming of process values and device alarms
- Reaction on emergencies, including hold logic
- Embedded 21 CFR Part 11 compliant audit trails (with SIMATIC logon; no electronic signatures)

In accordance with GAMP5, the design and development of the application software is based on:

- Software design specification (SDS)
- Functional design specification (FDS)
- Hardware design specification (HDS)

Figure 1: Automation concept for the Flexact® TFI



Process parameters are controlled via HMI and PLC:

- Indication of all process parameters based on system configuration and used hardware
- Alarm monitoring for process values and digital inputs
- Interlocks for critical process parameters (to be configured by customers according to process limitations)
- Calibration for analog values
- Totalizer for flow measurement
- PID control loops for flow, pressure, differential pressure, and pump speed
- Phases for operation of single process steps

Consumables

Configurable consumables are available for the Flexact® TFI skid, ensuring a streamlined and familiar setup for common applications (Figure 2). For processes requiring unique configurations, Sartorius also supports customized consumable solutions, developed in collaboration with the consumables engineering teams. For guidance on selecting or tailoring Flexact® TFI consumables, please contact your local Single-Use Technology Expert or Application Specialist.

Technical Specifications

Construction material	Stainless steel (surface quality Ra < 1.2 µm, mechanically polished)
Cabinet material	AISI 304
IP rating	IP54
Dimensions (H × W × D) [mm]	1,200 × 890 × 1,460
Weight [kg]	~300
Skid	Middle shelf height is adjustable or removable, includes system rails, e.g., for filter holders
Connection interfaces	■ 1 × pump (Watson-Marlow 530/630/730 or Quattroflow® 150/1200) ■ 2 × addition pumps (Watson-Marlow 530/630/730) ■ 3 × BioPAT® Pressure transmitters ■ 1 × BioPAT® Flow transmitter ■ 1 × load cell (RS232) ■ 5 × pinch valves ■ 5 × RIO-Connect for Palletank® (possible measuring values: weight, mixer speed, temperature, pH, and conductivity)

Figure 2: Example setup of the Flexact® TFI system (center) connected to a Palletank® with Flexsafe® Pro Mixer as the feed vessel (left) and a Palletank® with Flexsafe® Pro Mixer as the receiving vessel (right)



Pumps

Pump	WM730UM/R for endless tubing with 4.8 mm wall thickness	WM 630UN/R for endless tubing with 3.2 mm wall thickness	WM530UM/R2 for endless tubing with 2.4 mm wall thickness	Quattroflow® QF1200SU-HT with EZ-Set	Quattroflow® QF1200SU-HT	Quattroflow® QF150 SU with EZ-Set	Quattroflow® QF150 SU
Pump type	Peristaltic	Peristaltic	Peristaltic	Diaphragm	Diaphragm	Diaphragm	Diaphragm
Available as main pump	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Available as Addition pump	Yes	Yes	Yes	No	No	No	No
Speed range [rpm]	0.1 – 360	0.1 – 265	0.1 – 220	30 – 2,400	30 – 2,400	10 – 3,000	10 – 3,000
Flow rate [L/h]	0.12 – 2,000 (depending on the tubing)	Up to 900 (depending on the tubing)	Up to 90 (depending on the tubing)	6 – 1,200 (eccentric shaft 5° and ¾" TC inlet and outlet)	6 – 1,200 (eccentric shaft 5° and ¾" TC inlet and outlet)	1 – 180 (eccentric shaft 5° and ¾" TC inlet and outlet)	1 – 180 (eccentric shaft 5° and ¾" TC inlet and outlet)
Max. pressure [barg]	2	2	2	4	4	4	4
IP rating	IP66	IP66 NEMA 4X	IP66	IP54	IP54	IP54	IP54

Sensors

BioPAT® Pressure sensor

Article number	BPD0005
Type	Pressure transducer
IP rating	IP67
Dimensions (L × D) [mm]	100 × 48
Material	CrNi steel
Range [barg]	0 – 4
Accuracy	0 – 2 barg → 80 mbar 2 – 4 barg → 4% of the current value

Note. The BioPAT® Pressure measurement is the combination of a single-use pressure pipe and a multi-use sensor including the transmitter. The single-use BioPAT® Pressure pipe is part of consumable set.

BioPAT® Flow sensor

Description	Article number	Tube ID [in]	Flow range [Q; L/min]	Accuracy
BioPAT® Flow Clamp-on	BPL0330	¼	0.13 – 4.2	30 – 100% $Q_{max} \pm 5\%$ c.v.*
BioPAT® Flow Clamp-on	BPL0331	⅜	0.3 – 10	3 – 30% $Q_{max} \pm 0.09$ 30 – 100% $Q_{max} \pm 3\%$ c.v.*
BioPAT® Flow Clamp-on	BPL0332	½	0.6 – 20	3 – 30% $Q_{max} \pm 0.18$ 30 – 100% $Q_{max} \pm 3\%$ c.v.*
BioPAT® Flow Clamp-on	BPL0333	¾	1.5 – 50	30 – 100% $Q_{max} \pm 3\%$ c.v.*
BioPAT® Flow Clamp-on	BPL0334	1	2.3 – 77	30 – 100% $Q_{max} \pm 3\%$ c.v.*

Note. The BioPAT® Flow is the combination of a single-use flow pipe, a multi-use clamp-on sensor, and a 1-channel DIN rail transmitter mounted onto the Flexact® TFI control unit. BioPAT® Flow has an IP65 rating.

* Single-use BioPAT® Flow Pipe is part of the consumable set.

Ordering Information

Flexact® TFI

The Flexact® TFI is designed for high adaptability and supports a wide range of functions to meet specific application requirements. The package can be configured by defining the scope of deliverables, allowing alignment with process and operational needs.

Item	Standard included	Optional components
Trolley with cabinet	1	
Main pump	1	
Addition pump	0	1 – 2
Pressure sensors	1	1 – 2 additional sensors
Flow sensor	0	0 – 1 sensor
Pinch valves	0	0 – 5 valves
RIO-Connect for Palletank®	0	0 – 5 RIO-Connect units
Filter holders (e.g., depth filter holder)	0	On request

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