SARTORIUS

Product Datasheet

Flexact® Modular

The Single-Use Automation Solution

Benefits

- Standardize, harmonize & modularize preengineering process solutions
- Simplify interactions & automate
- Compliant sustainability
- Fitting to your process requirement
- Multi-functionality; one controller and many unit operations
- Suitable for ballroom layouts
- Openness to swap | add peripherals and update the process requirements

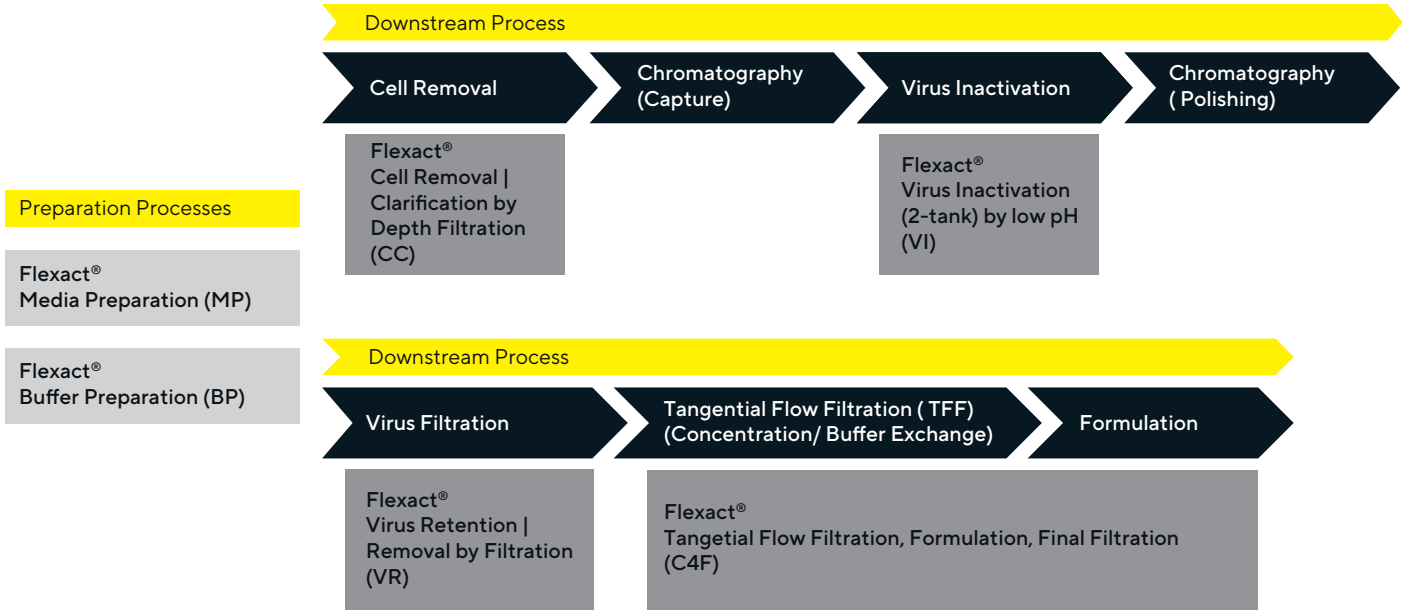
Product Information

A Flexact® Modular, engineered for single-use downstream and liquid processing when manufacturing biologics across a wide range of scales and molecules.

The Flexact® Modular is a platform solution bringing together hardware, software, wetware and documentation into a ready to produce package for single-use bioprocessing. Within the wide range of application and process throughputs available on the platform, a unit operation can be selected with recommended mass balance volumes, filtration areas, closures and process control levels. The platform uses pre-defined rules and a validated software library to generate the recipe based control of your process.

The software architecture allows easy interface to a Distributed Control Systems (DCS) for plant-wide integration. The build and connection of sensor, actuator and holder components allows them to be shared between unit operations, enabling a Flexact® Modular to perform up to 8 distinct unit operations at various process throughputs & volumetric scales as highlighted in the example below of a mAb Fed Batch Production Process Flow Diagram (PFD).

Example mAb Fed Batch Production Process Flow Diagram



Flexact® Modular Platform

The Flexact® platform offers the three different components:

- Flexact® Modular Control
- Flexact® RIO
- Flexact® Cleanroom cart

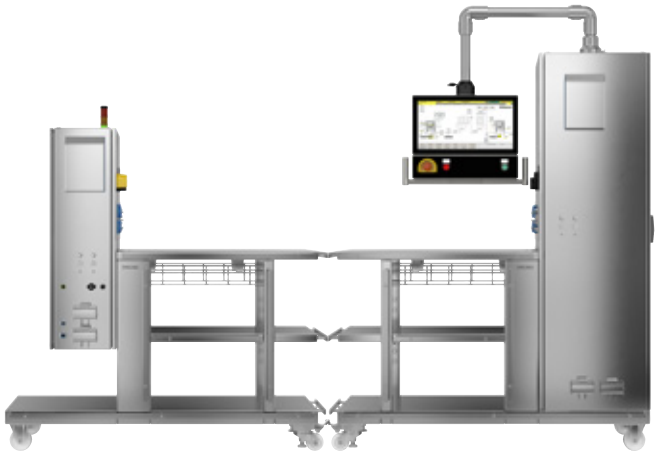
Each module has 0.72 m² operations space, an adjustable height of the middle shelf as well as the option to fully remove it. The three sides of the modules are equipped with system rails (spanning 2.6 m) and those can accommodate holders, actuators & sensors needed to perform the unit operation.

The Flexact® Platform modules can be used in different modes. Possible modes could be:

- Back to the wall
- Side to the wall
- As an island

Back to the wall

Side to the wall



As an island

Flexact® Modular Controller

The main unit of the Flexact® modular is the controller, equipped with an Human machine interface (HMI) and Programmable logic controller (PLC). It is the central point of interaction for your operator in any given unit operation.

The clean room compliant touch screen is fully 360 degree rotatable, telescopic at two points and tilt angle adjustable at the screen. Thus, the Flexact® is both ergonomic for all operators and allowing the system to be used in different modes.

The power panel is laser etched and equipped with (regionally adapted) covered power outlets. The sensor panel is also laser etched and equipped with and a I | O panel for all the sensor and actuator communications connections. On the sides of the control unit it can connect and power two Flexact® Modular RIO (Remote Input | Output) units (one to the left side, one to the right side). Additionally, it can digitally connect & control up to 4 RIO equipped Palletanks®.

Automation cabinet
Inside: Siemens (SBC) S7 1500, ET200, UPS.

Cable slot
Access for power and data cables on middle & bottom shelf

3 side system rails navigation
For flexible and easy mounting of holders for single-use assemblies

Low point system rails
For holder that bring tubing off the ground or 2-point stable fixing points

Controller interface design
360°, rotatable, telescopic extendable & tilt angle, cleanroom touch screen operation

optional CU8000
Multi Channel Photometric and Electrochemical Converter.
Powerful device in process monitoring in both conventional and single-use systems.

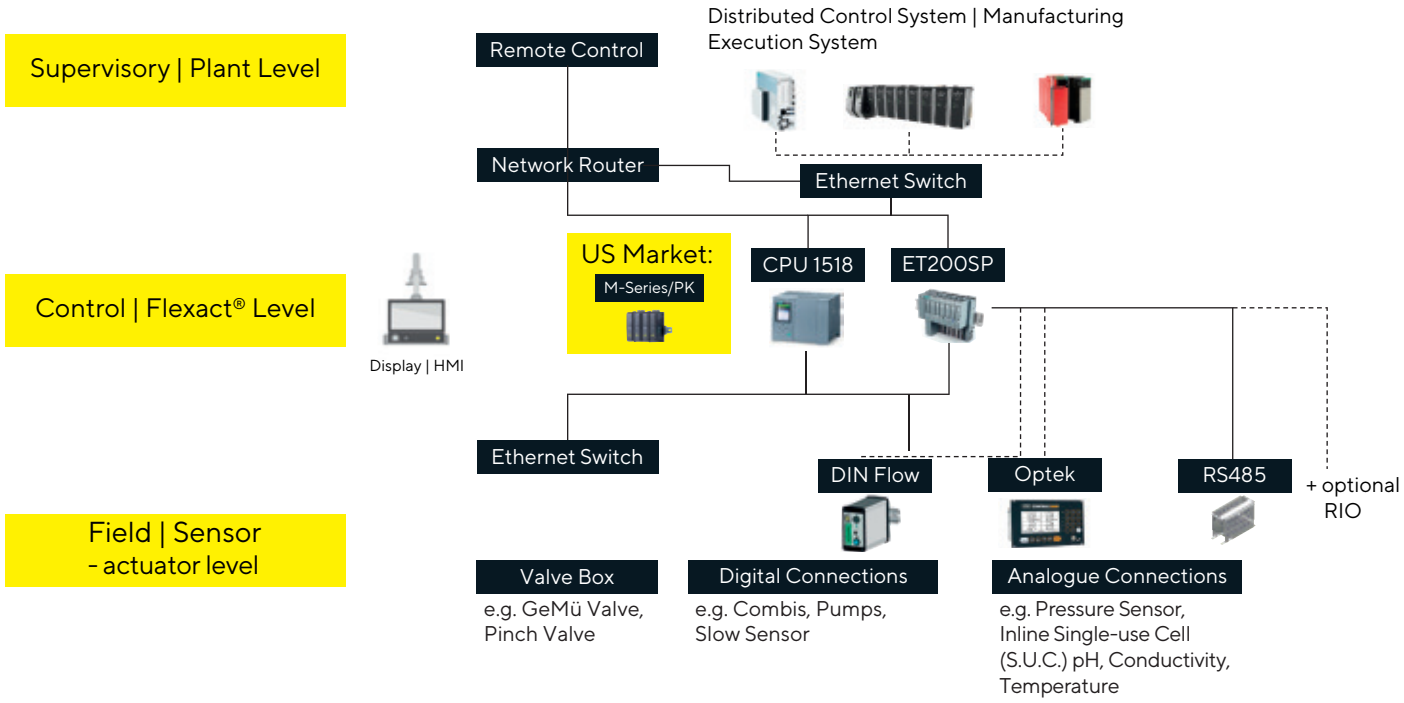
Digital & power interface
For connection of I|Os & hard powered actuators

RIO Module connections
2 Umbilical cord connection (1L 1R) up to 2 RIO module connections

Three shelves
For required peripheral equipment like pumps and cassette holders – middle shelf height adjustable or removable

Low friction casters & 4 drop down feet
For easy movement & relocation

Digital Connections



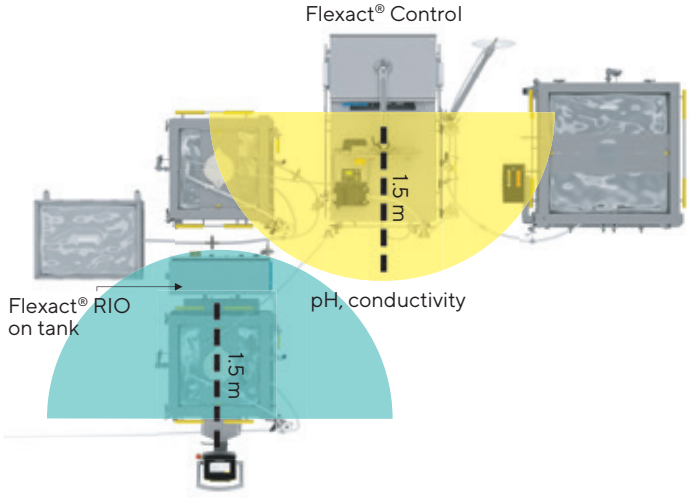
Flexact® RIO Box

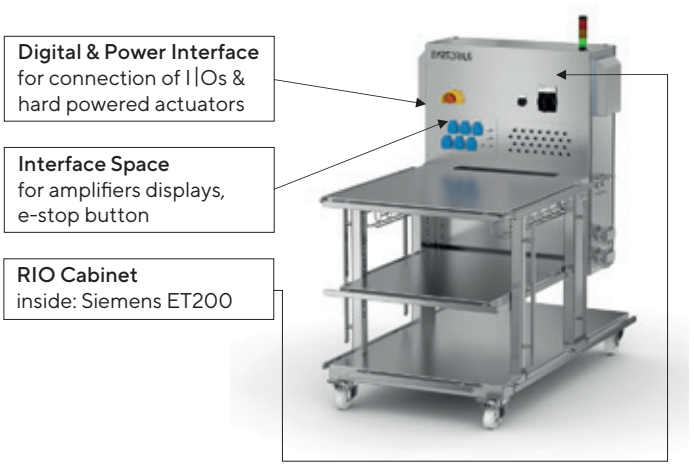
The Flexact® RIO Box is an extension to the Controller. It can either directly be installed to a Flexact® Cleanroom Card, a Palletank® or can be mounted on an individual stand or it can be fixed to a wall.

The RIO Box collects all process data from the Palletank®, such as temperature, mixer, pH, conductivity and weight on its own sensor interface plate. A single interconnection to the Flexact® Controller ensures the integration of the process values into the Flexact® application. The Flexact® RIO Box is benefitial in the case large distances between the Flexact® Controller and Palletanks® must be overcome. The RIO Box is equipped with a seperate power supply. The RIO Box is not a stand-alone system.

Below you can see the example of the Flexact® Modular RIO.

The RIO Box is a configurable electrical cabinet mounted on standard Palletank® for Mixing designed for collecting all critical mixing parameters on that system.
The connection of the RIO Box to a Flexact® Modular Controller ensures remote monitoring and recording of mixing parameters for process traceability and management along with remote control capabilities via a single point of connection.





Flexact® Cleanroom Cart

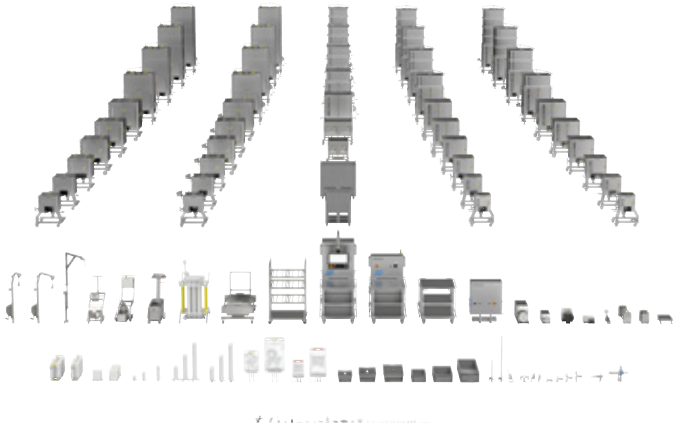
The Flexact® modular cleanroom cart offers a mechanical work space extension to the Flexact® Modular Solution where peripherals (e.g. pumps & 2D bags) can be held off the clean room floor. The height and dimensions of the cart's equipment platform and system rails match that of both the Flexact® Modular Control & RIO units. In that, it can be fixed to one of them without shelving steps or offering satellite stations where tubing lines can be made horizontal over a fixed distance.

General Operation Functionalities & Modules

Processing Throughput | Volumetric Scale | Speed

In order to accommodate the needs of different process streams, modules can be combined and reconfigured with other peripherals and Palletanks® to tailor the working space, fluid dimensions & overall footprint.

- Flexact® Modular Control
- Flexact® Modular RIO
- Flexact® Cleanroom Cart
- RIO on Palletank®

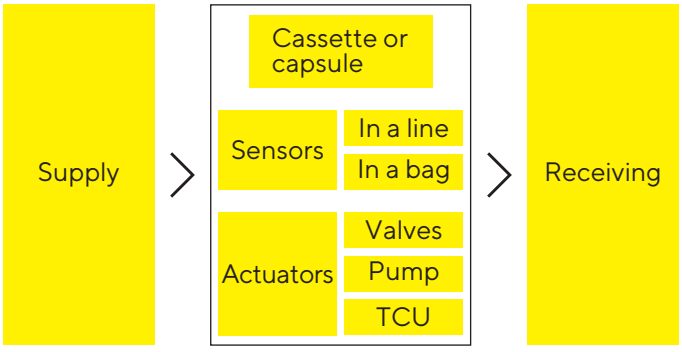


Processing Engineering Capabilities

- Pump Flow rates from 0.005 mL/min (¼" ID tubing) to 5000 L/h (@ 5 bar – 1" ID tubing)
- In process volumes from 1 L to 3000 L
- Storage volumes from 1 L to 3000 L
- In-line tubing pressure range from -150 mbar to 3.5 bar (4 transfer set tubing variants)

Example of Dead-end Filtration

Dead-end separation functionality enables a controlled unidirectional flow of a process stream from left (supply) to right (receiving). Depending on the software | hardware configuration, the system provides monitoring and | or control of process parameters such as pressure, temperature, pH, conductivity, flow, pump speed and weight. The integrated local control allows endusers to perform other tasks during the separation operation.



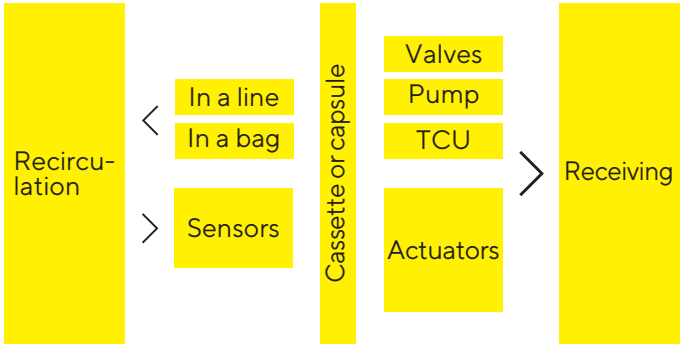
Example of Crossflow Filtration | TFF

Crossflow Filtration can take part in different process steps. The Flexact® Crossflow (CF) combines innovative single-use technology with the crossflow filtration performance.

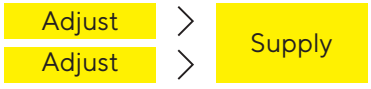
Examples for Ultrafiltration:
- Removal of unwanted materials e.g. macromolecules
- Final Formulation

Examples for Diafiltration:
- Concentration and buffer exchange
- Final Formulation

All product-contacting parts of the system are supplied sterile and are made from single-use components. The bag loop assemblies for Flexact® CF are supplied sterile and ready to use. Each assembly is optimized for ultra- and diafiltration applications.



Liquid Preparation & Adjustment



The Flexact® for liquid preparation is dedicated to media preparation in biopharmaceutical processes. It addresses the entire development cycle and production capacity needs from 50L to 3,000L for media and buffer preparation.

The material (liquid and | or solid) filling with optional fine (appropriate sensor | actuator) controlled adjustment of a mixed palletank for the purpose of preparing, combining or reacting liquid solutions prior to use in subsequent unit operations.

Combined with a Flexsafe® for Magnetic | Lev Mixer® | Flexsafe® Pro Mixer and Palletank® the Flexact® Modular Control enables the user to install, operate and monitor a fully single-use liquid preparation unit operation.

Common Add-on Packages

High Pressure Separation

- Use case virus filtration:
  The connections and tubing material of the transfer sets designs that are exposed to internal pressures of more than 1 bar are switch to re-enforced braided tubing. This increases the maximum allowable operating pressure to 3.0 barg enabling the required processing conditions

Palletank® Temperature Control

- Use case receiving tank virus inactivation:
  Up to two Palletanks® can be independently temperature controlled. Function, the thermowell inserted temperature sensor acts as the set-point guidance for temperature control unit (TCU). The system will send signals to a TCU which circulates warm or cool water for injection (WFI) around a jacketed pallettank to reach the internal temperature set-point.

Functionally Closed – Aseptic Processing

- Use case – self-contained crossflow filtration | virus filtration:
  The option changes the wetware connection technology from non-aseptic to aseptic. In the case of crossflow and Virus Filtration this updates the connections to CPC AseptiQuik®.
- Use case – Buffer | Media Preparation:
  This options changes design of wetware products and integrates the sterilizing grade filter onto the receiving bag filling line as well as updating the receiving bag(s) connections to aseptic connections.

Integrity | Leak Testing with Sartocheck® 5

- Single-use filter assemblies
- Cassettes & filters
- Preuse Post Sterilization Integrity Testing (PUPSIT)

Shared Operational or Intermediate Palletanks®

The interconnecting of unit operations where the receiving bag of one unit operation is the supply bag of subsequent unit operation. This function enables the sending of data to two controllers and the intercommunication of the controller units to achieve a safe steady state within that Palletank®

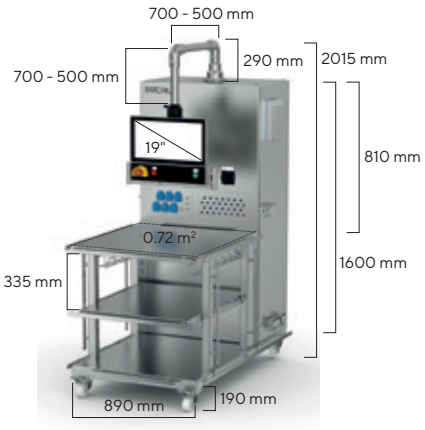
Inter-Cleanroom Transfer

- Use case virus filtration:
  Typically the receiving bag of the virus filtration unit operation is placed in higher classification room.
  Thus, the inter-cleanroom transfer allows the length and connection technology to span the rooms and enable room to room connection. The automation architecture and operator HMI(s) can be configured to enable operation in either room and maintain safe processing.

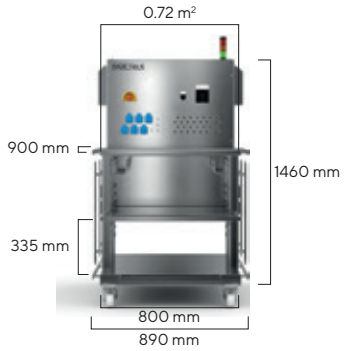
Technical Specification

Flexact® Modules

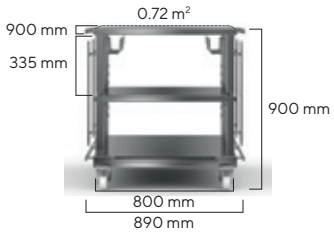
- Modules are designed for cGMP clean room use
- Mobile when not in process use
- Adequate cleanroom cleaning clearance between floor & lowest equipment platform
- Peripheral sizing & weight accommodated in the design and build



Flexact® Modular Control
Weight: 325 kg



Flexact® Modular RIO on Skid
Weight: 290 kg



Flexact® Cleanroom Card
Weight: 125 kg

Materials of Construction

EN 1.4301 (AISI 304) stainless steel

Work Surfaces and System Cleaning

Roughness of working surfaces:	Ra ≤ 1.2 µm
Design and edge finishing:	Plane without visible gaps or cavities

Suitable Cleaning Solutions

- Vesphene®
- LpH® family
- sporicidal agents like Spor-Klenz® and bleach
- 70:30 IPA
- 70% ethanol with a max exposition time of 0.5 hours
- 1% Sodium dodecyl sulphate solution with a max exposition time of 0.5hours
- 0.5M NaOH with a max exposition time of 0.5 hours
- Meliseptol®
- Kleralcohol
- quarternary ammonium compounds
- 0.5% Perform®
- fumigants such as formaldehyde

Utility Supply

Flexact® Modular Control cabinet is supplied with:

- 230 | 400 VAC, L1-L3, N, PE (TNS net), 50 – 60 Hz
- Uninterrupted Power Supply (UPS)
- In the event of power outage the system must be powered by the UPS until the diesel generator is started
  - The electric power supply will be 400 V, 50 Hz
  - UPS supply will be provided by the CLIENT
  - A diesel generator will be provided by CLIENT
- The control system together with the communication network must continue to work uninterruptedly in case of power failure
- 7.0 barg compressed air required for Festo Pilot Valve Box and pneumatic valves

	Unit	Value	Value
		400 V Version	**3x208 V Version**
Voltage	VAC	400 ± 10%	380 ± 10%
Frequency	Hz	50	60
Fuse	A		

Electrical Power Calculation

	Flexact® Modular CC, VI, MP, BP	Flexact® Modular CF (3.5 m²), VR	Flexact® Modular CF (7 m², 14 m²)
Electrical Devices	**Power consumption (approx.)**		
Supply Pumps	0.5 kW	0.95 kW	3.25 kW
Power supply for Electrical Cabinets, Instruments, lights, fans, etc.	2.5 kW	2.5 kW	2.5 kW
Total Effective Power Required	**3.0 kW**	**3.45 kW**	**5.75 kW**

Conditions at the Installation Site

	Unit	Value
Installation site: Conventional cleanrooms max. height above sea level	m	2000
Temperature	°C	+5 – +40
Relative humidity at temperatures of up to 31°C	%	30 – 80
Decreasing linearly there after: At temperatures of 31°C to 40°C	%	< 50
Explosion protection		None
Pollution degree in accordance with EN 61010		2
Base Protection class according to EN 60529		IP54
Base Protection class according to EN 61140		1
Acoustic pressure level, max., without components	dB (A)	< 70

Emergency Button Locations

- Flexact® Modular Control
  - One emergency pushbutton at the front of the HMI support arm
- Flexact® Modular RIO
  - One emergency pushbutton at the front of the electrical cabinet

Emergency Stop Functions

- Switch off all devices at the plugs
- Force all digital outputs to 0 V
- Force all analogue outputs to 0 V | 0 mA
- Bring phases to HOLD condition
- Bring actuators to “off” position (normally closed | normally open | off)

Manufacturer Certification

CE certification:	Yes
UL 508 certification NEMA 4X:	Option
Electrical certification EN 6204-1:	Yes
Machine directive 2006/-42-EG:	Yes
EMV 2014/30/EU:	Yes
Low voltage Directive 2014/35/EU:	Yes

Applied Standards

DIN EN ISO 12100:	Safety of machinery
EN 60204-1:	Safety of machinery – Electrical equipment of machinery
EN ISO 13849-1:	Safety of machinery – Safety-related parts of control systems

Basics of Planning

The detailed hardware design will be done by using the Software tool EPlan V8 or higher.

- Symbols: Acc. to EN 81 346
- Language: Operator messages, alarm messages, main HMI screen will be provided in English or local language. Labels on the system (e.g. cabinet sockets, on-off) in English or local language.

Sartorius uses the following software for creation of engineering documents.

- Layout drawing of cabinets: Eplan
- Wiring diagrams: Eplan
- I | O-List: Excel
- Equipment List: Eplan

The documents will be provided within the turn over package as PDF file.

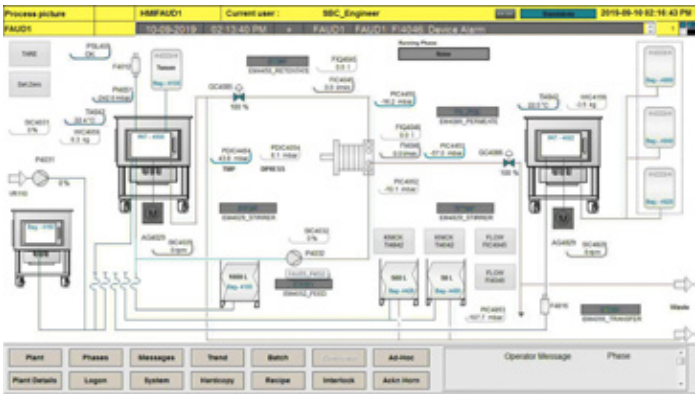
Sartorius Biotech Controller (SBC) Intuitive and Industry-Proven Local Control

For safety and user-friendly operation, an automation system for a bioprocess requires a proper strategy. Sartorius provides an automation platform consisting of a standardized software module library. Each software module consists of a defined set of control functions, running on Siemens SIMATIC S7 PLC family and faceplates for visualization and operation, running on the Siemens SIMATIC WinCC HMI. This library is named Sartorius Biotech Control (SBC).

ISA-S88 Standard
The SBC application software is based on the ISAS-88 standard for batch control, models and terminology. This standard provides structures and models that can be used to describe plants and processes in a uniform structure. The SBC platform provides a simplified ISA-S88 structure. Within the physical model the elements Unit, Equipment Module and Control Module are included. Within the Procedural Model Recipes and Phases are included.

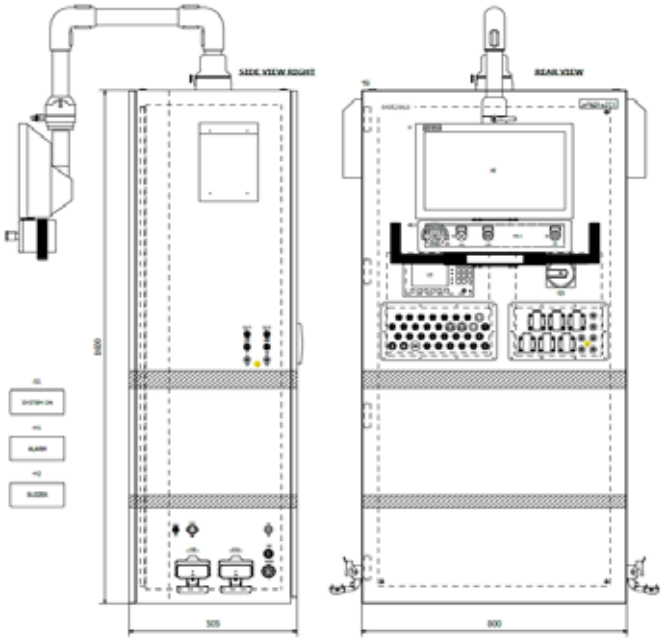
The SBC platform is designed for automated operation on Phase level. The SBC Phase Manager provides a structure for procedural control which allows a stepwise execution of control actions at the process equipment. A complete basic process can be executed by one or several phases.

For process execution, Phases acquire Equipment modules which represent a functional group of control modules e.g. heating system with all valves, pumps and temperature controllers. Each Equipment Modules provides states (e.g. heating) including the specific settings for each associated Control Module. During the runtime of a phase, the associated states are set by the phases.
Phases and Equipment Modules are predefined by Sartorius whereas recipes can be created and modified by an operator at the HMI.



Example HMI

Control Cabinet



The control cabinet will be built according to EN 60 204-1 and will contain:
- PLC Simatic S7 1500 series
- Fuses
- Contactors
- Industrial PC
- Emergency Stop Relay
- Power supply
- IO-Modules
- Measurement transmitters
- Power supply 24 VDC (for internal equipment and for balances)
- Uninterruptible Power Supply (UPS)

Internal Wiring

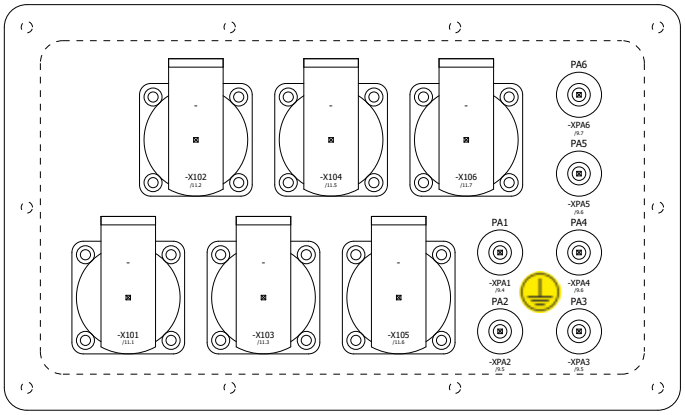
Each module's internal electrical wiring is color identifiable & bundled from their source to terminal.

Wire Labeling

All wires (included cable wires) must be labeled on both ends with the particular tag of the connection point.

For instance: connection on terminal strip X2, terminal 001 -> X2:001

Power Panel

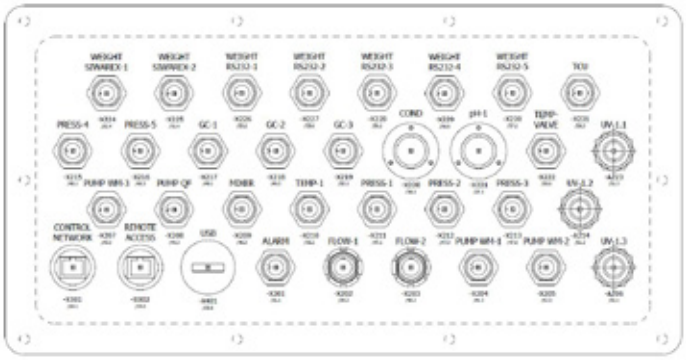


Example

Cable Management

Description Flexact® System Power Cord	Order Code
A Europe	BB-8847852
B USA	BB-8847909
C Ireland, UK	BB-8847879
E Italy	BB-8847887
F Australia	BB-8847941
G Denmark	BB-8847861
H Switzerland	BB-8847895
I Israel	BB-8847933
K Argentina	BB-8847917
L China	BB-8847925

Sensor & Actuator Panel



Example

Operator Station

Operations will be controlled by a Siemens WinCC V7 Server-Client-System. A touch panel will be located on the Flexact® Modular Control skid.

Ordering Information

For detailed ordering information please check our Flexact® Modular Selling Tool here.

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