



sartorius stedim
biotech

FlexAct® Platform Technology for Your Bioprocess



turning science into solutions

Platform Technology for Your Bioprocess

Key Benefits

FlexAct® is a platform system designed to perform nearly any step in upstream and downstream processing



It provides full operational flexibility and mobility

It allows manual as well as automatic control of your process

Both the hardware components and consumables can be configured to your precise needs



Discover more at:
www.sartorius.com/flexact ◀



Incorporating End-user Input at Its Best

FlexAct® is a fit-for-purpose and ready-to-use single-use technology platform that enables you to configure nearly any step in upstream and downstream processing. With one central operating module (COM) and an array of pre-sterilized bag assemblies, multiple steps in a biopharmaceutical process can be performed with the greatest operational flexibility and safety, and without the need for tedious cleaning.

Upstream



Media Preparation



Seed Cultivation



Polishing (IEX)



Low pH Virus Inactivation

Downstream



In-process Storage



Virus Removal (Filtration)



Final Filling



Freeze and Thaw

This Includes Process Steps, Such as

- Preparation of media and buffer
- Cell removal
- Virus inactivation (low pH)
- Concentration and buffer exchange
- Sterile and virus filtration
- Homogenization and pooling
- Formulation
- Fractionation



Fermentation



Cell Removal



Affinity Chromatography



Volume Reduction



Buffer Preparation



Concentration and Buffer Exchange



Storage | Fractionation



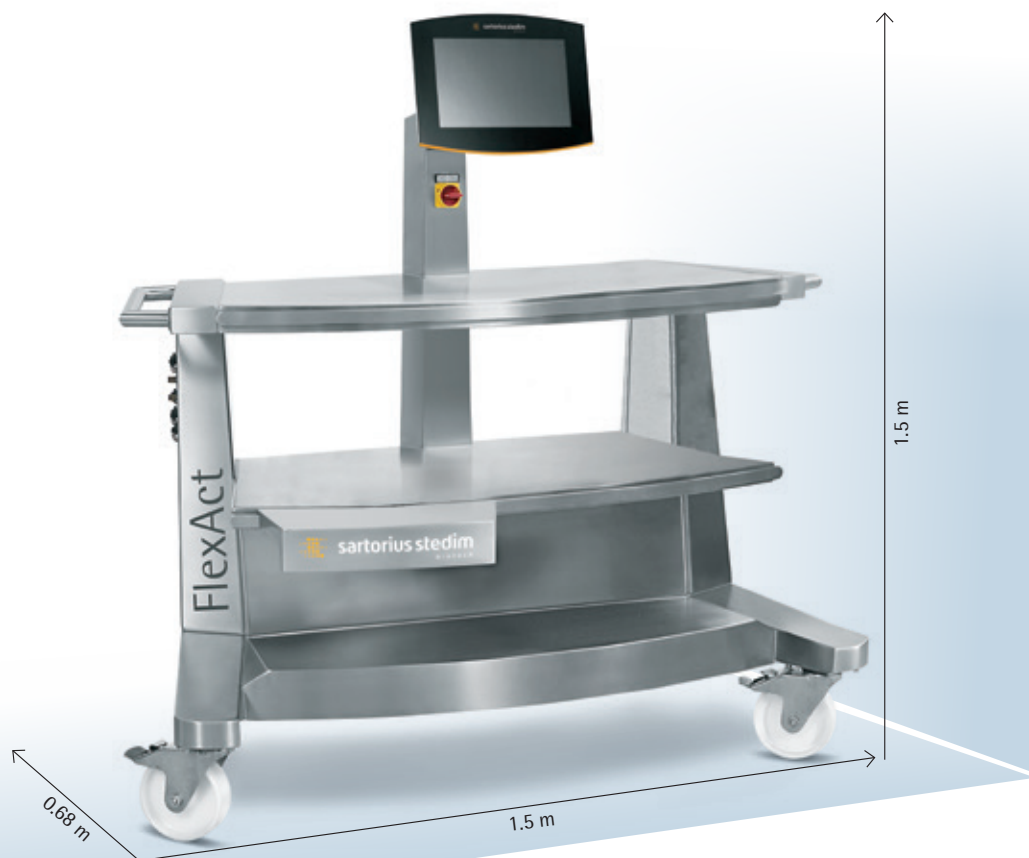
Formulation

Downstream

Form & Fill

Simplified scheme of a single-use bioprocess for the production of a monoclonal antibody. All mixing and filtration steps can be performed with FlexAct®.

The Central Operating Module (COM)



The compact build of the FlexAct® operating unit as a cart on wheels gives you maximum mobility and flexibility. It fits through any standard door. FlexAct® is exceptionally user-friendly as it is designed to be operated from the front only. Mixing and storage tanks can be placed right next to the COM, reducing its footprint to a bare minimum.

All equipment is securely positioned on the COM cart. As a result, further tables or storage space is not required. The control unit with touch-screen operation enables manual as well as automatic control of the pump speed, weight, pH, pressure, temperature, conductivity and (optional) flow rate. Via remote setting, the process can also be controlled externally.

When it comes to readiness, FlexAct® is extremely fast. All single-use products, such as bags, tubing, connectors, pressure transmitters and filters, are delivered as ready-to-connect assemblies for easy installation. The COM itself can be universally used for a wide variety of applications so that there is no need to make multiple investments for frequently changing applications. This means you can considerably save time, space and money.

Mixing Bag

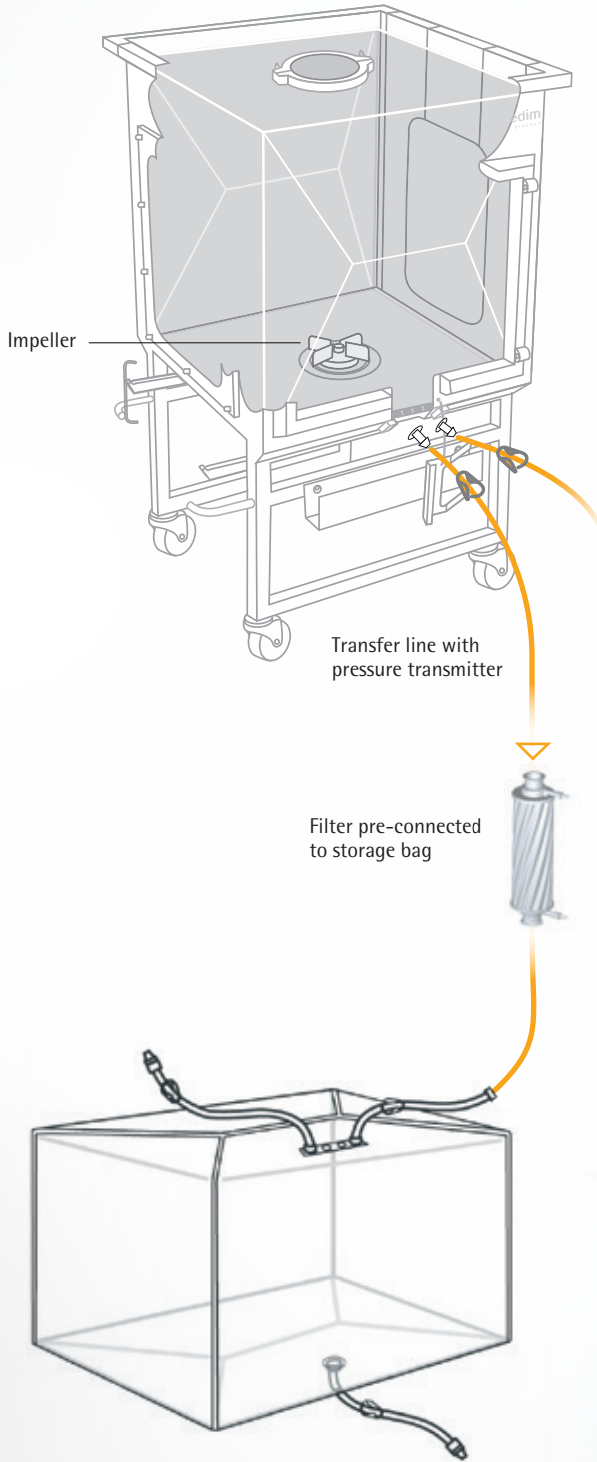
Mixing and storage bags are available for volumes from 50 L to 3,000 L. Include zero dead lag valves for maximum mixing efficiency.

Storage Bag

Mixing and storage bags can be connected by standard 1½" Triclamp or quick-coupling connectors. For aseptic connections, Opta® connectors can be integrated into the bag assembly. Thermoplastic tubing is included for sealing and welding as a standard.

Up to 4 top lines
(e.g. for pH regulation)

8" top port
for adding powder



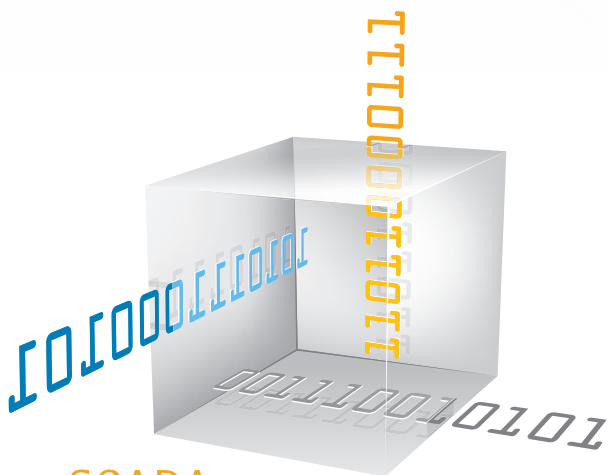
Consumables

To perfectly fit into your processes, our pre-sterilized single-use bag assemblies can be configured from a modular set of components. In the mixing bag, you can choose between impellers that are magnetically coupled for providing high torque forces or levitated for ultra-clean mixing. Single-use sensors for the measurement of pH, temperature, conductivity and pressure can be included into the assembly as required. The sensors for pH, temperature and conductivity are conveniently positioned on the mixing bag, while pressure and (optional) flow rate are measured in-line at the point of interest. The filter is pre-connected to a 3D Flexel® bag for storage or a 2D Flexboy® manifold for fractionation – whichever storage option you prefer.



Process Automation

At the core of the FlexAct® is the digital control unit. Its touch screen and pre-installed software packages make this unit exceptionally easy to use. With one COM and different software packages, you obtain a multifunctional system suitable for running many processes, reducing the need for extra space and investment costs. Besides easy and intuitive operation, the automation provides you with a significant increase in safety and reliability, for both the product and the operator, such as via reliable pressure control during filtration steps.



SCADA

Supervisory Control
And Data Acquisition

You can operate FlexAct® with pre-installed programs or create your own recipes by using our field-proven MFCS/win software package. Comprehensive reports on batches, alarms, messages, audit trails, etc., can be generated and analyzed. If you need to work in compliance with 21CFR Part 11, an additional package can be added as another option.

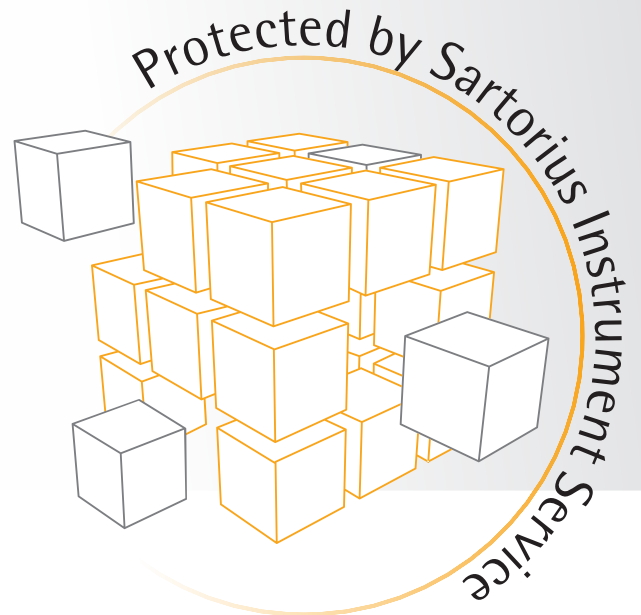
True Added-value Services for your FlexAct®

We are well aware of how important smooth-running equipment is for you. That is why we offer you our full-scale Instrument Services.

Sartorius has a local presence worldwide. Our portfolio covers a wide range of services, such as installation, qualification, preventive maintenance and repairs, including original spare parts with quick delivery times. We also offer extensive technical and application support to provide you with fast and effective solutions. Our individual operator training sessions will help you utilize your system with maximum security and efficiency.

The single-use FlexAct® components, like filters and bags, are accompanied by comprehensive Validation and Extractables Guides as a basis for safety assessment of your process and drug product. Additional product and process-specific validation testing may be required on a case-to-case basis. You can expect our CONFIDENCE® Validation Services experts to focus on your critical success factors when applying proven and effective risk-based and scientifically driven approaches.

Adherence to cGMP requirements and our ISO 9001: 2008 certified Quality Management System ensure that you receive services that meet the strictest quality requirements for reliable operation and regulatory compliance. We will do everything to make sure your FlexAct® will continue to run perfectly from day one and to protect your investment over the long term.



Test It!

We cordially invite you to visit the Sartorius Application Center, located in Goettingen, Germany, for a hands-on experience with FlexAct® and related equipment. For more information, just visit www.sartorius.com/application-center/.

Process Example 1: Buffer and Media Preparation

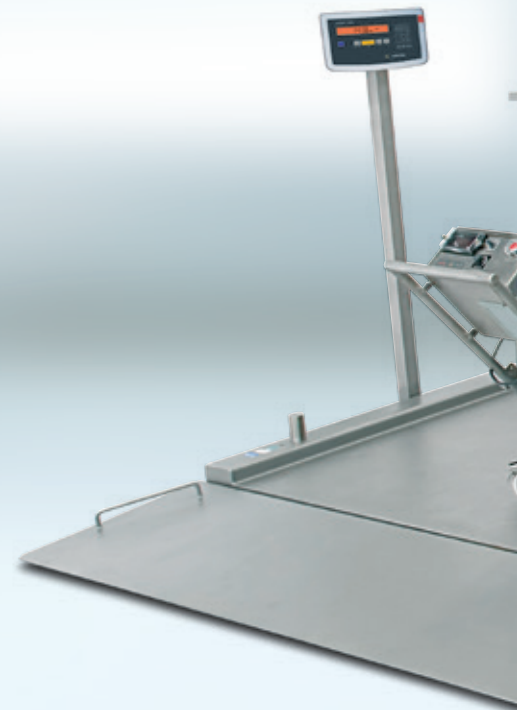
Main pump
(WM 720)

Dosing pumps for automated
pH adjustment (WM 520)

Touch
panel

Main
switch

Filter holder for up
to 3 filter cartridges



Mixing with Weight Monitoring
Using a Floor Scale

Powder bag holder

BioSealer® (optional)

Pressure sensor

Simply use a different software configuration and bag assembly, but with the same hardware to perform low pH virus inactivation, product formulation and other production steps.



FlexAct® Control Unit

Storage Tank or Bag Manifold

Process Example 2 Cell Harvest



Single-use Bioreactor

FlexAct® Control Unit

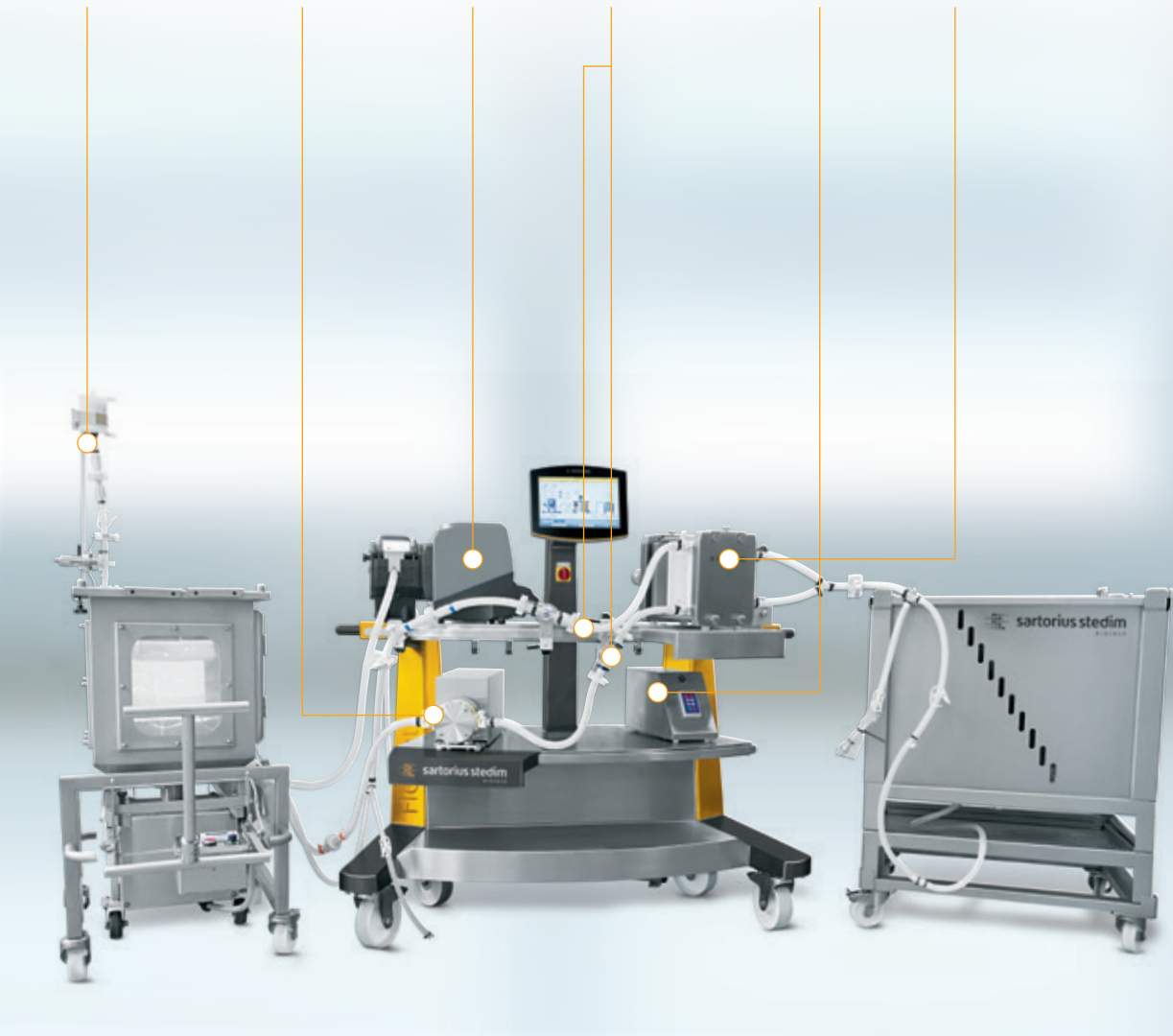
Filter Trolley

Storage Tank for Product

Process Example 3

Ultrafiltration and Diafiltration

Air vent filter & pressure sensor Recirculation pump (Quattroflow) Feed pump (WM 720) Pressure sensors (feed | retentate) Frequency converter Filter cassette holder



●
Recirculation Tank with Integrated Load Cells

●
FlexAct® Control Unit

●
Storage Tank for Permeate

Equipment that Rounds Up Your FlexAct® ...

...and many more, such as flat-bed floor scales, holders for powder bags, filters and tubing, racks for 2D bags, aseptic transfer systems, you name it, we'll supply it.



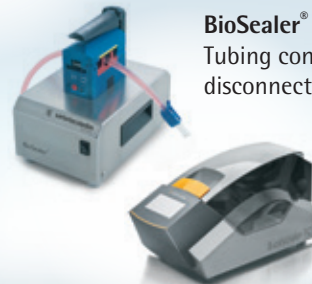
Pallettank for storage
Volumes from 50 L to 3,000 L.
Stackable. Shipping tanks
available



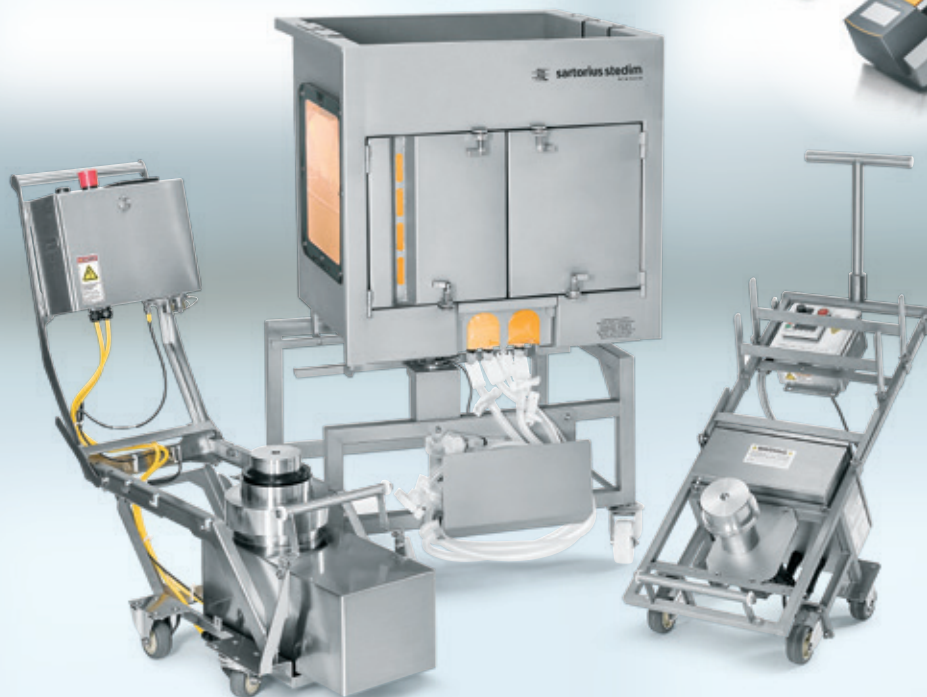
Sartocheck® 4 plus
Filter integrity tester



Draining system
For optimal product recovery
in 50 L to 2,000 L mixing tanks



BioSealer® & BioWelder® TC
Tubing connection |
disconnection



LevMixer®

For ultra-clean mixing with
low shear forces.

Pallettank for Mixing

Volumes from 50 L to 1,000 L
(customized up to 3,000 L).
Choose integrated load cells
for a minimum footprint
and jacketed tanks for
heating | chilling.

Magnetic Mixer®

For efficient mixing of large
volumes and viscous solutions.

Customize Your FlexAct®

Our in-house engineering team will customize the hardware and software of your FlexAct® to the exact requirements of your process. One such modified FlexAct® for ultrafiltration and diafiltration can be seen below with double the filtration area compared with the standard version.



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